Promoting shared decision-making in the surgical realm

From the surgeons' preferred treatment for patients to the patients' preferred treatment for surgery

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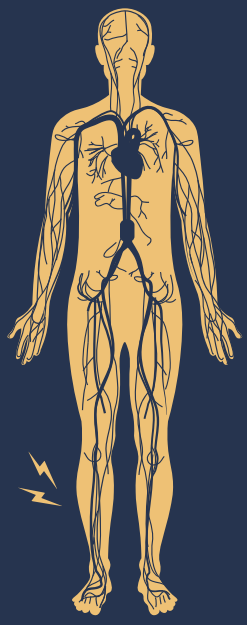

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Fabienne E. Stubenrouch

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Promoting shared decision-making in the surgical realm

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aan de Universiteit van Amsterdam
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ten overstaan van een door het College voor Promoties ingestelde commissie,
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Chapter 1

General introduction and outline of the thesis

Shared decision-making

In the last decades, doctor-patient interaction during the treatment decision-making process has shifted towards an active role for patients and a more coaching role for clinicians[1-3]. Initially this paradigm shift started by using evidence from the medical literature during doctor-patient encounters. This was followed by a growing awareness that the decision-making process should depend less on the expert opinion of the doctor and more on the opinion and preference of the patient. Nowadays, clinicians are not only expected to make treatment decisions based on the best available evidence, but also to better integrate the patients' preferences[4,5]. Combining evidence from scientific literature with the expertise of the clinician is known as 'evidence-based medicine' (EBM)[6]. Since the 1980's[7], the focus has gradually shifted towards integrating patients' preferences about their role during the doctor-patient consultation and in the decision-making process[8-10]. This development in the paradigm of EBM has become known as shared decision-making (SDM). SDM has been defined as the process in which clinicians and patients collaborate to make a joint decision about the best treatment option[11].

A growing body of evidence supports the value and importance of the SDM principle. First of all, it is an ethical and moral standard in medical decision-making[3,12]. Second, the patient's preferences may differ from the clinicians' view, but the former preferences should be leading[13,14]. Third, research shows that patients themselves desire a more active role in the decision-making process[15,16]. Fourth, SDM might reduce healthcare costs and overtreatment, particularly in surgery, because patients more often choose less invasive treatment options when engaged in the decision-making process[17,18].

SDM during a doctor-patient consultation is best conducted as a structured process. Several models have been described as handhold to practice SDM in a consultation when more than one treatment option exists[11,19,20]. These models usually define four essential steps.

1. First, the clinician informs and explains that different treatment options exist to choose from and that a decision has to be made, in which the patient is invited to play an essential role; the so-called "team talk".
2. Second, the clinician explains the available treatment options, each with their pros and cons ("option talk").
3. Third, the clinician explicitly gauges the patient's thoughts regarding these options and helps the patient weigh these pros and cons to arrive at his or her treatment preference, based on the patient's own goals and values ("choice talk").
4. Lastly, the clinician integrates this preference in the final decision, the so called "decision-talk".

Shared decision-making in surgery

Especially surgical conditions are relevant and suited for SDM, because a surgical treatment is irreversible and complications can be life-changing. In particular the treatments for vascular surgical disorders are suited for SDM[21], such as for abdominal aortic aneurysm (AAA), intermittent claudication (IC), varicose veins (VV) and a carotid artery stenosis (CAS), as several treatment options are available from which patients and clinicians can choose. Each option has its own pros and cons, which makes these treatment options preference-sensitive[22].

Therefore, surgeons should master how to involve their patients in the decision-making

process during consultations. On the other hand, patients must indicate -or be asked by their clinician about- the extent of involvement they desire. Hence, as a starting point for this thesis, we studied the current extent in which surgeons involve their patients in the decision-making process regarding a surgical treatment (**Part I**).

Decision-making support tools

Over the last years, various tools have been developed to support patients and clinicians in the process of SDM, for example decision aids (DAs), consultation cards (CCs), and decision cards (DCs). In addition, more generic communication training sessions are available with a professional actor as simulation patient, guided by a medical psychologist[23], as well as SDM e-learning modules for doctors and patients[24-26]. Such tools have shown to improve the level of SDM-performance in general surgery[18,27]. Also in vascular surgery these tools promote shared treatment decision-making in patients with, for example, an aortic aneurysm[28].

Typically, a decision aid is an internet application that informs patients about their disease, the different treatment options, and the evidence regarding the pros and cons of these options, usually based on current clinical guidelines. These decision aids are developed and validated according to (inter)national criteria[29]. They also include an interactive section with questions to test the patients' disease specific-knowledge and to elicit his or her preferences regarding the treatment options. Decision aids are intended to be used by the patient prior to the consultation with their clinician, but do not replace the decision-making process during the doctor-patient encounter.

Consultation Cards, also known as Option GridsTM, are evidence-based, easily understood one-page summaries of answers to patients' frequently asked questions[27,30]. These cards can be used in the consultation room to stimulate SDM by asking the patient which of these questions he or she would like to discuss. This gives the clinician insight in what is important for the patient when making the treatment decision. These decision cards have also been converted into graphical tools; the so-called consultation cards. These cards present the frequently asked questions by showing the answers in the form of icons or images[31], which makes the same information more attractive to use and easier to interpret, although in slightly less detail.

As mentioned above, non-disease-specific tools to support SDM are consultation training sessions and e-learnings. In the training sessions clinicians can bring their own clinical case and can practice with a simulation patient how to apply SDM in a structured way during their consultations, with or without the use of decision tools[32]. Also, and more recently, various e-learnings have been developed for both clinicians and patients about the various aspects of SDM during doctor-patient encounters[25,26,33].

Risk communication

Patients need to be optimally informed to be able to weigh the benefits and risks of the different treatment options. Hence, risk communication is an important part of clinician-patient consultations. Clinicians should be able to convert scientific evidence into intelligible numbers or figures to discuss with their patients, who usually are not very familiar with interpreting such data. Earlier studies showed that clinicians insufficiently inform patients about the pros and cons of the different treatment options[34,35]. However, even when surgeons explain the possible outcomes, patients may not always understand this. Several reasons for

this have been put forward, for example lack of time during the consultation, innumeracy among clinicians and patients, and health illiteracy[36,37]. To improve risk communication several supporting tools, such as visual aids, have been developed[38]. These tools provide a graphical display of the benefits and risks of different treatment options. For example by using icons arrays, natural frequency trees and bar charts[39,40]. Several studies showed the positive effects of the visual representation of possible outcomes, i.e., increased patient knowledge, better understanding of the benefits and risks, and reducing the effect of positive framing[38,41-44].

For these reasons, several tools have been designed to assess and improve communication and SDM behavior among both clinicians and patients in the consultation room. Such tools are likely to be useful and applicable, but have not been developed for vascular surgery. Therefore, the development and testing of such tools was the second aim of this thesis (**Part II**).

Implementation of shared decision-making

In the Netherlands, clinicians are legally obliged to inform patients about their disorder and possible treatments[45]. A recent update of this law in 2020 specifically includes shared decision-making[46]. Nevertheless, previous studies showed that vascular surgeons find it hard to fully address the topics as prescribed by the law[34], and to practice SDM in the clinical encounter[34,47]. Hence, SDM in vascular surgery could be improved by implementing various SDM tools for both clinicians and patients. Implementation of these tools in vascular surgery was the third aim of this thesis (**Part III**).

Aim and outline of this thesis

I. To investigate the current level of SDM among clinicians and patients facing a surgical treatment option;
II. To develop assessment instruments, risk communication tools, and SDM aids for (vascular) surgery;
III. The implementation of risk communication as well as SDM tools to promote SDM in vascular surgical practice.

Part I: State of the art

Chapter 2 provides a systematic overview of the available literature on the current, objectively and subjectively scored levels of SDM in surgery. In **Chapter 3** more specifically, the current level of SDM in vascular surgery is evaluated by analyzing audio-recordings from consultations in the surgical outpatient clinic. To compare these results with a closely related specialty in the chain of care, we also investigated the level of SDM at the preoperative outpatient clinic of the department of anesthesiology. These results are presented in **Chapter 4**.

Apart from the current level of SDM in the outpatient clinic, it is important to know how the benefits and harms of treatment options are reported in medical scientific publications, being crucial input for the risk communication with the patient. To investigate the reporting of these benefits and harms in surgical trials, a systematic review was performed and presented in **Chapter 5**.

Part II: New tools for shared decision-making

In this part the current level of SDM among patients and clinicians is determined, and the extent in which SDM tools are applied in daily surgical consultations is explored.

Decision support tools (DSTs) for four vascular disorders were developed with support from the Netherlands Organisation for Health Research and Development. The development process of these DSTs in vascular surgery, i.e., decision aids, decision cards and consultation cards, is presented in **Chapter 6**.

Several instruments exist to measure various aspects of the SDM-process and the SDM level reached in doctor-patient encounters. One of these tools that focusses on the objective measurement of SDM is the OPTION-instrument. Initially a 12-item version was developed, later followed by a condensed version with only 5 items. The discriminative power of these two OPTION-instruments is compared in **Chapter 7**.

To improve risk communication between doctor and patient, we developed a digital application (the so-called Mapping All Patient Probabilities In Numerical Graphs (MAPPING) app), to provide multiple visual, rather than numerical, representations of the evidence-based benefits and risks of treatment options. The development and evaluation of this app is presented in **Chapter 8**.

Part III: Implementation of shared decision-making

Chapter 9 provides the study protocol of the Operative Vascular Intervention Decision-making Improvement Using SDM-tools (OVIDIUS) trial. This stepped-wedge cluster-randomised trial was designed to evaluate the effectiveness of DSTs we had developed, in order to promote SDM and the implementation of these tools in outpatient vascular surgical clinics in the Netherlands. The results obtained from this OVIDIUS study are presented in **Chapter 10**.

To improve SDM implementation, it is also helpful to gain more insight into the predictors of the level of SDM in vascular surgery. Therefore, a sub-cohort of the OVIDIUS trial was used to investigate these predictors, which is described in **Chapter 11**.

Chapter 12 is a summary of the main findings reported in this thesis. **Chapter 13** presents an overall discussion of the findings in this thesis and future perspectives.

References

1. Konn AA. The shared decision-making continuum. JAMA 2010; 305:903-904

2. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision-making in the NHS. BMJ 2010;341:c5146

3. Salzburg Global Seminar. Salzbug statement on shared decision-making. BMJ 2011;342:d1745

4. Barry MJ, Edgman-Levitan S. Shared decision-making--pinnacle of patient-centered care. N Engl J Med 2012;366(9):780-1

5. Ubbink DT, Hageman MG, Legemate DA. Shared Decision-Making in Surgery. Surg Technol Int 2015;26:31-6

6. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what is it and what isn't. BMJ 1966;312(7023):71-2

7. Strull WM, Lo B, Charles G. Do patients want to participate in medical decision-making? JAMA 1984;252(21):2990-4

8. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango) Soc Sci Med 1997;44(5):681-92

9. Mazur DJ, Hickam DH. Patients' preferences for risk disclosure and role in decision-making for invasive medical procedures. J Gen Intern Med 1997;12(2):114-7

10. Coulter A. Partnerships with patients: the pros and cons of shared clinical decision-making. J Health Serv Res Policy 1997;2(2):112-21

11. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, Cochran N, Frosch D, Galasiński D, Gulbrandsen P, Han PKJ, Härter M, Kinnersley P, Lloyd A, Mishra M, Perestelo-Perez L, Scholl I, Tomori K, Trevena L, Witteman HO, Van der Weijden T. A three-talk model for shared decision-making: multistage consultation process. BMJ 2017;359:j4891

12. Fowler FJ Jr, Levin CA, Sepucha KR. Informing and involving patients to improve the quality of medical decisions. Health Aff 2011;30(4):699-706

13. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. BMJ 2012;345:e6572

14. Glasziou P, Moynihan R, Richards T, Godlee F. Too much medicine; too little care. BMJ 2013;347:f4247

15. Tariman JD, Berry DL, Cochrane B, Doorenbos A, Schepp K. Preferred and actual participation roles during health care decision-making in persons with cancer: a systematic review. Ann Oncol. 2010;21(6):1145-1151

16. https://www.patientenfederatie.nl/downloads/rapporten/200-rapport-samen-beslissen/file

17. Arterburn D, Wellman R, Westbrook E, Rutter C, Ross T, McCulloch D, Handley M, Jung C. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. Health Aff 2012;31(9):2094-104

18. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg. 2013;257(5):860-6

19. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, Cording E, Tomson D, Dodd C, Rollnick S, Edwards A, Barry M. Shared decision-making: a model for clinical practice. J Gen Intern Med. 2012;27(10):1361-7

20. Stiggelbout AM, Pieterse AH, De Haes JC. Shared decision-making: Concepts, evidence, and practice. Patient Educ Couns. 2015;98(10):1172-9

21. de Mik SML, Stubenrouch FE, Balm R, Ubbink DT. Systematic review of shared decision-making in surgery. Br J Surg. 2018;105(13):1721-1730

22. Ubbink DT, Koelemay MJW. Shared Decision-making in Vascular Surgery. Why Would You? Eur J Vasc Endovasc Surg. 2018;56(5):749-750

23. Henselmans I, van Laarhoven HWM, van Maarschalkerweerd P, de Haes HCJM, Dijkgraaf MGW, Sommeijer DW, Ottevanger PB, Fiebrich HB, Dohmen S, Creemers GJ, de Vos FYFL, Smets EMA. Effect of a Skills Training for Oncologists and a Patient Communication Aid on Shared Decision-making About Palliative Systemic Treatment: A Randomized Clinical Trial. Oncologist. 2020;25(3):e578-e588

24. www.qruxx.com/e-learnings-samen-beslissen

25. http://sdm.visieintoekomst.nl/zorgverleners

26. http://sdm.visieintoekomst.nl/patienten

27. Elwyn G, Pickles T, Edwards A, Kinsey K, Brain K, Newcombe RG, Firth J, Marrin K, Nye A, Wood F. Supporting shared decision-making using an Option Grid for osteoarthritis of the knee in an interface musculoskeletal clinic: A stepped wedge trial. Patient Educ Couns. 2016;99(4):571-577

28. Knops AM, Goossens A, Ubbink DT, Balm R, Koelemay MJ, Vahl AC, de Nie AJ, van den Akker PJ, Willems MC, Koedam NA, de Haes JC, Bossuyt PM, Legemate DA; DECAID Trial Group. A decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm: a randomised clinical trial. Eur J Vasc Endovasc Surg. 2014;48(3):276-83

29. Joseph-Williams N, Abhyankar P, Boland L, Bravo P, Brenner AT, Brodney S, Coulter A, Giguere A, Hoffman A, Körner M, Langford A, Légaré F, Matlock D, Moumjid N, Munro S, Dahl Steffensen K, Stirling C, van der Weijden T. What Works in Implementing Patient

Decision Aids in Routine Clinical Settings? A Rapid Realist Review and Update from the International Patient Decision Aid Standards Collaboration. Med Decis Making. 2020; PMID: 33319621.

30. Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand MA, Edwards A. Option Grids: shared decision-making made easier. Patient Educ Couns. 2013;90(2):207-12

31. Mullan RJ, Montori VM, Shah ND, Christianson TJ, Bryant SC, Guyatt GH, Perestelo-Perez LI, Stroebel RJ, Yawn BP, Yapuncich V, Breslin MA, Pencille L, Smith SA. The diabetes mellitus medication choice decision aid: a randomized trial. Arch Intern Med. 2009;169(17):1560-8

32. http://deelkunde.nl/sdm/uitvoering/

33. http://nfk.nl/e-learning

34. Knops AM, Ubbink DT, Legemate DA, de Haes JC, Goossens A. Information communicated with patients in decision-making about their abdominal aortic aneurysm. Eur J Vasc Endovasc Surg. 2010;39(6):708-13

35. Kunneman M, Marijnen CAM, Rozema T, Ceha HM, Grootenboers DARH, Neelis KJ, et al. Besluitvorming over preoperatieve radiotherapie bij rectumcarcinoom. Variatie in de informatievoorziening. Ned Tijdschr Geneeskd. 2015;159:A9093

36. Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. BMJ 2003;327(7417):741-4

37. Nayak JG, Hartzler AL, Macleod LC, Izard JP, Dalkin BM, Gore JL. Relevance of graph literacy in the development of patient-centered communication tools. Patient Educ Couns. 2016;99(3):448-454

38. Zipkin DA, Umscheid CA, Keating NL, Allen E, Aung K, Beyth R, Kaatz S, Mann DM, Sussman JB, Korenstein D, Schardt C, Nagi A, Sloane R, Feldstein DA. Evidence-based risk communication: a systematic review. Ann Intern Med. 2014;161(4):270-80

39. Paling J. Strategies to help patients understand risks. BMJ 2003;327(7417):745-8

40. Legemate DA, Koelemay MJ, Ubbink DT. Number Unnecessarily Treated in Relation to Harm: A Concept Physicians and Patients Need to Understand. Ann Surg. 2016;263(5):855-6

41. Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. BMJ 2002;324(7341):827-30

42. Timmermans D, Molewijk B, Stiggelbout A, et al. Different formats for communicating surgical risks to patients and the effect on choice of treatment. Patient Educ Couns 2004;54(3):255–63

43. Hawley ST, Zikmund-Fisher B, Ubel P, et al. The impact of the format of graphical presentation on health-related knowledge and treatment choices. Patient Educ Couns 2008;73(3):448–55

44. Waldron CA, van der Weijden T, Ludt S, Gallacher J, Elwyn G. What are effective strategies to communicate cardiovascular risk information to patients? A systematic review. Patient Educ Couns. 2011;82(2):169-81

45. www.knmg.nl/advies-richtlijnen/dossiers/behandelingsovereenkomst-wgbo/wijzigingen-wgbo.htm

46. www.knmg.nl/advies-richtlijnen/dossiers/behandelingsovereenkomst-wgbo/wijzigingen-wgbo.htm

47. Santema TB, Stubenrouch FE, Koelemay MJ, Vahl AC, Vermeulen CF, Visser MJ, Ubbink DT. Shared Decision-making in Vascular Surgery: An Exploratory Study. Eur J Vasc Endovasc Surg. 2016;51(4):587-93

Part I

State of the art

Chapter 2

Systematic review of shared decision-making in surgery

Sylvana M.L. de Mik
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Ron Balm
Dirk T. Ubbink

British Journal of Surgery 2018; 105: 1721–30

Abstract

Background

Multiple treatment options are generally available for most diseases. Shared decision-making (SDM) helps patients and physicians choose the treatment option that best fits a patient's preferences. This review aimed to assess the extent to which SDM is applied during surgical consultations, and the metrics used to measure SDM and SDM-related outcomes.

Methods

This was a systematic review of observational studies and clinical trials that measured SDM during consultations in which surgery was a treatment option. Embase, MEDLINE and CENTRAL were searched. Study selection, quality assessment and data extraction were conducted by two investigators independently.

Results

Thirty-two articles were included. SDM was measured using nine different metrics. Thirty-six per cent of 13.176 patients and surgeons perceived their consultation as SDM, as opposed to patient or surgeon-driven. Surgeons more often perceived the decision-making process as SDM than patients (43.6 versus 29.3% respectively). SDM levels scored objectively using the OPTION and Decision Analysis System for Oncology instruments ranged from 7 to 39%. Subjective SDM levels as perceived by surgeons and patients ranged from 54 to 93%. Patients experienced a higher level of SDM during consultations than surgeons (93 versus 84%). Twenty-five different SDM-related outcomes were reported.

Conclusion

At present, SDM in surgery is still in its infancy, although surgeons and patients both think of it favourably. Future studies should evaluate the effect of new interventions to improve SDM during surgical consultations, and its assessment using available standardized and validated metrics.

Introduction

More than one treatment option is usually available to treat a patient's disease. If none of these treatments is superior when weighing the benefits and possible harms, a treatment dilemma exists. In this case the best treatment option is the one that best fits the patient's preferences[1]. Shared decision-making (SDM) is a process that, on the one hand, helps patients to consider and share their preferences regarding the pros and cons of the treatment options. On the other hand, SDM helps physicians explicitly to evoke these preferences and incorporate them into the final decision[2,3]. SDM has been shown to improve patient satisfaction and adherence to therapy, and may also reduce undesired care[4-7]. Therefore, it is important to involve patients in the decision-making process. This is particularly relevant within surgical practice, when decisions have to be made between different types of surgery or surgery versus no surgery[8]. Surgical interventions are typically irreversible and patients have to deal with potential harmful consequences. Moreover, surgical complications do not resolve as easily as side-effects from some medications.

Because of the importance and increasing recognition of SDM in improving quality of (surgical) care[8], the extent to which it has currently been implemented in surgeon–patient encounters and the metrics used to measure SDM were reviewed systematically. This review aimed to answer the following questions: what are the objective and subjective measurements of SDM during surgeon–patient encounters; and which metrics are used to measure SDM and SDM-related outcomes?

Methods

Protocol and registration

This systematic review is reported in accordance with the guidelines of the PRISMA statement[9]. The review protocol was registered in PROSPERO, the international prospective register of systematic reviews database (http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017073406).

Eligibility criteria

Studies were eligible if they reported on SDM during the consultation between patient and physician in which a treatment decision was made. Surgery had to be at least one of the possible treatment options. In addition, studies needed to measure and report the extent to which SDM was applied with any type of metric. The following specialties were included: vascular surgery, trauma surgery, gastrointestinal surgery, hepatopancreatobiliary surgery, orthopaedic surgery, urological surgery, plastic surgery and cardiothoracic surgery. Cross-sectional studies and RCTs were eligible. Cross-referencing was performed to identify additional eligible studies.

Studies were excluded if not written in English or Dutch, if the study evaluated the effectiveness of decision-making support tools, and if the study focused only on informed decision-making. The publication interval was not restricted.

Search

The Embase, MEDLINE and CENTRAL electronic databases were searched. The final search was undertaken on 14 June 2017. The Population, Intervention, Comparison and Outcome

(PICO) framework was used to construct the search strategy with the assistance of a clinical librarian. The full search strategy is shown in *Appendix A (supporting information)*.

Study selection

Titles and abstracts of the studies identified by the search strategy were screened independently for eligibility by two review authors. Eligibility was based on the aforementioned inclusion and exclusion criteria. Full-text screening was also performed independently. Disagreements were resolved by discussion. If necessary, a third review author acted as arbitrator.

Data collection

Data extraction was carried out independently and in duplicate by two review authors using a predefined data extraction form. Disagreements, if any, were once again resolved by discussion.

The following study characteristics were extracted: first author, publication year, country or countries in which the study was performed, study design, number of participating patients and/or surgeons, patient diagnosis and available treatment options.

Recorded outcomes were the extent to which SDM was applied, irrespective of the metric used. SDM can be scored subjectively by patients and/or physicians[10-13], or objectively by independent observers using checklists[14,15].

In addition, information was collected about other questionnaires or instruments that measured outcomes associated with SDM, for example quality of life[16] or decisional conflict[17].

Risk of bias in individual studies

Risk of bias was evaluated independently by two investigators using checklists. Cross-sectional studies were evaluated using the critical appraisal tool for analytical cross-sectional studies from the Joanna Briggs Institute[18]. RCTs were evaluated by means of the critical appraisal checklist issued by the Dutch Cochrane collaboration[19].

Summary measures

SDM and SDM-related outcomes were expressed in the metrics used by the authors.

Synthesis of results

Meta-analysis was performed if the metric used to measure SDM was reported in more than two studies using a similar questionnaire or instrument. If statistical heterogeneity was limited (I2 value 50% or less), a fixed-effect model was used. If statistical heterogeneity was present (I2 value over 50%), a random-effects model was used.

Additional analyses

SDM measured among patients was compared with that measured among surgeons in studies that provided data from both groups. In addition, SDM scored subjectively (by patients or physicians) was compared with SDM scored objectively, if these were measured in the same study.

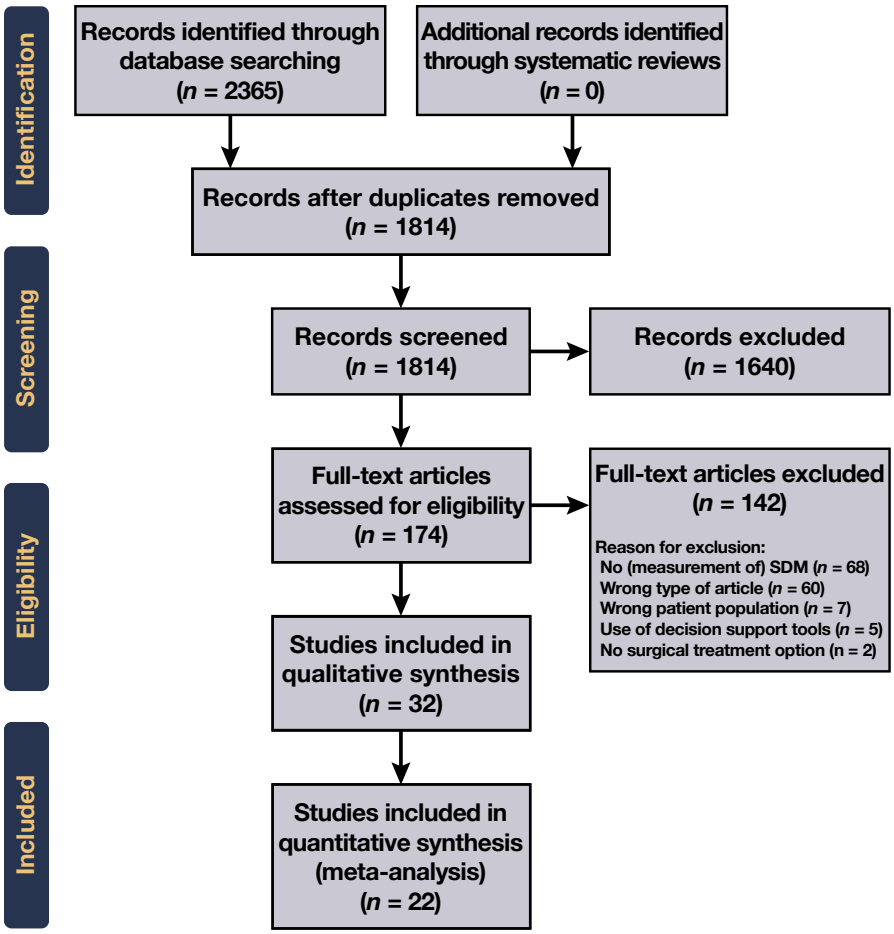

Figure 1. Flow diagram of study inclusion (PRISMA 2009).

Results

Study selection

A total of 2365 articles was identified. After removing duplicates, 1814 articles were screened based on title and abstract. Full-text screening of 174 articles was undertaken. Cross-referencing did not provide any additional eligible articles. Sixty-eight articles were excluded as they did not measure SDM. Thirty-two articles were included for data extraction and 22 articles were eligible for meta-analysis (*Figure 1*).

Study characteristics

All 32 included publications[20-51] had a cross-sectional study design, 11 of which derived their patient population from previous cohort studies, or from the control group of a randomized trial[33]. Twenty of the 32 studies were published after 2010, 11 between 2000 and 2010, and one in 1989[38].

These 32 studies had a median of 130 participants (range 20–4825). Participants were studied across North America, Europe, Asia and Australia. Twenty-six studies scored SDM from the patient's perspective, three from the surgeon's perspective, and another three scored both perspectives. Seventeen studies focused on treatment decisions in women with breast cancer. Colorectal cancer and lung cancer were each studied three times and carpal tunnel syndrome twice. Four studies included patients with various diagnoses who needed to decide between surgery or no surgery (*Table 1*).

Risk of bias in included studies

Overall, the methodological quality of the included studies was good. Inclusion criteria were defined clearly in 31 studies. The validity of the measures used was unclear in 15 of the 32 studies. Thirty studies described at least two of three items: demographics, location and time interval. Eight studies did not include participants based on a specified diagnosis or definition. Twenty-four studies identified confounders and all but one of these studies stated how they dealt with them. Sixteen studies reported the use of at least one validated questionnaire to study outcomes. Thirty-one studies stated the statistical analysis used clearly (*Table S1, Supporting information*).

Results of individual studies

Shared decision-making scored by patients and/or surgeons (subjectively)

Table 2 provides an overview of the metrics used to measure SDM and their results. The Control Perception Scale (CPS) questionnaire[13] uses a five-item Likert scale to measure whether the decision-making process was perceived as more patient-driven, shared or physician-driven. The CPS questionnaire, or adapted versions, were used in 22 studies to study the number of patients and/or surgeons who perceived the decision-making process as SDM. The adapted versions either used a three-item rather than a five-item Likert scale, or asked the same question without actually calling it the CPS questionnaire, or without referring to the original publication of this questionnaire. Two other questionnaires were also used to measure whether the decision-making process was perceived as SDM. This was accomplished by deciding between four decision-making strategies (paternalistic; some shared accepting or declining suggested treatment; shared; informed) and by asking which strategy best matched the consultation[35,43]. Overall, between 10 and 37% of patients and surgeons perceived the decision-making process as SDM.

Other metrics used to measure SDM subjectively were questionnaires that ask patients or physicians to score several statements related to the (shared) decision-making process. For example, 'My doctor and I thoroughly weighed the different treatment options' is one of nine statements used in the SDM-Q-9 questionnaire. This questionnaire was used in two studies[46,51]. Other questionnaires used, in which statements related to the decision-making process are scored, were the SDM-Q-Doc questionnaire[46], the Perceived Involvement in Care Scale (PICS) questionnaire[39] and the physicians' participatory decision-making style questionnaire[45]. Each of these three instruments was used in a single study. The SDM-Q-9 and PICS questionnaires are to be used by patients. The SDM-Q-Doc and physicians' participatory decision-making style questionnaires are meant for physicians. Overall, levels of SDM as measured by the different metrics ranged from 54 to 93% (*Table 2*).

Table 1. Characteristics of included studies.

Author	Publication year	Country	Diagnosis	Treatment options	Number of participants
Argawal[20]	2012	India	Breast Cancer	- Breast conserving surgery - Mastectomy	47
Ananian[21]	2004	France	Breast Cancer	- Direct breast reconstruction - Delayed breast reconstruction - No breast reconstruction	181
Ankuda[22]	2014	USA	Various	- Surgery - No surgery	1034
Aravind[23]	2010	USA	Severe Lower Leg Trauma	- Primary amputation - Reconstruction	20
Bleicher[24]	2008	USA	Breast Cancer	- Breast conserving surgery - Mastectomy	1131
Budden[25]	2014	Australia	Breast Cancer	- Breast conserving surgery - Mastectomy	104
Burton[26]	2017	UK	Breast Cancer	- Surgery + endocrine therapy - Endocrine therapy alone	93
Cyran[27]	2001	USA	Breast Cancer	- Breast conserving surgery - Mastectomy	198
Garcia-Retamero[28]	2014	Switzer-land	Various	- Surgery - No surgery	292*
Gong[29]	2011	South-Korea	Carpal Tunnel Syndrome	- One-sided surgery - Two-sided surgery - No Surgery	78
Hawley[30]	2008	USA	Breast Cancer	- Breast conserving surgery + radi-ation - Mastectomy	925
Hawley[31]	2007	USA	Breast Cancer	- Breast conserving surgery + radi-ation - Mastectomy	1038
Hou[32]	2014	China	Colorectal Cancer	- Defunctioning stoma - No defunctioning stoma	113
Janz[33]	2004	USA	Breast Cancer	- Breast conserving surgery - Mastectomy	99 8*
Katz[34]	2005	USA	Breast Cancer	- Breast conserving surgery - Mastectomy	1422
Keating[35]	2002	USA	Breast Cancer	- Breast conserving surgery - Mastectomy	1081
Kehl[36]	2015	USA	Colorectal Cancer & Lung Cancer	- Surgery - Chemotherapy - Radiation	4825
Lam[37]	2014	Hong Kong	Breast Cancer	- Breast conserving surgery - Mastectomy	283

Author	Publication year	Country	Diagnosis	Treatment options	Number of participants
Larsson[38]	1989	Sweden	Various	- Surgery - No surgery	666
Mandelblatt[39]	2006	USA	Breast Cancer	- Breast conserving surgery - Mastectomy	613
Mohkles[40]	2017	The Netherlands	Lung Cancer	- Surgery - Radiation	46*
Morgan[41]	2015	UK	Breast Cancer	- Surgery - Endocrine therapy	729
Nam[42]	2014	South-Korea	Carpal Tunnel Syndrome	- Surgery - Orthosis - Corticosteroid injections	85
Nguyen[43]	2014	Canada & France	Breast Cancer	- Breast conserving surgery - Mastectomy	121
O'Conner[44]	2003	Canada	Various	- Surgery - No surgery	122
Orom[45]	2014	USA	Prostate Cancer	- Active surveillance - Cryotherapy - Brachytherapy - External been radiation - Surgery	120
Santema[46]	2016	The Netherlands	Abdominal Aortic Aneurysm & Peripheral Artery Disease	- Conservative treatment - Endovascular surgery - Open surgery	54 12*
Seror[47]	2013	France	Breast Cancer	- Breast conserving surgery - Mastectomy	415
Snijders[48]	2014	The Netherlands	Colorectal Cancer	- Anastomosis - defunctioning stoma - Anastomosis + defunctioning stoma - End-colostomy	32*
Vogel[49]	2008	Germany	Breast Cancer	- Breast conserving surgery - Mastectomy - Neo-adjuvant treatment	137
Winner[50]	2016	USA	Gastro-intestinal & Lung Cancer	- Surgery - No surgery	106 10*
Woltz[51]	2017	The Netherlands	Mid-shaft Clavicle Fracture	- Sling - Open reduction & plate fixation	50

* Surgeons

Shared decision-making scored by independent observers (objectively)

SDM was measured objectively in two studies[46,48] using the 12-item OPTION instrument and in one study[37] using the Decision Analysis System for Oncology (DAS-O). The 12-item OPTION and DAS-O instruments are scored by two observers independently using

audio and audiovisual recordings respectively. Overall, SDM levels as measured by these two metrics ranged from 7 to 39% (*Table 2*).

Outcomes related to shared decision-making

The 32 included studies reported on 25 different outcomes, which are summarized in *Table 3*. Meta-analysis was not possible owing to clinical heterogeneity. Nine of 25 SDM-related outcomes were measured using validated questionnaires. The disabilities of the arm, shoulder and hand questionnaire was used and the effect of SDM on the treatment decision was measured in multiple studies. Six studies presented SDM-related outcomes as the combined effect of SDM and patient-driven decision-making compared with the effect of surgeon-driven decision-making.

Synthesis of results

Data from the CPS questionnaire reported in 22 studies (patients and surgeons) were pooled to estimate the overall proportion of patients and surgeons who perceived the decision-making process as SDM. Nineteen of these studies reported patient data alone, one reported only surgeon data, and two studies reported data from both patients and surgeons. A random-effects model was used for meta-analysis as the I^2 value was 94%. Some 36% (95% CI 32 to 40%) of 13.176 patients and surgeons perceived their consultations as SDM, 34% (30 to 38) as patient-driven and 25% (19 to 31) as surgeon-driven.

Table 2. Overview of questionnaires or instruments to measure shared decision-making and their results

Metrics	Results
Shared decision-making scored by patients and/or surgeons (subjectively)	
Control Preference Scale questionnaire	36% (meta-analysis) 95% CI [32%–40%] range 0-100%[20-24,26-34,36,41,42,44,47,49-51]
Description of 4 decision-making strategies	33% of patients (357 out of 1081) matched with SDM range 0–100%[35] 10% of patients (18 out of 184) matched with SDM range 0–100%[43] 23% of surgeons (16 out of 70) matched with SDM range 0–100%[43]
Asking surgeons if they always use SDM	37% of surgeons (38 out of 103) always use SDM range 0–100%[48]
SDM-Q-9 questionnaire	93% (interquartile range 79–100%) range 0–100%[46] 74% (*SD* 23%) range 0–100%[51]
Perceived Involvement in Care Scale	67-74 years of age 62% (*SD* 25.0) range 0–100%[39] >75 years of age 54% (*SD* 27.4) range 0–100%[39]
SDM-Q-Doc questionnaire	84% (IQR 73–92) range 0–100%[46]
Physicians' participatory decision-making style	65% (*SD* 29.89) range 0–100%[45]
Shared decision-making scored by independent observers (objectively)	
12-item OPTION instrument	31% (*SD* 11%) range 0–100%[46] 7% range 0–100%[48]
Decision Analysis System for Oncology	39% (*SD* 6.4) range 0–100%[37]

SDM = shared decision-making, *SD* = standard deviation

Table 3. Overview of additional outcomes associated with shared decision-making.

Decisional conflict	Decisional Conflict Scale =[37]
Quality of life	World Health Organization Quality of Life short form =[47]* Impact of breast cancer on life ↑[39]
Treatment decision	Breast Conserving surgery > Mastectomy[20,26] Breast Conserving surgery < Mastectomy[24]*,[34]* Breast Conserving surgery = Mastectomy[39,47]* Mastectomy < Mastectomy + Breast reconstruction[21] Surgery ↓ vs. surgeon-driven and ↑ vs. patient-driven[41] Endocrine therapy ↓ vs. patient-driven and ↓ vs. surgeon-driven[41]
Depression	Center for Epidemiologic Studies – Depression Scale =[47]* Brief Symptom Inventory-18 ↓[25]*
Anxiety or distress	Brief Symptom Inventory-18 ↓[25]* Global Severity Index ↓[25]* Unsure about surgery ↓[22]*
Decision regret	Decision regret scale ↑ (SDM framework present)[37] Decision regret scale ↓ (SDM clear unbiased information present)[37]
Satisfaction with	Amount of discussion ↑[22]* Amount of information ↑ vs. surgeon-driven and ↓ vs. patient-driven[35] Information provided ↑[47]* Treatment decision process ↓[25]* Decision Scale ↑[33]* Treatment choice =[35] Quality of care ↑ vs. surgeon-driven and = vs. patient-driven[36] Communication ↑ vs. surgeon-driven and = vs. patient-driven[36] Medical consultation ↑ (SDM framework present)[37] Medical consultation ↓ (SDM clear unbiased information present)[37] Overall breast cancer surgery ↑[39] Decision-making process =[49]
Functional outcome measures	Disabilities of the arm, shoulder and hand questionnaire =[29,42]
Effect on treatment	Adhering to active surveillance ↑[45] Antidepressants consumption ↑[47]* Tranquilizing/sedative consumption =[47]*
Effect on consultation	Duration =[33]*

Increase (↑), decrease (↓) or no effect (=) caused by shared decision-making, SDM = shared decision-making* combined effect of shared decision-making and patient-driven decision *vs*. surgeon-driven decision

Additional analyses

Two studies[33,50] compared SDM among patients and among surgeons using the CPS questionnaire. Eighty-nine of 204 surgeons (43.6%) perceived the decision-making process as SDM. In comparison, 60 of 205 patients (29.3%) perceived the decision-making process as SDM.

In addition, one study[46] compared the 12-item OPTION instrument with the SDM-Q-9 and SDM-Q-DOC questionnaires, showing that the level of SDM scored objectively was much lower (31%) than that scored subjectively by patients (93%) and surgeons (84%).

Discussion

A substantial number of studies have addressed SDM in surgeon–patient encounters,

indicating growing interest in SDM in surgery. Despite this interest, the present review shows that use of SDM within surgical practice, interpreted subjectively by patients and surgeons as well as the objectively scored level, is infrequent. Subjectively, however, patients and surgeons appear to have a more optimistic view than the objective measurements show. Surgeons report using SDM more often than their patients, whereas patients report a higher level of SDM during the consultation than surgeons. The large number of metrics used to measure SDM and SDM-related outcomes makes comparison between studies difficult.

Based on the overall results of the CPS questionnaire, the decision-making process scored subjectively during surgeon–patient encounters was most commonly perceived as shared or patient-driven. The prevalence of SDM among surgeon–patient encounters reviewed here is slightly higher than in the usual-care group in the review on decision aids by Stacey and colleagues[7]. They also reported a high level of patient-driven decision-making. This may be related to the predominance of studies on breast cancer, an area in which patient-driven decision-making has become common. Another explanation may be that patients perceived the decision-making process as patient-driven, just because they were asked whether they agreed with the proposed treatment (gave informed consent)[46]. Nevertheless, the CPS questionnaire appears useful for comparing the preferred decision-making approach before the encounter with the perceived level of involvement in the treatment decision after the encounter.

Other subjective metrics, such as the SDM-Q-9 and SDM-Q-Doc questionnaires, showed slightly higher levels of SDM in surgery than in other medical specialties. For example, Doherr and co-workers[52] reported mean total SDM-Q-9 and SDM-Q-Doc scores ranging from 42 to 75%. These high subjective SDM levels in surgical studies may also be caused by a misinterpretation of the informed consent procedure for SDM.

Data obtained using the objective instruments OPTION and DAS-O showed low SDM levels in surgical settings. Similar scores were seen in patient encounters with other medical specialties[14], showing an overall mean (*SD*) of 23% (14) using the OPTION instrument.

The large difference between objective and subjective SDM scores has been explained previously by the inability of the OPTION instrument to account for non-verbal communication[53]. However, the DAS-O instrument, as used by Lam and colleagues[37], was adjusted to include non-verbal communication using audiovisual recordings. These audiovisual recordings also showed low SDM scores, but this instrument was not compared with subjective questionnaires.

This difference between objectively and subjectively scored SDM levels may be due to insufficient knowledge of what SDM really means. This was confirmed in a recent study among trauma surgeons[51]. Under these circumstances, the subjectively scored metrics suffer from a ceiling effect when users express their satisfaction with the consultation or informed consent procedure, rather than the level of SDM if unaware of what SDM entails.

The use and scoring of SDM may be improved by educating both surgeons and patients about it[54]. Programmes have been initiated to make physicians aware of the benefits of SDM, and to make patients mindful that they are allowed and even encouraged to give their opinion. These initiatives comprise, for instance, national campaigns, training sessions and the development of decision support tools[55].

Nevertheless, it remains unclear whether the focus should be on improving objectively scored SDM levels. Perhaps subjective high SDM scores by patients might also bring forth beneficial SDM-related outcomes. Unfortunately, none of the included studies evaluated the

correlation of both objective instruments and subjective questionnaires with SDM-related outcomes.

In addition to the wide range of instruments and questionnaires available to study the level of SDM, the list of metrics used to measure outcomes associated with SDM was also extensive. None of these outcomes could be compared with each other, because the questionnaires used were either non-validated, used in only one study, disease-specific, combined SDM and patient-driven decision-making, or provided outcomes for different subscales of SDM. In addition, very few studies reported absolute data, making comparison with other studies even more difficult.

As advised by both the Core Outcome Measures in Effectiveness Trial (COMET) initiative[56] and the International Consortium for Health Outcomes Measurement (ICHOM)[57], the use of standard instruments or questionnaires is particularly valuable as it permits pooling of results to determine, for instance, the effectiveness of new interventions to improve SDM, such as the development of decision support tools. In addition, being able to compare levels of SDM and SDM-related outcomes may provide insight into which medical specialties are SDM frontrunners, or, in contrast, which low-performing specialties require additional support.

From the perspective of SDM, the authors advocate the use of currently available standardized, validated and preferably generic instruments and questionnaires. To measure the level of SDM in a surgeon–patients encounter in which treatment decisions are made, the CPS questionnaire, the OPTION instrument, and SDM-Q-9 and SDM-Q-DOC questionnaires are recommended. More research is needed on whether subjectively or objectively scored metrics for SDM correlate best with SDM-related outcomes, such as decisional conflict and satisfaction with treatment. In addition, studies should find out which SDM metrics can be used to evaluate new interventions for improving SDM.

Limitations of this study include the heterogeneity of the outcome measures used. This made it difficult to compare studies and to perform meta-analyses. Despite this heterogeneity, a decision was made to continue pooling the CPS questionnaire data, to provide an overall sense of the extent to which patients and surgeons currently perceive SDM. Exploring this heterogeneity by selecting only articles that used the CPS questionnaire with the five-item Likert scales, articles published since 2010, or articles focusing on breast cancer or no breast cancer, did not yield valuable information. Furthermore, all studies were observational. Although SDM can effectively be measured outside a trial setting, there may have been some limitations owing to the observational design. It was often unclear how much time had passed between the consultation and the moment patients and surgeons were asked to evaluate the consultation. Perhaps, over time, patients and surgeons may not exactly remember how the decision was made. The observational design also makes it difficult to know the extent to which patients and surgeons were informed about SDM before both the consultation and the evaluation. Finally, only three studies compared the level of SDM between patients and surgeons in the same investigation, using two different questionnaires. Thus, no clear statements could be made about whether there is a true difference between patients and surgeons in how they view the decision-making process.

The difference between the present systematic review and other reviews regarding SDM in surgery is that previous studies focused mostly on the availability or effectiveness of tools developed to improve SDM[58,59]. This review concludes that, before focusing on ways to improve SDM, it is first necessary to evaluate the current use of SDM and, even more importantly, how to measure SDM uniformly.

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Disclosure

The authors declare no conflict of interest.

References

1. Barry MJ, Edgman-Levitan S. Shared decision-making--pinnacle of patient-centered care. N Engl J Med. 2012;366:780-781.

2. Stiggelbout AM, Pieterse AH, De Haes JC. Shared decision-making: Concepts, evidence, and practice. Patient Educ Couns. 2015;98:1172-1179.

3. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision-making: multistage consultation process. BMJ. 2017;359:4891.

4. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg. 2013;257:860-866.

5. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. BMJ. 2012;345:6572.

6. Oshima Lee E, Emanuel EJ. Shared decision-making to improve care and reduce costs. N Engl J Med. 2013;368:6-8.

7. Stacey D, Legare F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017;4:CD001431.

8. Ubbink DT, Hageman MG, Legemate DA. Shared Decision-Making in Surgery. Surg Technol Int. 2015;26:31-36.

9. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Int J Surg. 2010;8:336-341.

10. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. J Med Internet Res. 2014;16:2.

11. Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M. The 9-item Shared Decision-making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient Educ Couns. 2010;80:94-99.

12. Scholl I, Kriston L, Dirmaier J, Buchholz A, Harter M. Development and psychometric properties of the Shared Decision-making Questionnaire--physician version (SDM-Q-Doc). Patient Educ Couns. 2012;88:284-290.

13. Degner LF, Kristjanson LJ, Bowman D, Sloan JA, Carriere KC, O'Neil J, et al. Information needs and decisional preferences in women with breast cancer. JAMA. 1997;277:1485-1492.

14. Couet N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, et al. Assessments of the extent to which health-care providers involve patients in decision-making: a systematic review of studies using the OPTION instrument. Health Expect. 2015;18:542-561.

15. Stubenrouch FE, Pieterse AH, Falkenberg R, Santema TK, Stiggelbout AM, van der Weijden T, et al. OPTION(5) versus OPTION(12) instruments to appreciate the extent to which healthcare providers involve patients in decision-making. Patient Educ Couns. 2016;99:1062-1068.

16. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996;34:220-233.

17. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995;15:25-30.

18. Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, et al. Joanna Briggs Institute Reviewer's Manual. The Joanna Briggs Institute; 2017.

19. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions. The Cochrane Collaboration; 2011.

20. Agrawal S, Goel AK, Lal P. Participation in decision-making regarding type of surgery and treatment-related satisfaction in North Indian women with early breast cancer. J Cancer Res Ther. 2012;8:222-225.

21. Ananian P, Houvenaeghel G, Protiere C, Rouanet P, Arnaud S, Moatti JP, et al. Determinants of patients' choice of reconstruction with mastectomy for primary breast cancer. Ann Surg Oncol. 2004;11:762-771.

22. Ankuda CK, Block SD, Cooper Z, Correll DJ, Hepner DL, Lasic M, et al. Measuring critical deficits in shared decision-making before elective surgery. Patient Educ Couns. 2014;94:328-333.

23. Aravind M, Shauver MJ, Chung KC. A qualitative analysis of the decision-making process for patients with severe lower leg trauma. Plast Reconstr Surg. 2010;126:2019-2029.

24. Bleicher RJ, Abrahamse P, Hawley ST, Katz SJ, Morrow M. The influence of age on the breast surgery decision-making process. Ann Surg Oncol. 2008;15:854-862.

25. Budden LM, Hayes BA, Buettner PG. Women's decision satisfaction and psychological distress following early breast cancer treatment: a treatment decision support role for nurses. Int J Nurs Pract. 2014;20:8-16.

26. Burton M, Kilner K, Wyld L, Lifford KJ, Gordon F, Allison A, et al. Information needs and decision-making preferences of older women offered a choice between surgery and primary endocrine therapy for early breast cancer. Psycho Oncology. 2017;26:2094-2100.

27. Cyran EM, Crane LA, Palmer L. Physician sex and other factors associated with type of breast cancer surgery in older women. Arch Surg. 2001;136:185-191.

28. Garcia-Retamero R, Wicki B, Cokely ET, Hanson B. Factors predicting surgeons' preferred and actual roles in interactions with their patients. Health Psychol. 2014;33:920-928.

29. Gong HS, Huh JK, Lee JH, Kim MB, Chung MS, Baek GH. Patients' preferred and retrospectively perceived levels of involvement during decision-making regarding carpal tunnel release. J Bone Joint Surg Am. 2011;93:1527-1533.

30. Hawley ST, Janz NK, Hamilton A, Griggs JJ, Alderman AK, Mujahid M, et al. Latina patient perspectives about informed treatment decision-making for breast cancer. Patient Educ Couns. 2008;73:363-370.

31. Hawley ST, Lantz PM, Janz NK, Salem B, Morrow M, Schwartz K, et al. Factors associated with patient involvement in surgical treatment decision-making for breast cancer. Patient Educ Couns. 2007;65:387-395.

32. Hou XT, Pang D, Lu Q, Xu Z, Zhou YJ. Preferred and actual participation roles in operation treatment decision-making of patients with colorectal cancer. Int J Nurs Sci. 2014;1:376-380.

33. Janz NK, Wren PA, Copeland LA, Lowery JC, Goldfarb SL, Wilkins EG. Patient-physician concordance: preferences, perceptions, and factors influencing the breast cancer surgical decision. J Clin Oncol. 2004;22:3091-3098.

34. Katz SJ, Lantz PM, Janz NK, Fagerlin A, Schwartz K, Liu L, et al. Patient involvement in surgery treatment decisions for breast cancer. J Clin Oncol. 2005;23:5526-5533.

35. Keating NL, Guadagnoli E, Landrum MB, Borbas C, Weeks JC. Treatment decision-making in early-stage breast cancer: should surgeons match patients' desired level of involvement? J Clin Oncol. 2002;20:1473-1479.

36. Kehl KL, Landrum MB, Arora NK, Ganz PA, van Ryn M, Mack JW, et al. Association of Actual and Preferred Decision Roles With Patient-Reported Quality of Care: Shared Decision-making in Cancer Care. JAMA Oncol. 2015;1:50-58.

37. Lam WW, Kwok M, Chan M, Hung WK, Ying M, Or A, et al. Does the use of shared decision-making consultation behaviors increase treatment decision-making satisfaction among Chinese women facing decision for breast cancer surgery? Patient Educ Couns. 2014;94:243-249.

38. Larsson US, Svardsudd K, Wedel H, Saljo R. Patient involvement in decision-making in surgical and orthopaedic practice: the Project Perioperative Risk. Soc Sci Med. 1989;28:829-835.

39. Mandelblatt J, Kreling B, Figeuriedo M, Feng S. What is the impact of shared decision-making on treatment and outcomes for older women with breast cancer? J Clin Oncol. 2006;24:4908-4913.

40. Mokhles S, Maat A, Aerts J, Nuyttens J, Bogers A, Takkenberg JJM. Opinions of lung cancer clinicians on shared decision-making in early-stage non-small-cell lung cancer. Interact cardiovasc thorac surg. 2017;25:278-284.

41. Morgan JL, Burton M, Collins K, Lifford KJ, Robinson TG, Cheung KL, et al. The balance of clinician and patient input into treatment decision-making in older women with operable breast cancer. Psychooncology. 2015;24:1761-1766.

42. Nam KP, Gong HS, Bae KJ, Rhee SH, Lee HJ, Baek GH. The effect of patient involvement in surgical decision-making for carpal tunnel release on patient-reported outcome. J Hand Surg Am. 2014;39:493-498.

43. Nguyen F, Moumjid N, Charles C, Gafni A, Whelan T, Carrere MO. Treatment decision-making in the medical encounter: comparing the attitudes of French surgeons and their patients in breast cancer care. Patient Educ Couns. 2014;94:230-237.

44. O'Connor AM, Drake ER, Wells GA, Tugwell P, Laupacis A, Elmslie T. A survey of the decision-making needs of Canadians faced with complex health decisions. Health Expect. 2003;6:97-109.

45. Orom H, Homish DL, Homish GG, Underwood W, 3rd. Quality of physician-patient relationships is associated with the influence of physician treatment recommendations among patients with prostate cancer who chose active surveillance. Urol Oncol. 2014;32:396-402.

46. Santema TB, Stubenrouch FE, Koelemay MJ, Vahl AC, Vermeulen CF, Visser MJ, et al. Shared Decision-making in Vascular Surgery: An Exploratory Study. Eur J Vasc Endovasc Surg. 2016;51:587-593.

47. Seror V, Cortaredona S, Bouhnik AD, Meresse M, Cluze C, Viens P, et al. Young breast cancer patients' involvement in treatment decisions: the major role played by decision-making about surgery. Psychooncology. 2013;22:2546-2556.

48. Snijders HS, Kunneman M, Bonsing BA, de Vries AC, Tollenaar RA, Pieterse AH, et al. Preoperative risk information and patient involvement in surgical treatment for rectal and sigmoid cancer. Colorectal Dis. 2014;16:43-49.

49. Vogel BA, Helmes AW, Hasenburg A. Concordance between patients' desired and actual decision-making roles in breast cancer care. Psychooncology. 2008;17:182-189.

50. Winner M, Wilson A, Yahanda A, Kim Y, Pawlik TM. A cross-sectional study of patient and provider perception of "cure" as a goal of cancer surgery. J Surg Oncol. 2016;114:677-683.

51. Woltz S, Krijnen P, Meylaerts SAG, Pieterse AH, Schipper IB. Shared decision-making in the management of midshaft clavicular fractures: Nonoperative

treatment or plate fixation. Injury. 2017;48:920-924.

52. Doherr H, Christalle E, Kriston L, Harter M, Scholl I. Use of the 9-item Shared Decision-making Questionnaire (SDM-Q-9 and SDM-Q-Doc) in intervention studies: a systematic review. PLoS One. 2017;12:0173904.

53. Kasper J, Heesen C, Kopke S, Fulcher G, Geiger F. Patients' and observers' perceptions of involvement differ. Validation study on inter-relating measures for shared decision-making. PLoS One. 2011;6:26255.

54. Legare F, Labrecque M, Cauchon M, Castel J, Turcotte S, Grimshaw J. Training family physicians in shared decision-making to reduce the overuse of antibiotics in acute respiratory infections: a cluster randomized trial. CMAJ. 2012;184:726-734.

55. van der Weijden T, Post H, Brand PLP, van Veenendaal H, Drenthen T, van Mierlo LA, et al. Shared decision-making, a buzz-word in the Netherlands, the pace quickens towards nationwide implementation. Z Evid Fortbild Qual Gesundhwes. 2017;123-124:69-74.

56. Kryworuchko J, Stacey D, Bennett C, Graham ID. Appraisal of primary outcome measures used in trials of patient decision support. Patient Educ Couns. 2008;73:497-503.

57. Ong WL, Schouwenburg MG, van Bommel ACM, Stowell C, Allison KH, Benn KE, et al. A Standard Set of Value-Based Patient-Centered Outcomes for Breast Cancer: The International Consortium for Health Outcomes Measurement (ICHOM) Initiative. JAMA Oncol. 2017;3:677-685.

58. Fowler GE, Baker DM, Lee MJ, Brown SR. A systematic review of online resources to support patient decision-making for full-thickness rectal prolapse surgery. Tech Coloproctol. 2017;21:853-862.

59. Nicholas Z, Butow P, Tesson S, Boyle F. A systematic review of decision aids for patients making a decision about treatment for early breast cancer. Breast. 2016;26:31-45.

Supplementary materials

Appendix A Search strategy

PubMed

("Decision Making"[Mesh] OR "Decision Support Techniques"[Mesh:NoExp] OR shared decision*[tiab] OR sharing decision*[tiab] OR patient decision*[tiab] OR informed decision*[tiab]) AND ("Patient Participation"[Mesh] OR (patient*[tiab] AND (involv*[tiab] OR participat*[tiab] OR shared decision*[tiab] OR shared medical decision*[tiab])) AND (("Physician-Patient Relations"[MAJR] OR doctor*[tiab] OR clinician[tiab] OR physician*[tiab] OR surgeon*[tiab])) AND ("Patients"[Majr] OR patient*[tiab] OR decision making[ti])) AND ("General Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh] OR "Surgeons"[Mesh] OR surgery[tiab] OR surgical[tiab] OR operat*[ti])

EMBASE (Ovid)

(exp *decision making/ or patient decision making/ or decision support system/ or (shared decision* or sharing decision* or patient decision* or informed decision*).ti,ab,kw.) AND (patient participation/ or (patient* and (involv* or participat* or shared decision* or shared medical decision*)).ti,ab,kw. or informed.ti) AND ((doctor patient relation/ or (doctor* or clinician or physician* or surgeon*).ti,ab,kw.) AND (*patient/ or patient*.ti,ab,kw. or decision making.ti.)) AND (general surgery/ or exp *surgery/ or elective surgery/ or (surgery or surgical).ti,ab,kw. or operat*.ti.)

Cochrane Library

ID	Search
#1	MeSH descriptor: [Decision Making] explode all trees
#2	MeSH descriptor: [Decision Support Techniques] explode all trees
#3	shared decision* or sharing decision* or patient decision* or informed decision*:ti,ab,kw
#4	#1 or #2 or #3
#5	MeSH descriptor: [Patient Participation] explode all trees
#6	patient* and (involv* or participat* or shared decision* or shared medical decision*):ti,ab,kw
#7	#5 or #6
#8	MeSH descriptor: [Physician-Patient Relations] explode all trees
#9	doctor* or clinician or physician* or surgeon*:ti,ab,kw
#10	#8 or #9
#11	MeSH descriptor: [Patients] explode all trees
#12	patient*:ti,ab,kw
#13	decision making:ti
#14	#11 or #12 or #13
#15	#10 and #14
#16	MeSH descriptor: [General Surgery] explode all trees
#17	MeSH descriptor: [Surgical Procedures, Operative] explode all trees
#18	MeSH descriptor: [Surgeons] explode all trees
#19	surgery or surgical:ti,ab,kw
#20	operat*:ti
#21	#16 or #17 or #18 or #19 or #20
#22	#4 and #7 and #15 and #21

Supplementary Table S2. Risk of bias analysis.

Author	Were the criteria for inclusion in the sample clearly defined?	Were the study subjects and the setting described in detail?	Were objective, standard criteria used to measure the condition?	Were confounders identified?	Were strategies to deal with confounders stated?	Were outcomes measured in a valid and reliable way?	Was appropriate statistical analysis used?
Agrawal *et al.*[20]	-	+	-	-	+	?	-
Ananian *et al.*[21]	-	-	-	-	-	-	-
Ankuda *et al.*[22]	-	-	+	-	-	-	-
Aravind *et al.*[23]	-	-	-	+	NA	-	-
Bleicher *et al.*[24]	-	-	-	-	-	?	?
Budden *et al.*[25]	-	-	-	-	-	-	-
Burton *et al.*[26]	-	-	-	-	-	+	-
Cyran *et al.*[27]	-	-	-	-	-	?	-
Garcia-Retamero *et al.*[28]	-	-	?	-	-	-	-
Gong *et al.*[29]	-	-	-	-	-	-	-
Hawley *et al.*[30]	-	-	-	-	-	?	-
Hawley *et al.*[31]	-	-	-	-	-	?	-
Hou *et al.*[32]	-	-	-	+	NA	-	-
Janz *et al.*[33]	-	-	-	-	-	?	-
Katz *et al.*[34]	-	-	-	-	-	?	-
Keating *et al.*[35]	-	-	-	-	-	?	-
Kehl *et al.*[36]	+	-	-	-	-	?	-
Lam *et al.*[37]	-	-	+	-	-	-	-
Larsson *et al.*[38]	-	-	+	-	-	?	-
Mandelblatt *et al.*[39]	-	-	-	-	-	?	-
Mokhles *et al.*[40]	-	-	-	+	NA	?	-
Morgan *et al.*[41]	-	-	+	+	NA	-	-
Nam *et al.*[42]	-	+	-	+	NA	-	-
Nguyen *et al.*[43]	-	-	-	-	-	?	-
O'Conner *et al.*[44]	-	-	+	-	-	?	-
Orom *et al.*[45]	-	-	-	-	-	?	-
Santema *et al.*[46]	-	-	-	-	-	-	-
Seror *et al.*[47]	-	-	-	-	-	-	-
Snijders *et al.*[48]	-	-	-	-	-	-	-
Vogel *et al.*[49]	-	-	+	+	NA	-	-
Winner *et al.*[50]	-	-	+	+	NA	-	-
Woltz *et al.*[51]	-	-	-	+	NA	-	-

- = Low risk of bias, + = high risk of bias, ? = unclear, NA = not applicable

Chapter 3

Shared decision-making in vascular surgery: an exploratory study.

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Abstract

Objectives

Shared decision-making (SDM) is a process in which patients and their doctors collaborate in choosing a suitable treatment option by incorporating patient values and preferences, as well as the best available evidence. Particularly in vascular surgery, several conditions seem suitable for SDM because there are multiple treatment options. The objective of this study was to assess the degree of SDM behavior in vascular surgery.

Methods

Vascular surgeons of four Dutch hospitals selected consultations with patients who were facing a treatment decision. Immediately after the consultation, patients and surgeons completed the (subjective) SDM Q-9 and SDM Q-doc questionnaires respectively, to appreciate the perceived level of SDM behavior. Two evaluators independently and objectively rated SDM behavior in the audiotaped consultations, using the Observing Patient Involvement (OPTION[12]) scale.

Results

Nine vascular surgeons and three vascular surgeons in training conducted 54 consultations. The patients' median SDM Q-9 score was high, 93% (IQR 79–100%), and 16/54 (29.6%) of them gave the maximum score. The surgeons' median score was also high, 84% (IQR 73–92%), while 4/54 (7.4%) gave the maximum score. In contrast, mean OPTION score was 31% (*SD* 11%). Surgeons hardly ever asked the patients for their preferred approach to receive information, whether they had understood the provided information, and how they would like to be involved in SDM.

Conclusions

Currently, objective SDM behavior among vascular surgeons is limited, even though the presented disorders allow for SDM. Hence, SDM in vascular surgical consultations could be improved by increasing the patients' and surgeons' awareness and knowledge about the concept of SDM.

Introduction

The aim of most surgical procedures is to cure the patient of a disease or to prevent sequelae by early intervention. However, invasive treatment options always carry the risk of developing complications that may lead to direct and sometimes even permanent injury to the patient. In weighting the benefits and risks of surgery it is essential to inform the patient about the pros and cons of all available treatment options and to invite them to express their personal preferences[1].

Shared decision-making (SDM) is a process in which patients and clinicians collaborate in choosing a suitable treatment option by incorporating patient preferences, patient values, and best evidence[2]. SDM is increasingly recognized as an ethical and moral standard in medical decision-making as it is essential for respecting the patient's autonomy, especially when patients and clinicians are facing complex decisions[3,4].

Previous studies have found that patients involved in the decision-making process are more satisfied, less anxious, and have more knowledge about their disease and possible treatment options[5-7]. As SDM increases the likelihood that patients receive treatments consistent with their personal values, improved health outcomes and higher treatment adherence are reported[8,9].

Particularly in vascular surgery, several conditions (e.g., abdominal aortic aneurysm (AAA), peripheral arterial disease (PAD), or carotid artery disease) seem particularly suitable for SDM, because multiple treatment options exist and clinicians often face a treatment dilemma. However, little is known to what extent SDM is currently applied in this field. The aim of our study was therefore to explore the extent in which SDM is applied in daily vascular surgical practice.

Methods

To assess the level of SDM, vascular surgeons and vascular surgeons in training at three Dutch university hospitals and one large teaching hospital were invited to participate in the study. Vascular surgeons in training only participated if they were in their last year of training.

Between July 2014 and January 2015, participating surgeons were asked to select consecutive patient consultations in which a treatment decision was to be made. The aim was to obtain at least four audio recordings per surgeon to be able to appreciate intra-doctor variation and to reliably assess the individual surgeon's general performance.

Table 1. SDM-Q-9 and SDM-Q-Doc items[11,12].

Item 1	Clarifying a decision needs to be made
Item 2	Eliciting the patients' preferred involvement
Item 3	Stating there is more than one way to deal with the problem
Item 4	Explaining pros and cons of treatment options
Item 5	Investigating whether the patient has understood all the information
Item 6	Identifying the patients' preferred treatment option
Item 7	Weighting the treatment options
Item 8	Making a shared decision
Item 9	Agreement on follow up arrangements

Table 2. OPTION items[13].

Item 1	Identifying a problem needing a decision-making process
Item 2	Stating there is more than one way to deal with the identified problem
Item 3	Assessing the patients' preferred approach to receive information
Item 4	Listing treatment options
Item 5	Explaining pros and cons of treatment options
Item 6	Exploring patients' expectations
Item 7	Exploring patients' concerns
Item 8	Checking whether the patient understood the information
Item 9	Offering explicit options to ask questions
Item 10	Eliciting the patients' preferred involvement
Item 11	Indicating the need for a decision-making stage
Item 12	Indicating the need to review a decision

None of the surgeons received any training in SDM before this study. Although surgeons were aware of the topic of the study, both surgeons and patients were not aware of the specific items that were to be measured during the consultation. Patients visited the vascular surgery outpatient clinic with a disorder for which multiple treatment options were available or for which the option not to treat (yet) was also a legitimate alternative.

The consultations were audiotaped after the patient had given written informed consent. Patients were excluded from study participation when they were not able to give informed consent or were unable to complete the questionnaire (e.g., due to cognitive impairment).

The duration of the consultation was recorded as the time the vascular surgeon spent with the patient, excluding the time spent reading the case records or documenting the consultation afterwards.

This study was conducted according to the principles of the Declaration of Helsinki[10]. The medical ethics review board of the Academic Medical Center approved the study but waived the need for ethico-legal adjudication as the study did not have a serious impact on the patients involved and did not interfere with the standard treatment process.

Questionnaires and SDM measures

Before the consultation started, basic demographic data were collected from the patient regarding age, gender, and diagnosis. Immediately after the consultation, patients completed the SDM-Q-9 questionnaire. This previously validated questionnaire appreciates subjectively the experienced level of SDM by assessing nine stages of the decision-making process from the patients' perspective on a six-point Likert scale, ranging from 0 (completely disagree) to 5 (completely agree)[11]. The surgeon also filled in the SDM-Q-Doc questionnaire directly after the consultation. This questionnaire was developed to measure the SDM behavior from the perspective of the physician and addresses the same items as the SDM-Q-9 for patients[12]. The nine SDM items are shown in *Table 1*.

To assess the extent to which the surgeon involved the patients in the decision-making process objectively, two evaluators (T.B.S., D.T.U.) independently rated the audiotaped consultations using the Observing Patient Involvement (OPTION) instrument and the accompanying interpretation guide. This instrument measures 12 SDM specific behaviors on

a five point Likert scale, ranging from 0 (no SDM behavior observed) to 4 (SDM behavior exhibited at a high standard)[13]. The 12 items of the OPTION instrument are presented in *Table 2*. When agreement between the two evaluators was good (≤ 1 point difference in score for an individual item) the average OPTION scores of the two evaluators were calculated for each item separately, so scoring half points was possible. When there was moderate disagreement between the evaluators (i.e., > 1 point difference in score for an individual item) consensus was reached by discussion. Non-verbal communication could obviously not be appreciated from the audio recordings, except for meaningful periods of silences.

SDM-Q-9, SDM-Q-Doc, and OPTION scores were transformed from the original score into percentages (SDM-Q-9 and Q-Doc original scores between 0 and 45, OPTION raw scores between 0 and 48) to simplify the interpretation of the scoring (0% = no SDM behavior; 100% = ideal SDM behavior). Transforming this score into percentages of the maximum score is in accordance with other research on this topic[14-16].

Statistical analyses

Statistical analyses were performed using the Statistical Package for the Social Sciences version 21 (IBM SPSS Inc., Armonk, NY, USA). Descriptive statistics were expressed as mean and standard deviation (*SD*), or median with range or interquartile range (IQR), depending on their (non-)normal distribution. A Bland–Altman plot was made to investigate the agreement between the SDM-Q-9 and SDM-Doc questionnaires. This plot also gives information about possible systematic differences and the magnitude of the variation between the two scores across the range of scores[17].

Univariable and stepwise multivariable linear regression analysis was used to explore possible predictors of the OPTION score. The categorical variable "diagnosis" was recoded

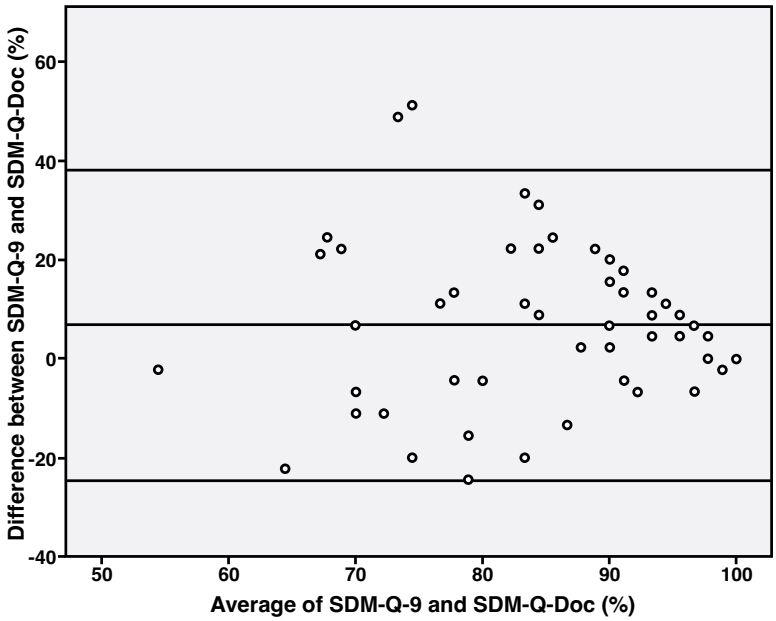

Figure 1. Bland–Altman plot of the differences between SDM-Q-9 and SDM-Q-Doc scores. The horizontal lines indicate the mean difference and 95% limits of agreement.

into dummy variables before analyzing the data. Possible predictors were entered in the multivariable analysis when showing a (nearly) significant (i.e., $p < .10$) relation with the OPTION score according to the univariable analysis. The level of significance was defined as $p < .05$

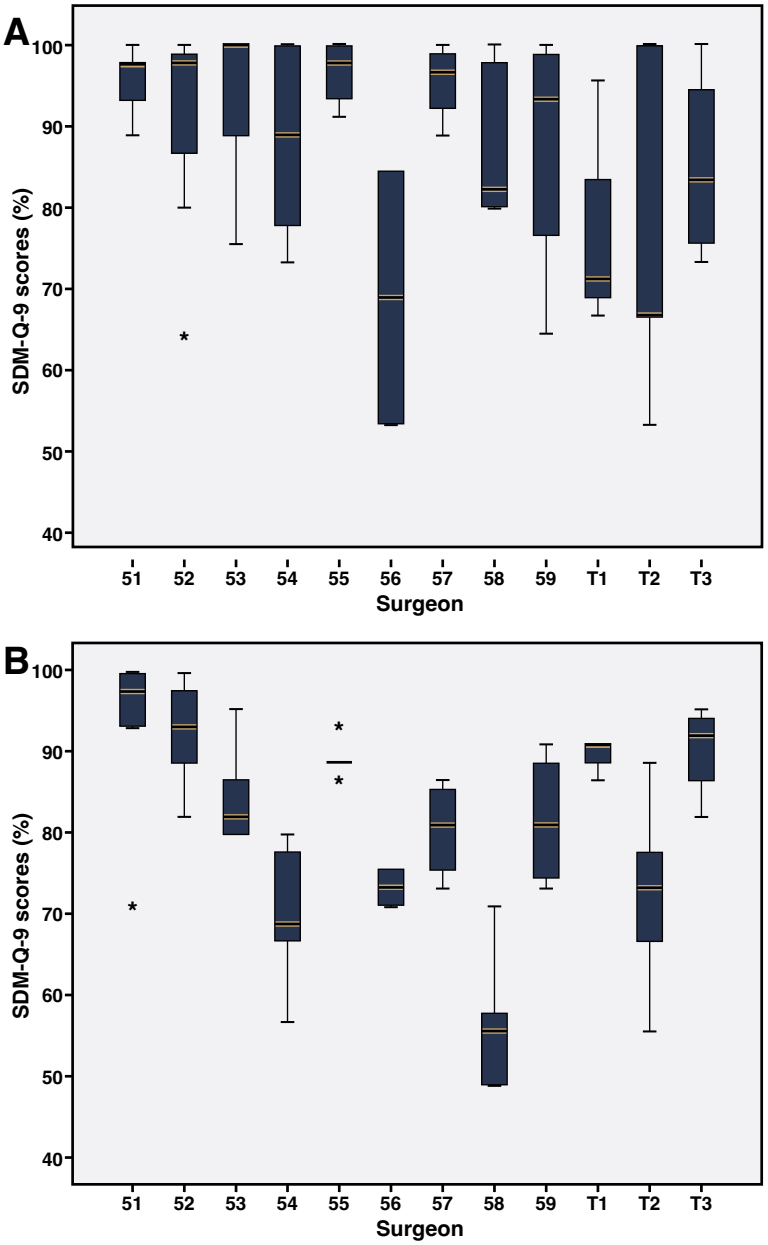

Figure 2. (A) SDM-Q-9 scores per surgeon. (B) SDM-Q-Doc scores per surgeon.
Boxes represent values between the 25th and 75th percentiles, whiskers the upper and lower adjacent values, and the horizontal lines represent the median values. Outliers are displayed as asterisks. S = surgeon; T = surgeon in training.

Results

Fifty-eight consultations were audiotaped. Nine vascular surgeons and three vascular surgeons in training conducted the consultations.

After exclusion of three consultations without a decisional purpose (e.g., the decision whether or not to treat had already been discussed in an earlier consultation) and one recording that failed for technical reasons, 54 consultations were included in this study.

Patients had a mean age of 69.1 (*SD* 15.2) years and 57.4% (31/54) of them were males. Most frequently discussed disorders were symptomatic PAD (claudication $n = 20$ and critical limb ischemia $n = 4$; total 44.4%; 24/54), AAA (35.2%; 19/54), or venous disease (13%, 4/54). Other diagnoses were a popliteal artery aneurysm, a carotid artery disease, and an arteriovenous malformation. The mean duration of the consultations was 19.4 minutes (*SD* 8.5) and ranged from 3.2 to 42.1 minutes.

SDM-Q-9 and SDM-Q-Doc scores

Median SDM-Q-9 score among the patients was 93% (IQR 79–100%). The maximum SDM-Q-9 score was given by 29.6% of the patients (16/54). All SDM-Q-9 items scored high (median 5; IQR 4–5).

Median SDM-Q-Doc score among the vascular surgeons was 84% (IQR 73–92%). The maximum SDM-Q-Doc score was given by 7.4% of the surgeons (4/54). All SDM-Q-Doc items had a median score of 4 or 5 (IQR 3–5).

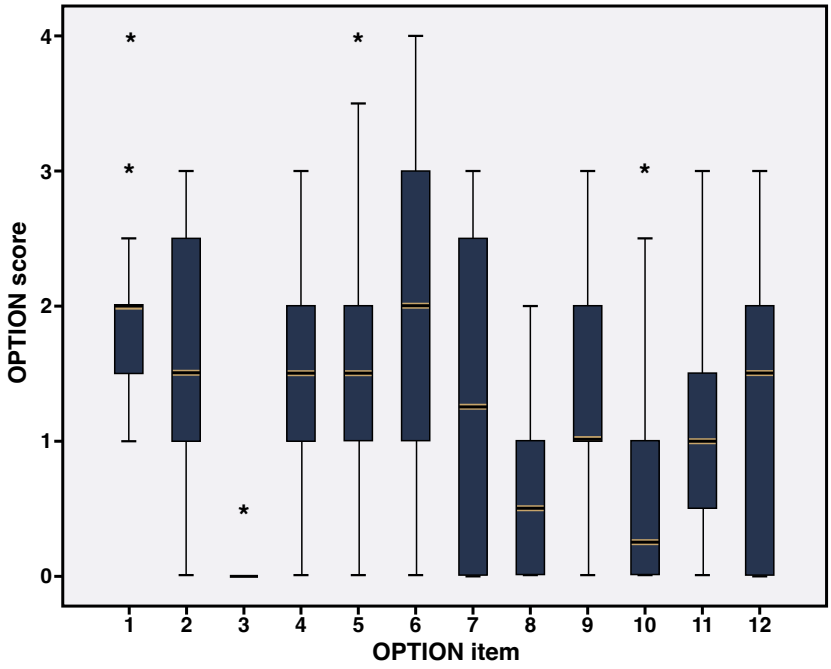

Figure 3. OPTION scores for each of the 12 items.
OPTION score 1 = not observed; 2 = baseline skill level; 3 = good standard; 4 = high standard. Boxes represent values between the 25th and 75th percentiles, whiskers the upper and lower adjacent values, and the horizontal lines represent the median values. Outliers are displayed as asterisks.

The differences between the SDM-Q-9 and SDM-Q-Doc scores are presented in *Figure 1*. This shows that the SDM-Q-9 scores were systematically higher than the SDM-Q-Doc scores (mean difference 7%) but a few opposing scores were also found.

As shown in *Figure 2A,B*, SDM-Q-9 scores varied per surgeon. Some surgeons consistently received high ratings from their patients (e.g., surgeons 1, 5, and 7), whereas others were rated variably (e.g., surgeon 6 and surgeon in training 2).

OPTION scores

The two evaluators had a high level of agreement on most of the OPTION scores. In only 15 of the 648 OPTION scores (54 consultations × 12 items) was moderate disagreement observed (> 1 point difference in OPTION score for that item). For these items consensus was reached by discussion.

Mean total OPTION score was 31% (*SD* 11%). As shown in *Figure 3*, three of the OPTION items were rated as "not observed" in the majority of the consultations (i.e., median scores < 1). These items covered "assessing the patient's preferred approach to receive information" (item 3), "checking if the patient understood the information" (item 8), and "eliciting the patient's preferred involvement" (item 10). Highest scores were found for "the identification of a problem needing a decision-making process" (item 1) and "exploring the patient's expectations" (item 6), as median scores for these items were ≥ 2.

Total OPTION scores ranged widely among the surgeons as shown in *Figure 4*. The lowest overall score was 9%, the highest 58%. In contrast with the SDM-Q-9 scores, most surgeons scored nearly the same OPTION scores during several consultations (maximum range was 33%, most scores ranged less than 20%).

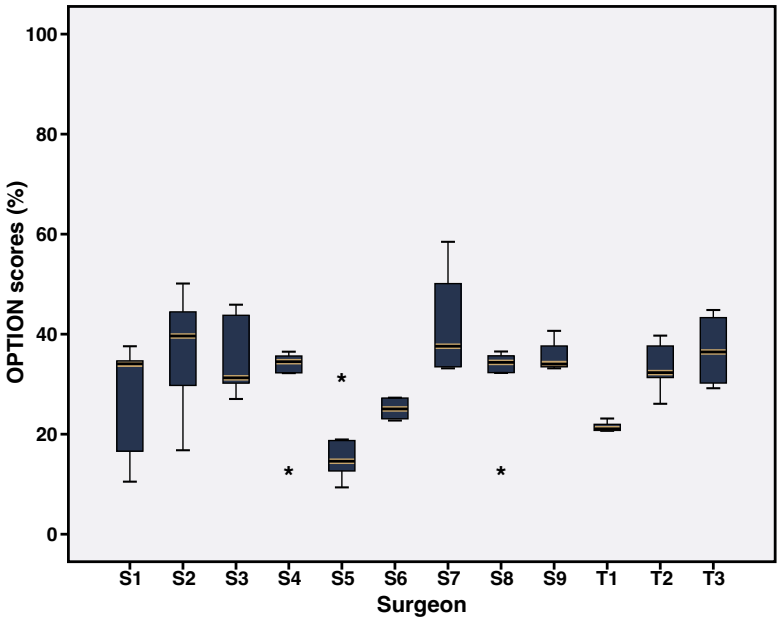

Figure 4. OPTION scores per surgeon.
Boxes represent values between the 25th and 75th percentiles, whiskers the upper and lower adjacent values, and the horizontal lines represent the median values. Outliers are displayed as asterisks. S = surgeon; T = surgeon in training.

Table 3. Linear regression analysis of OPTION score.

	Univariable analysis		
	B	**95% CI**	***P* value**
Patient age	-0.022	-0.217 to 0.173	0.842
Patient gender, female	1.083	-4.850 to 2.956	0.716
Diagnosis			
- Mixed group*	RC		
- Abdominal aortic aneurysm	6.078	-3.387 to 15.542	0.203
- Peripheral arterial disease	1.290	-7.905 to 10.485	0.779
- Venous disease	0.335	-13.082 to 13.751	0.960
Duration of the consultation	**0.006**	**0.001 to 0.011**	**0.032**

** Diagnoses in this category consisted of some less frequently occurring disorders, like peripheral aneurysm, carotid artery disease, or arteriovenous malformation.*

Results of the linear regression analyses are shown in *Table 3*. Only the duration of the consultation was found to be significantly associated with the OPTION score in the univariable analysis and therefore no multivariable model was composed. The OPTION score increased 1.8 points per minute of consultation.

Although it was found that the mean overall OPTION score was somewhat higher in consultations with AAA patients than with PAD patients (35% vs. 30%), the type of diagnosis was not significantly associated with the OPTION score (p = .203 for AAA and p = .799 for PAD).

Discussion

This study explored the application of SDM in vascular surgery from three different perspectives: the patient, the surgeon, and independent observers. Although surgeons and patients scored high on the SDM questionnaires, objective SDM behavior is not yet manifest, even though the investigated disorders are common and particularly call for SDM. One explanation for this discrepancy might be that surgeons and their patients are not yet familiar with the SDM approach. This leads to a ceiling effect (erroneously high scores) when using the questionnaire. When patients were asked whether they have been involved in the decision-making process, they tended to interpret the question as one about satisfaction with the consultation in general rather than with its level of SDM[18,19]. From the surgeons' point of view, they were positive about their performance as they usually provided information about what they saw as the best option and asked for informed consent. Apparently, this is what the high scores in the questionnaires reflect, rather than the two-directional approach needed for SDM, because the patient's preference is neither asked for nor taken into account. Furthermore, clinicians tend to underestimate the number of patients who want to be involved in decision-making[20,21]. Recent literature suggests that over 70% of patients prefer shared decision roles[22], although it is conceivable that this desire is mitigated in severely diseased or aged vascular patients.

Not all surgeons offered a clear treatment choice in the recorded consultations. This could be because there was no clear equipoise (e.g., improvement could easily be achieved by a non-invasive or low risk intervention such as an angioplasty) or the decision to treat was already discussed in an earlier consultation. Furthermore, the initial level of health literacy

may have differed among patients. Some patients may have been browsing the internet to look for information about treatment options. However, all treatment options, including the option not to operate, should always be presented with their pros and cons to give room for the patient's preference.

Surgeons varied in their application of SDM behavior, but in the majority of consultations SDM behavior was below the level considered as "baseline skill". Yet, the level of SDM observed in our study is similar to, or even slightly higher than, most studies included in the review by Couët *et al*.[28], who reported a mean OPTION score of 23% (*SD* 14%) based on 28 studies. It is important to note that some of the OPTION items were rated as "not observed" in the majority of the consultations. These OPTION items (i.e., items 3 and 10) specifically address SDM behavior but scored lowest. In addition, individual surgeons had quite constant OPTION scores, despite different patient characteristics and wishes, suggesting a standard approach. Literature shows that a similar approach to all patients is not likely to meet all patients' wishes[23]. This suggests that vascular surgeons should be trained in SDM by focusing mainly on these specific issues.

In this study, all consultations were evaluated independently by two assessors who used the accompanying interpretation guide of the OPTION instrument and refined this to facilitate an easier and more uniform interpretation. Scoring of the OPTION items was performed liberally, for example if the patient him or herself expressed concerns (rather than the surgeon inquiring for concerns), the item was scored based on the subsequent explorative behavior of the surgeon. Furthermore, by discussing moderate discrepancies between evaluators and calculating mean scores when there was a minimal score deviation, it was ensured that the OPTION scores were less likely to be influenced by observer variations. However, a general, more refined, and expanded version of the interpretation guide would strengthen future OPTION assessments.

This exploratory investigation of the current baseline level of SDM in vascular surgery should be followed by more focused studies that address whether SDM is dependent on specific patient or surgeon characteristics and whether SDM behavior can be improved by training. The fact that the inter-surgeon variation in OPTION scores was considerably larger than the inter-consultation variation within surgeons is an interesting finding that should be investigated in more detail. Apparently, surgeons have a fixed routine regarding the "amount of SDM" they apply during their consultations, irrespective of the patient or disorder they encounter.

Study limitations

First, as we audiotaped the consultations overtly, surgeons may have behaved differently because of the awareness of being recorded. Being aware of participating in a study may have influenced the interaction between the surgeon and the patient. However, there is evidence that audio recordings of consultations do not substantially influence physicians' behavior or time spent, as they quickly forget about being recorded and resume their habitual way of consultation[24,25]. Since it was the surgeon who selected the consultations, selection bias cannot be ruled out: those patients assumed to perform best may have been selected. If this were the case, the results are even more disappointing.

Second, the SDM-Q-9 and SDM-Q-Doc questionnaires are very generic instruments to appreciate the perceived level of SDM behavior, with an apparent ceiling effect. Some surgeons and patients indicated that the questions did not always match their situation or that

the questions were difficult to understand, and this may have affected the way they completed the questionnaires (e.g., the option not to operate is not always considered as an option, and therefore some patients had problems answering item 3 and 7). This was reflected by some contradictory scores between the doctor and the patient on the SDM questionnaires on the same item.

Third, in this study OPTION scores were equated with general SDM behavior. However, the OPTION instrument focuses on the SDM behavior of the physician. To measure the complete degree of SDM in a consultation, an optimal instrument should also comprise more patient centered components[26]. The OPTION instrument is currently the best validated tool available and has been used in many previous studies. The results are similar to other research findings on this topic[16,27,28].

Fourth, a consecutive sample of patients in whom a treatment decision was to be made was included. This has led to a random inclusion of different pathologies and a remarkable, but unintended, absence of patients with carotid artery disease in the sample. Although a significant difference between type of diagnosis and total OPTION score was not found, differences between these groups might have influenced the results. On the other hand, the aim was to assess the surgeons' behavior overall, which seemed to be more dominated by their habitual performance than the diagnosis involved. As they had had no previous training in SDM, they were either not (yet) convinced of the need for SDM or they already felt they were doing a good job. The knowledge gained from this study may help enable surgeons to improve their SDM skills.

Conclusion

SDM in vascular surgical consultations could and should be improved by increasing the knowledge of surgeons and patients of the SDM concept. By increasing the level of SDM behavior, patients are more often treated in accordance with their personal values, which may avoid unwanted operations and reduce over-treatment and costs[3]. The need to involve patients is supported by evidence that physicians tend to neglect patient values as to outcomes of care[29].

This study also showed that SDM requires some additional time, as was suggested earlier by other studies[28,30]. It is conceivable that surgeons are not aware of the potential benefits of SDM or feel that they do not have enough time to invest in SDM, although there is evidence that trained clinicians can incorporate SDM behavior without affecting the duration of the consultation[31]. However, for the successful implementation of SDM in daily practice, it seems essential to increase the surgeon's awareness and knowledge of the concept and conduct of SDM. Furthermore, patients can be prepared for the decision-making consultation, for example by offering decision aids that inform them about the disease, treatment options, the benefit and harm involved in each of the options, and some preference eliciting questions[5,32].

Conflict of interest

None.

Funding

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References

1. Ubbink DT, Hageman GJ, Legemate DA. Shared decision-making in surgery. Surg Technol Int 2015;26:31-6.

2. Moumjid N, Gafni A, Bremond A, Carrere MO. Shared decision-making in the medical encounter: are we all talking about the same thing? Med Decis Making 2007;27(5):539-46.

3. Fowler FJ, Levin CA, Sepucha KR. Informing and involving patients to improve the quality of medical decisions. Health Aff 2011;30(4):699-706.

4. Stiggelbout AM, Van der Weijden T, De Wit MP, et al. Shared decision-making: really putting patients at the centre of healthcare. BMJ 2012;344:e256.

5. Knops AM, Legemate DA, Goossens A, et al. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg 2013;257(5): 860-6.

6. Bekker HL, Hewison J, Thornton JG. Understanding why decision aids work: linking process with outcome. Patient Educ Couns 2003;50(3):323-9.

7. Oshima Lee E, Emanuel EJ. Shared decision-making to improve care and reduce costs. N Engl J Med 2013;368(1):6-8.

8. Naik AD, Kallen MA, Walder A, Street Jr RL. Improving hypertension control in diabetes mellitus: the effects of collaborative and proactive health communication. Circulation 2008;117(11): 1361-8.

9. Wilson SR, Strub P, Buist AS, et al. Shared treatment decision-making improves adherence and outcomes in poorly controlled asthma. Am J Respir Crit Care Med 2010;181(6):566-77.

10. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013;310(20):2191-4.

11. Kriston L, Scholl I, Holzel L, et al. The 9- item Shared Decision-making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient Educ Couns 2010;80(1):94-9.

12. Scholl I, Kriston L, Dirmaier J, et al. Development and psychometric properties of the Shared Decision-making Questionnaire-physician version (SDM-Q-Doc). Patient Educ Couns 2012;88(2):284-90.

13. Elwyn G, Edwards A, Wensing M, et al. Shared decision-making: developing the OPTION scale for measuring patient involvement. Qual Saf Health Care 2003;12(2):93-9.

14. Goossensen A, Zijlstra P, Koopmanschap M. Measuring shared decision-making processes in psychiatry: skills versus patient satisfaction. Patient Educ Couns 2007;67(1e2):50-6.

15. De Las Cuevas C, Penate W, Perestelo-Perez L, SerranoAguilar P. Shared decision-making in psychiatric practice and the primary care setting is unique, as measured using a 9-item Shared Decision-making Questionnaire (SDM-Q-9). Neuropsychiatr Dis Treat 2013;9:1045-52.

16. Weiss MC, Peters TJ. Measuring shared decision-making in the consultation: a comparison of the OPTION and informed decision-making instruments. Patient Educ Couns 2008;70(1):79-86.

17. Altman DG, Bland JM. Measurement in medicine: the analysis of method comparison studies. Statistician 1983;32(3): 307-17.

18. Entwistle V, Prior M, Skea ZC, Francis JJ. Involvement in treatment decision-making: its meaning to people with diabetes and implications for conceptualisation. Social Sci Med 2008;66(2):362-75.

19. Entwistle VA, Watt IS. Patient involvement in treatment decision-making: the case for a broader conceptual framework. Patient Educ Couns 2006;63(3):268-78.

20. Strull WM, Lo B, Charles G. Do patients want to participate in medical decision-making? JAMA 1984;252(21):2990-4.

21. Tariman JD, Berry DL, Cochrane B, et al. Preferred and actual participation roles during health care decision-making in persons with cancer: a systematic review. Ann Oncol 2010;21(6):1145-51.

22. Chewning B, Bylund CL, Shah B, et al. Patient preferences for shared decisions: a systematic review. Patient Educ Couns 2012;86(1):9-18.

23. Brom L, Hopmans W, Pasman HR, et al. Congruence between patients' preferred and perceived participation in medical decision-making: a review of the literature. BMC Med Inform Decis Mak 2014;14:25.

24. Coleman T. Using video-recorded consultations for research in primary care: advantages and limitations. Fam Pract 2000;17(5):422-7.

25. Henry SG, Jerant A, Iosif AM, et al. Analysis of threats to research validity introduced by audio recording clinic visits: selection bias, Hawthorne effect, both, or neither? Patient Educ Couns 2015;98(7):849-56.

26. Epstein RM, Franks P, Fiscella K, et al. Measuring patient-centered communication in patient-physician consultations: theoretical and practical issues. Soc Sci Med 2005;61(7):1516-28.

27. Goss C, Moretti F, Mazzi MA, et al. Involving patients in decisions during psychiatric consultations. Br J Psychiatry 2008;193(5):416e21.

28. Couët N, Desroches S, Robitaille H, et al. Assessments of the extent to which healthcare providers involve patients in decision-making: a systematic review

of studies using the OPTION instrument. Health Expect 2015;18(4):542e61.

29. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. BMJ 2012;345:e6572.

30. Pellerin MA, Elwyn G, Rousseau M, et al. Toward shared decision-making: using the OPTION scale to analyze resident-patient consultations in family medicine. Acad Med 2011;86(8):1010-8.

31. Stacey D, O'Connor AM, Graham ID, Pomey MP. Randomized controlled trial of the effectiveness of an intervention to implement evidence based patient decision support in a nursing call centre. J Telemed Telecare 2006;12(8):410-5.

32. Knops AM, Goossens A, Ubbink DT, et al. A decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm: a randomised clinical trial. Eur J Vasc Endovasc Surg 2014;48(3): 276-83.

Chapter 4

The current level of shared decision-making in anesthesiology: an exploratory study.

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Abstract

Background

Shared decision-making (SDM) seeks to involve both patients and clinicians in decision-making about possible health management strategies, using patients' preferences and best available evidence. SDM seems readily applicable in anesthesiology. We aimed to determine the current level of SDM among preoperative patients and anesthesiology clinicians.

Methods

We invited 115 consecutive preoperative patients, visiting the pre-assessment outpatient clinic of the department of Anesthesiology at the Academic Medical Center of Amsterdam. Inclusion criteria were patients who needed surgery in the arms, lower abdomen or legs, and in whom three anesthesia techniques were feasible. The SDM-level of the consultation was scored objectively by independent observers who judged audio-recordings of the consultation using the OPTION[5] scale, ranging from 0% (no SDM) to 100% (optimum SDM), as well as subjectively by patients (using the SDM-Q-9 and CollaboRATE questionnaires) and clinicians (SDM-Q-Doc questionnaire). Objective and subjective SDM-levels were assessed on five-point and six-point Likert scales, respectively. Both scores were expressed as percentages.

Results

Data of 80 patients could be analysed. Objective SDM scores were low (30.5%). Subjective scores of the SDM-Q-9 and CollaboRATE were high among patients (91.7% and 96.3%, respectively) and among clinicians (SDM-Q-Doc; 84.3%). Apparently, they appreciated satisfaction rather than SDM, being poorly aware of what SDM entails.

Conclusion

The level of SDM in an outpatient anesthesiology clinic where preoperative patients receive information about various possible anesthesia options, was found to be low. Thus, there is room for improving the level of SDM. Some suggestions are given how this can be achieved.

Background

Shared decision-making (SDM) is the process in which healthcare providers and patients decide together about the preferred treatment choice when more than one treatment option is available, using the best available evidence[1,2]. SDM is one of the three pillars in the definition of evidence-based medicine[3]. The principle of evidence-based medicine has been widely accepted and includes appreciation of the situation and preference of the patient. However, many healthcare providers mainly focus on the finding and application of evidence, while the SDM-aspect tends to be neglected[3]. This became particularly clear from studies in surgical settings[4,5].

There are several arguments that favour the application of SDM in various specialties. First, SDM is considered a moral and ethical principle6. Second, patients' preferences may differ from the doctors', and when there is equipoise between two or more different treatment options, patients' preferences should be guiding the final choice[2,7]. Third, SDM may reduce overdiagnosis and may lower surgical overtreatment[7,8]. Fourth, research has shown that patients usually desire a more active role in decision-making[9,10].

Currently there is little evidence regarding the extent to which SDM is applied in anesthesiology, although the vast majority of patients requiring anesthesia wishes to be involved in the decision-making process[11]. Furthermore, this specialty seems particularly suitable for SDM as it offers a range of equally effective anesthesia techniques for various patients undergoing surgery.

The aim of the present study is to determine the current level of SDM at the anesthesiology department of a university hospital during consultations between clinicians and preoperative patients.

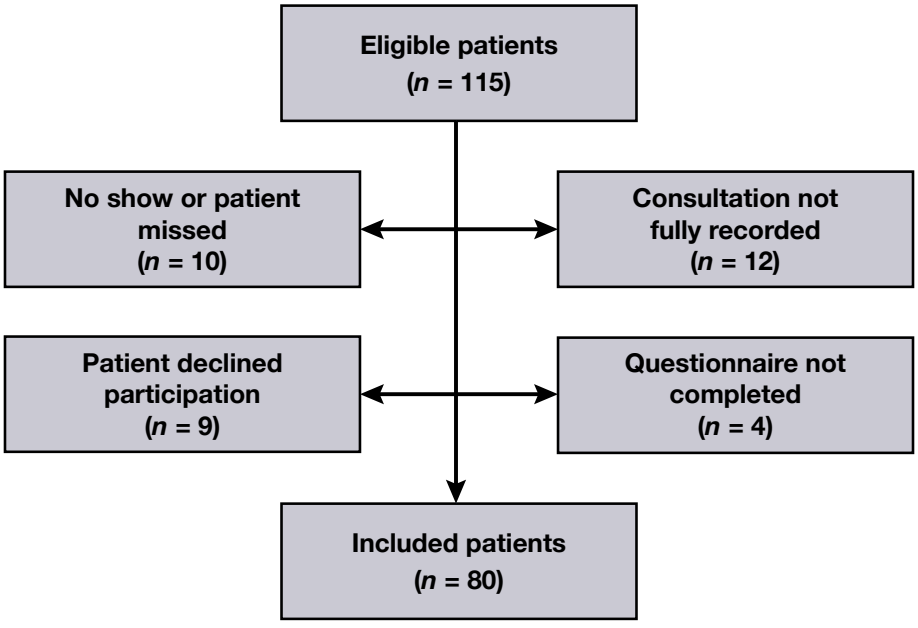

Figure 1. Flowchart of patient inclusion.

Methods

The hospital's medical ethics review board approved the study and waived the need for full assessment, because the study did not have a serious impact on patient integrity or their treatment. This study was conducted in a tertiary care university hospital, in the pre-assessment outpatient clinic at the department of Anesthesiology. During this pre-assessment, patients scheduled for a surgical intervention are screened and informed about the options for per-operative anesthesia and post-operative analgesia.

We invited anesthesiologists, anesthesiologists in training, and anesthesia assistants who, by rotation, see these patients at the outpatient clinic to participate in this study. Clinicians did not receive any SDM training prior to this study.

Patient selection

A consecutive series of eligible patients was included. Patients should require surgery in the arms, lower abdomen or legs, for which three anesthesia techniques were feasible (i.e., general, spinal or epidural anesthesia or nerve block), and should have provided written informed consent. Patients under the age of 18, not able to participate in their decision-making process, or not able to comply and complete the questionnaires were excluded. Also patients already admitted and requiring re-interventions, as well as those presenting at the emergency department were not included.

Sample size

For generalisability purposes we involved all staff members of the outpatient clinic (i.e., 21 care professionals, comprising anesthesiologists, anesthesiologists in training, and anesthesia assistants). For this descriptive part of the study, we planned to include an average of 5 patients per care professional to account for possible intra-clinician variation, as suggested in a previous study[5]. A sample size of 68 consultations would be sufficient to detect an intermediate effect size of 0.4 regarding the differences between the SDM-Q and Collaborate questionnaires, using a Mann-Whitney U-test with a .05 two-sided significance level and a 90% power.

SDM-measures

All questionnaires used had been translated into Dutch previously[12]. The 5-item OPTION instrument was used to score the level of SDM objectively by independent observers (EMKM, JWL). These observers were experienced in judging clinician-patient encounters, but were not present during the consultations studied here. The five items are scored on a scale from 0; "the behavior is not observed" to 4; "the behavior is observed and executed to high standard"[13,14] which means that total OPTION scores can range between zero and 20. We used the general description in the original manual to score each OPTION-item[15].

To assess the OPTION scores, the consultations between patient and clinician were audiotaped for analysis. The results of this instrument were used as primary outcome of the study.

The SDM-Q-9 is a validated, nine-item questionnaire. It was developed as a brief patient-reported instrument for measuring SDM in clinical encounters[16,17]. The items are scored on a six-point Likert scale, ranging from "completely disagree" to "completely agree". Hence, the total SDM-Q-9 scores vary between zero and 54. The 9-item SDM-Q-Doc questionnaire, in

which the SDM-Q-9 questions are rephrased to reflect the clinicians' point of view, aims to assess the clinician's perspective of the SDM process in clinical encounters[17]. The SDM-Q-9 and SDM-Q-Doc questionnaires were used, because these are the most commonly applied tools to assess the patient-reported and doctor-reported levels of SDM.

We also applied the Collaborate scale, which was developed more recently as a 'fast and frugal', valid and reliable, patient-reported measure of the SDM process[18]. It has only three items addressing the effort made regarding patient involvement in the decision-making process. The items are scored on a ten-point Likert scale, ranging from "no effort made" to "every effort made". Thus, the total CollaboRATE scores can vary between zero and 30.

Study conduct

Before the consultation patients were asked informed consent. During the consultation, which has a rather standard structure, the anesthesiology clinician asks about previous surgical interventions and the patient's experience with the type of anesthesia during that procedure, and possible conditions that would interfere with possible anesthesia techniques. The clinician conducts a standard physical examination and proposes the possible anesthesia procedure, which is documented in the electronic medical record.

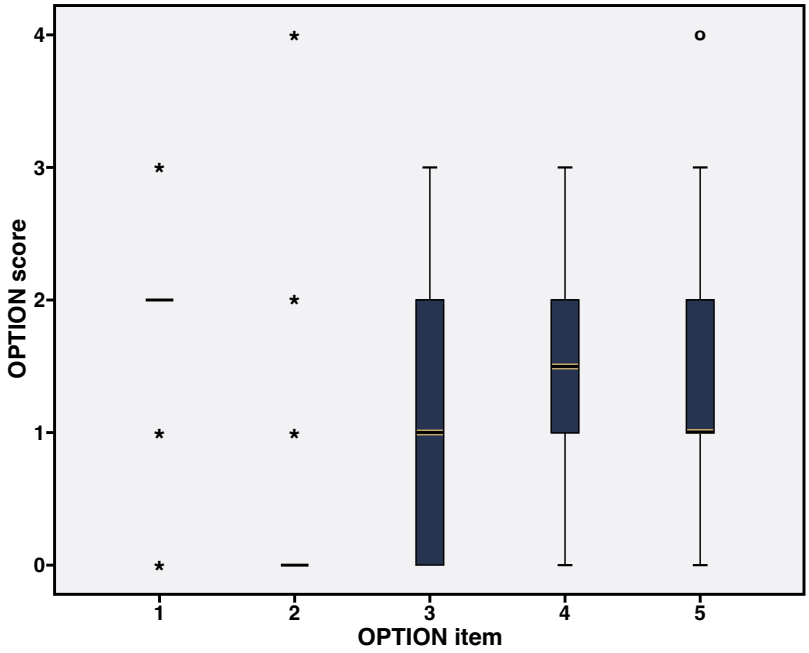

Figure 2. OPTION scores per item. OPTION items: 1= Identifying a problem(s) needing a decision-making process; 2 =the provider will support/explain the need to deliberate about the options; 3 = the provider list the options and explains the pros/cons; 4 = the provider explores the personal preference of the patient; 5 = the provider makes an effort to integrate the patient's preferences as decisions are either made by the patient or arrives at by a process of collaboration and discussion. OPTION scores: 0 = not observed; 1 = there is a perfunctory or unclear attempt to perform the behavior; 2 = the behavior is performed at baseline skill level; 3 = the behavior is performed to a good standard; 4 = the behavior is performed to a high standard. Boxes represent values between 25th and 75th percentiles, whiskers the upper and lower adjacent values and the horizontal lines represent the median values. Outliers are displayed as asterisks.

Table 1. Characteristics of included patients.

	Included patients (*n* = 80)
Male	39 (48.8%)
Age (mean)	49.3 (*SD* 14.9)
Specialty	
Surgery	11 (13.8%)
Urology	5 (6.3%)
Orthopaedics	52 (65.0%)
Plastic surgery	12 (15.0%)
Highest level of education	
Primary education	18 (22.5%)
Mean general education	18 (22.5%)
Secondary education	14 (17.6%)
Higher professional education	19 (23.8%)
University	11 (13.8%)
Underwent previous surgery	68 (85.0%)
Preference for anesthesia after previous surgery	
No preference	19 (23.8%)
Preference for the same type of anesthesia	37 (46.3%)
Preference for another type of anesthesia	12 (15.0%)
Anesthesia technique chosen	
General anesthesia	42 (52.5%)
Spinal anesthesia	18 (22.5%)
Peripheral nerve blockade	19 (23.8%)
No decision made	1 (1.3%)

Directly after the consultation, the perceived level of SDM during the consultation was subjectively assessed by patients (using the SDM-Q-9 and CollaboRATE questionnaires) and clinicians (using the SDM-Q-Doc questionnaire). Finally, the investigators recorded the patients' baseline characteristics using a short questionnaire: age, gender, education level, previous operations, possible preferences regarding the anesthesia technique based on previous experiences, and type of disorder.

Statistical analysis

To ensure reliable assessment of the OPTION scores, three investigators initially scored ten random consultations to assess inter-observer agreement by calculating the kappa ($\varkappa$) value. A $\varkappa$ value expresses the level of agreement above chance. $\varkappa$ values above 0.8 denotes almost perfect agreement, between 0.8 and 0.6 substantial, between 0.6 and 0.4 moderate, and between 0.4 and 0.2 fair agreement[19]. If $\varkappa$ was above 0.8 the remaining consultations were scored by only one investigator (EMKM).

The Statistical Package for the Social Sciences version 22 (IBM SPSS Inc., Armonk, NY, USA) was used to perform statistical analyses. The scores of all questionnaires were considered to have a non-normal distribution and were therefore presented as medians and interquartile ranges (IQR). Differences between SDM-Q-9 scores and CollaboRATE scores were analysed using a Mann-Whitney U test. Differences in SDM-Q scores between clinicians and patients were investigated using a Bland-Altman plot[20]. This plot shows the agreement between two different assays and offers the possibility to detect systematic differences between the assays

and trends across the range of scores, if any. The scores of the OPTION[5] instrument were also presented as box plots for each item as well as for the clinician groups separately, to detect possible differences in preferred levels of patient involvement. The SDM-Q-Doc scores were also presented as a box plot for each clinician.

To compare the results of individual clinicians, we only chose clinicians in whom at least five recordings were made to reliably detect any intra-clinician variation[5].

The responses to the SDM-Q-9, SDM-Q-Doc, CollaboRATE, and OPTION[5] instruments were expressed as percentages of the maximum scores to allow comparison of the scores (0% = no SDM, 100% = optimum SDM). To analyse whether the different OPTION5- and SDM-Q-9 scores were due to variation among patients or among caregivers, we calculated intra-class correlation coefficients (ICC). A possible relationship between duration of the consultation and SDM-Q-9, SDM-Q-doc, and Collaborate scores, the OPTION[5]-score, clinicians' background, and the patients' age was analysed by means of multivariable linear regression analysis.

If the threshold of five patients per clinician was not reached, these data were not used to compare intra-clinician differences. However, these data were included in the overall analysis. If a questionnaire or audio-recording was missing, the data set was considered not complete. In these cases the subjective and objective data could not be compared.

Results

Patient selection took place between September 2015 and February 2016. Based on the appointment list of the outpatient clinic, we eventually searched 115 possibly eligible patients as ten of these did not show up. Of the 105 remaining patients, 25 could not be included for several reasons (see *Figure 1*), resulting in an inclusion rate of 76%. The 80 remaining consultations were performed by 21 clinicians; 3 anesthesiologists, 10 anesthesiologists in training, and 8 anesthesia assistants, aged 25-64 years and of whom 8 were men. The consultations had a mean duration of 12 minutes and ranged from 1.3 to 24.3 mins. This duration was not significantly related to the SDM-Q-9, SDM-Q-doc, Collaborate scores, or the clinicians' background, but a significant positive association was found between the conversation duration and the OPTION score (p = .001), as well as a small but significant association with the patient's age (p = .03). In 9 out of the 21 clinicians involved we were able to record at least five consultations.

Characteristics and preferences of included patients are shown in *Table 1*.

OPTION-scores

The original OPTION[5] manual was found to be not specific enough to unequivocally assess the OPTION scores in this setting. Therefore, the evaluators discussed and specified how to score a certain level for each item. This adapted, more specific manual as developed is this study is presented in *Table 2*. After refining the manual, the $\varkappa$ values rose above 0.80.

Overall, the objectively scored SDM levels using the OPTION instrument were low. Mean total OPTION score was 30.5% (*SD* 10.5%). *Figure 2* shows the OPTION scores per item. Item 2 "justify the work of deliberation as a team" was rated as "not observed" in almost all consultations (77/80). The highest median score (2; baseline skill level) was found for item 1 "naming options", but with a large variation. Item 3 showed the largest variation, representing differences in the amount of information given about the anesthesia options.

Figure 3 shows the mean OPTION scores per clinician. OPTION scores were low, ranging from a median score of 20% to 35%, and did not substantially differ among the groups of clinicians.

SDM-Q-9, SDM-Q-Doc and CollaboRATE scores

Subjectively perceived SDM scores among patients and clinicians were high. Median SDM-Q-9 score was 91.7% (IQR 83.3-100) in patients and 84.3% (IQR 74.3-90.5) in clinicians. Patients scored significantly higher than clinicians ($p < .001$). *Figure 4* shows the

Table 2. Refined scoring definitions for the OPTION[5] manual.

Item	Description	Specification
1	The provider draws attention to, or re-affirms, a problem where alternate treatment or management options exist, and which requires the initiation of a decision-making process. If the patient draws attention to the availability of options, and the provider responds by agreeing that the options need consideration, the item can also be scored positively.	0 – not observed 1 – stating that several options exist 2 – listing the options 3 – equality of the options 4 – is it clear / any questions
2	The provider reassures the patient, or re-affirms, that the provider will support the patient to become informed. The provider will support/explain the need to deliberate about the options.	0 – not observed 1 – decide together 2 – mention is it a difficult choice 3 – will support irrespective of the choice of the patient 4 – both options are o.k., depends on the preferences of the patient, provider has a supportive role
3	The provider gives information, or re-affirms/checks understanding, about options that are considered reasonable (including taking 'no action'), to support the patient in understanding/comparing the pros and cons.	0 – no information 1 – explaining pros and cons of one treatment 2 – explaining pros and cons of more than one treatment 3 – is it clear / any questions 4 – ask the patient to repeat the information
4	The provider supports the patient to examine, voice, and explore his/her personal preference in response to the options that have been described.	0 – not observed 1 – exploring one of the following items: preferences, concerns, expectations 2 – exploring two of the following items: preferences, concerns, expectations 3 – exploring all of the following items: preferences, concerns, expectations 4 – integrates preferences / concerns / expectations for recommendation
5	The provider makes an effort to integrate the patient's preferences as decisions are either made by the patient or arrives at by a process of collaboration and discussion.	0 – not observed 1 – indicates need for decision 2 – indicates need for decision based on the preferences of the patient 3 – asking the patient if the patient is in agreement with the decision 4 – provider indicates that the patient can abandon earlier choice
	Total score 0-20 Rescale 0-100	_____

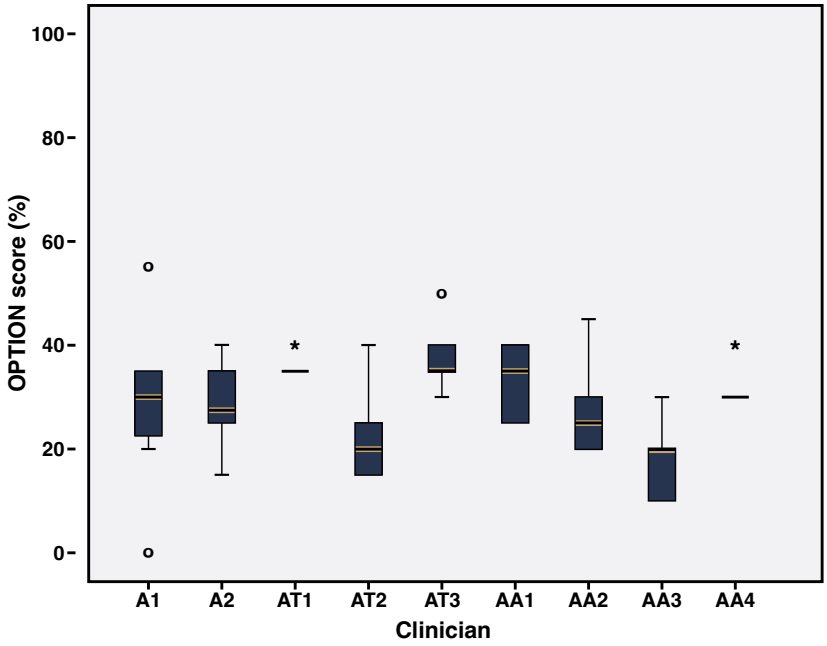

Figure 3. OPTION scores per clinician.
'A' stands for anesthetists, 'AT' stands for anesthetists in training and 'AA' stands for anesthesiology assistant.

relation between the SDM-Q-9 and SDM-Q-Doc scores. Again, patients scored systematically higher than clinicians (on average 7.1%, 95% CI 19.6 to 33.8%). CollaboRATE scores (96.3%; IQR 88.9-100.0) were slightly but significantly (p = .031) higher than the SDM-Q-9 scores (91.7%; IQR 83.3-100.0).

SDM-Q-9, SDM-Q-Doc and CollaboRATE scores per clinician

We found an ICC of 0.16 between caregivers and OPTION[5] scores and an ICC of 0.06 between caregivers and SDM-Q-9 scores, indicating that the variance was mainly due to differences among patients, rather than among caregivers. The SDM-Q-Doc scores of the nine clinicians in whom five consultations were recorded are shown in *Figure 5*. The clinicians' scores were generally high; ranging from a median of 68.5% to 100.0%, and did not differ substantially among them. Patients (SDM-Q-9) also scored high, ranging from 72.2% to 100.0%, irrespective of the clinician involved. The same was true for the CollaboRATE scores, varying between 81.5% to 100.0%.

Discussion

In an era of patient-related outcome measures (PROMs) and patient-related expectation measures (PREMs), shared decisions between doctors and patients are of crucial importance. Evidence suggests that doctors are but faintly aware of what matters most to their patients in the perioperative setting[2]. Shared decision enables doctors to gain more insight into the patients' individual demands and expectations. For many patients scheduled for surgery,

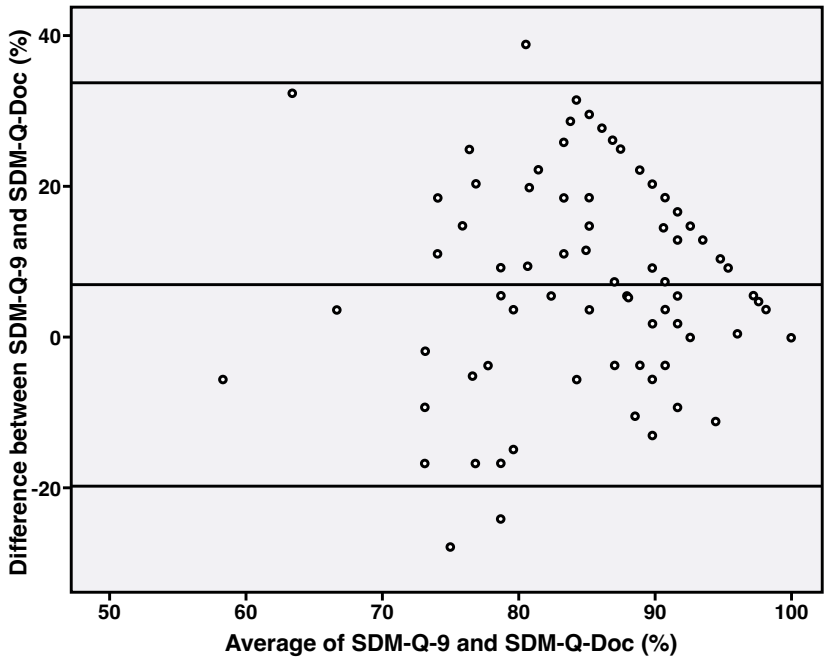

Figure 4. Bland-Altman plot of the differences between SDM-Q-9 and SDM-Q-Doc scores. The middle horizontal line indicates the mean difference between SDM-Q-9 and SDM-Q-Doc, while the upper and lower horizontal lines show the 95% limits of agreement.

several anesthesia techniques are feasible to choose from. Hence, the patient could and should have a voice in this decision.

However, this study showed that in preoperative patients in whom a decision about the anesthesia technique is to be made the level of patient involvement during pre-assessment by anesthesiology clinicians is low. In contrast, patients and clinicians subjectively perceived the consultation as satisfactory. One could argue about the need for SDM when patients and clinicians are satisfied with the current situation. However, the amount of evidence is growing that SDM contributes to a better quality, safety and cost-effectiveness of care[1,7,21], and has been acknowledged as a moral and ethical requirement of present-day care[6]. This awareness is still burgeoning among physicians and patients.

The low level of patient involvement in decision-making as found in this study is in agreement with earlier studies in various other clinical settings[5,13], so there is room for improvement. Clearly, the majority of anesthesiology clinicians were still insufficiently aware of what SDM entails. Although they generally inform patients about the options and (some of) their pros and cons, they hardly invite patients to share in the decision-making process, even though more than one anesthesia option is feasible. This requires a change of attitude from informing and advising the patient what should be done towards showing the patients they have an important role in the decision-making process and engaging them in this collaboration.

Obviously, anesthesiologists are experts in their medical field, but patients are the better expert as to their values, goals and preferences when more options are feasible and properly explained. Thus, SDM may be fostered by explicitly stating patients have a voice in the

decision-making process, explaining the pros and cons of each anesthesia option, supporting them to express their values and preferences regarding the types of anesthesia, and deliberate these options together to reach a final – shared – decision[22].

One of the explanations for the discrepancy observed between the subjective and objective appreciations of the level of SDM is that patients and clinicians often express their degree of satisfaction with the consultation rather than the perceived level of SDM. For example, patients judge subjective aspects, like the tone of voice and amount of empathy of the clinician, the way they felt during the consultation, etc.[23,24]. When patients are not familiar with the concept of SDM, they probably tend to involve the factors mentioned above to a greater extent in their assessment. Second, the subjectively appreciated level of SDM can be higher than what is observed objectively, since assessment of the levels of SDM by patients and clinicians may be biased because of leniency and gratitude[18]. Furthermore, clinicians usually underestimate the amount of information patients desire and spend less time on the discussion about therapy than patients would appreciate[9,11,25]. Therefore, clinicians should discuss the patients' preferred level of SDM in their consultations. If the desired level of involvement remains unclear, it is preferable to use a high level of SDM, as this was found not to impair the satisfaction of the patient[11].

Patients were found to score higher SDM levels than clinicians. Earlier research showed that patients are more willing to score maximum scores compared to clinicians[26]. The CollaboRATE instrument resulted in higher scores than the SDM-Q-9 tool. Although this difference was statistically significant, both scores were still much higher than the objectively scored level of patient involvement using the OPTION instrument. This indicates that the

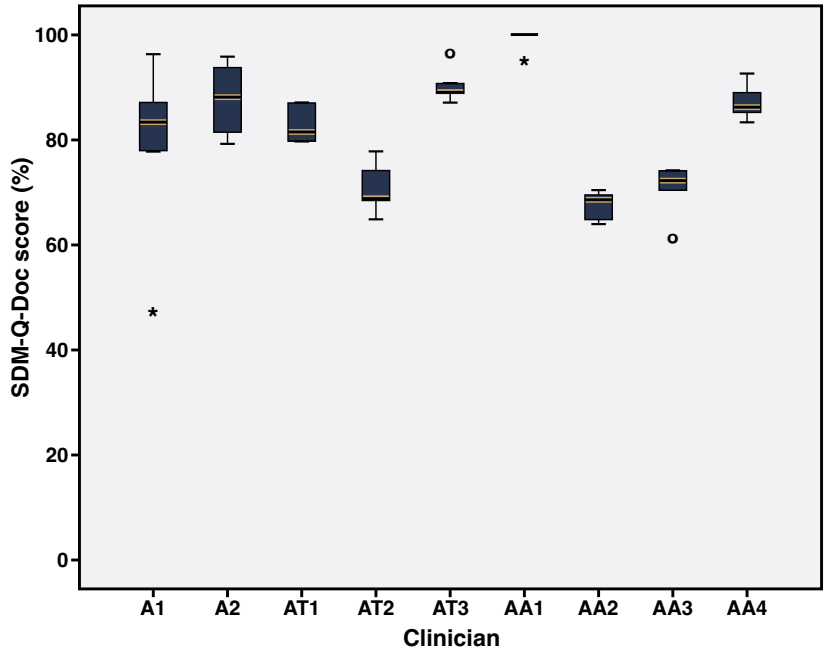

Figure 5. SDM-Q-Doc scores of each of the clinicians.
'A' stands for anesthetists, 'AT' stands for anesthetists in training and 'AA' stands for anesthesiology assistant.

CollaboRATE instrument, developed as a 'fast and frugal' tool to assess the level of SDM[18], is also strongly biased by how much patients know what SDM really is. If they are ignorant about this, the CollaboRATE scores tend to be erroneously high, as do the SDM-Q-9 scores. Thus, the OPTION instrument seems to more accurately reflect the actual level of patient involvement. The substantial variation in item 3 scores may be explained by the fact that a large proportion of patients had been operated before. Therefore, they probably needed less information about the options. Besides, some recordings were short, because the clinician started the audio-recording after the patient's physical exam, whereas others recorded the whole visit, in which the exam was alternated with the conversation. This may explain the variation in consultation duration. Apparently, a better information and involvement of the patient as to the decision-making resulted in a longer duration of the conversation as well as a higher OPTION score.

The SDM-Q-Doc showed less intra-clinician variation than the SDM-Q-9. This is likely because physicians perform their consultations in a routine, unvarying way, and therefore with a similarly constant level of SDM. Different patients have different opinions and therefore the level of SDM may differ among patients, resulting in a greater intra-clinician variation.

Some limitations of this study should be mentioned. We did not reach the intended five patients per caregiver. However, this number is merely a rule of thumb used in other studies. As this was merely used for a descriptive part of the study (i.e., assessing the level of patient involvement in SDM), it was not used for a sample size calculation. Moreover, in other similar studies using the OPTION scale, sample sizes the number of rated consultations per study ranged from 8 to 352, averaging 95[5,13,14]. Despite this relatively small patient sample, it is not likely that a larger sample size would have resulted in a different conclusion.

The care professionals varied widely as to their background. This is common practice in pre-assessment clinics. Although we could not actually test differences in SDM levels between these groups because of small subgroup sizes, it is unlikely that the differences in background would have led to differences in the level of SDM. None of the clinicians were trained and did not receive SDM training during this inclusion period. Hence, they could not have changed their consultation technique. Furthermore, we did not instruct them how to apply SDM. In addition, the patient sample used seems generalizable because it is not likely that excluded patients were different from those analysed, as they were excluded for mere technical reasons or time constraints. Initially, despite the existing manual, it was hard to achieve an acceptable inter-observer reliability due to differences in interpretation of the conversations. For this reason, the manual was refined. This was also found to be necessary in a previous study[5]. However, there is no reason to assume that the refined manuals deviate from the interpretation as intended by the original authors.

Audiotaping the consultations made clinicians aware of being recorded. This may have stimulated their effort to apply SDM in their consultations and might have overestimated the level of SDM we observed. However, earlier studies showed that the recording of consultations does not influence the clinicians' behavior because they quickly forget that the consultation is being recorded[27,28].

The vast majority of included patients had undergone surgery before. Most of them stated to have a preference for a particular anesthesia technique. Because these patients were likely to be better aware of the possibilities, the level of SDM could have been higher. However, our results do not support this and might have been even worse if more patients had contributed who needed surgery for the first time.

Conclusion

The level of SDM in an outpatient anesthesiology clinic where preoperative patients receive information about various possible anesthesia options, was found to be low. As long as the personal preferences of patients are influenced by the expert opinion given by the caregiver, SDM falls short of the intended purpose. Thus, there is room to improve the level of SDM. For example: decision aids to better inform patients about possible anesthesia techniques and to invoke their preferences[29], option grids for care professionals to support the SDM process in the consultation room[22], and SDM e-learning modules to instruct patients and care professionals how SDM should be performed in clinical practice[30]. At this moment a patient decision aid and option grid are currently being developed explaining patients about the anesthesia and analgesia options.

Abbreviations

ICC: intra-class correlation coefficients; IQR: interquartile ranges; PREMs: patient-related expectation measures; PROMs: patient-related outcome measures; SDM: shared decision-making; $\varkappa$: kappa.

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Availability of data and materials

The datasets used during the current study are available from the corresponding author on reasonable request.

Authors' contributions

Study design: DTU, EMH. Study conduct: DTU, EMKM. Data analysis: FES, EMKM, DTU, JWL. Writing paper: FES, EMKM, DTU, JWL. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The hospital's medical ethics review board approved the study and waived the need for full assessment, because the study did not have a serious impact on patient integrity or their treatment. All patients signed informed consent for participation in this study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Barry MJ, Edgman-Levitan S: Shared decision-making--pinnacle of patient-centered care. N Engl J Med 2012, 366:780-781.

2. Mulley AG, Trimble C, Elwyn G: Stop the silent misdiagnosis: patients' preferences matter. BMJ 2012, 345:e6572.

3. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS: Evidence based medicine: what it is and what it isn't. BMJ 1996, 312:71-72.

4. Knops AM, Ubbink DT, Legemate DA, de Haes JC, Goossens A: Information communicated with patients in decision-making about their abdominal aortic aneurysm. Eur J Vasc Endovasc Surg 2010, 39:708-713.

5. Santema TB, Stubenrouch FE, Koelemay MJ, Vahl AC, Vermeulen CF, Visser MJ, Ubbink DT: Shared Decision-making in Vascular Surgery: An Exploratory Study. Eur J Vasc Endovasc Surg 2016, 51:587-593.

6. Salzburg Global S: Salzburg statement on shared decision-making. BMJ 2011, 342:d1745.

7. Glasziou P, Moynihan R, Richards T, Godlee F: Too much medicine; too little care. BMJ 2013, 347:f4247.

8. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT: Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg 2013, 257:860-866.

9. Tariman JD, Berry DL, Cochrane B, Doorenbos A, Schepp K: Preferred and actual participation roles during health care decision-making in persons with cancer: a systematic review. Ann Oncol 2010, 21:1145-1151.

10. Spies CD, Schulz CM, Weiss-Gerlach E, Neuner B, Neumann T, von Dossow V, Schenk M, Wernecke KD, Elwyn G: Preferences for shared decision-making in chronic pain patients compared with patients during a premedication visit. Acta Anaesthesiol Scand 2006, 50:1019-1026.

11. Flierler WJ, Nubling M, Kasper J, Heidegger T: Implementation of shared decision-making in anaesthesia and its influence on patient satisfaction. Anaesthesia 2013, 68:713-722.

12. Rodenburg-Vandenbussche S, Pieterse AH, Kroonenberg PM, Scholl I, van der Weijden T, Luyten GP, Kruitwagen RF, den Ouden H, Carlier IV, van Vliet IM, et al: Dutch Translation and Psychometric Testing of the 9-Item Shared Decision-making Questionnaire (SDM-Q-9) and Shared Decision-making Questionnaire-Physician Version (SDM-Q-Doc) in Primary and Secondary Care. PLoS One 2015, 10:e0132158.

13. Couet N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, Elwyn G, Legare F: Assessments of the extent to which health-care providers involve patients in decision-making: a systematic review of studies using the OPTION instrument. Health Expect 2015, 18:542-561.

14. Stubenrouch FE, Pieterse AH, Falkenberg R, Santema TK, Stiggelbout AM, van der Weijden T, Aarts JA, Ubbink DT: OPTION versus OPTION instruments to appreciate the extent to which healthcare providers involve patients in decision-making. Patient Educ Couns 2015.

15. Barr PJ, O'Malley AJ, Tsulukidze M, Gionfriddo MR, Montori V, Elwyn G: The psychometric properties of Observer OPTION(5), an observer measure of shared decision-making. Patient Educ Couns 2015, 98:970-976.

16. Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M: The 9-item Shared Decision-making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient Educ Couns 2010, 80:94-99.

17. Scholl I, Kriston L, Dirmaier J, Buchholz A, Harter M: Development and psychometric properties of the Shared Decision-making Questionnaire--physician version (SDM-Q-Doc). Patient Educ Couns 2012, 88:284-290.

18. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G: The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. J Med Internet Res 2014, 16:e2.

19. Landis JR, Koch GG: The measurement of observer agreement for categorical data. Biometrics 1977, 33:159-174.

20. Bland JM, Altman DG: Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986, 1:307-310.

21. Oshima Lee E, Emanuel EJ: Shared decision-making to improve care and reduce costs. N Engl J Med 2013, 368:6-8.

22. Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand MA, Edwards A: Option Grids: shared decision-making made easier. Patient Educ Couns 2013, 90:207-212.

23. Scholl I, Koelewijn-van Loon M, Sepucha K, Elwyn G, Legare F, Harter M, Dirmaier J: Measurement of shared decision-making - a review of instruments. Z Evid Fortbild Qual Gesundhwes 2011, 105:313-324.

24. Shay LA, Lafata JE: Where is the evidence? A systematic review of shared decision-making and patient outcomes. Med Decis Making 2015, 35:114-131.

25. Strull WM, Lo B, Charles G: Do patients want to participate in medical decision-making? JAMA 1984, 252:2990-2994.

26. Hirsch O, Keller H, Albohn-Kuhne C, Krones T, Donner-Banzhoff N: Pitfalls in the statistical examina-

tion and interpretation of the correspondence between physician and patient satisfaction ratings and their relevance for shared decision-making research. BMC Med Res Methodol 2011, 11:71.

27. Coleman T: Using video-recorded consultations for research in primary care: advantages and limitations. Fam Pract 2000, 17:422-427.

28. Henry SG, Jerant A, Iosif AM, Feldman MD, Cipri C, Kravitz RL: Analysis of threats to research validity introduced by audio recording clinic visits: Selection bias, Hawthorne effect, both, or neither? Patient Educ Couns 2015, 98:849-856.

29. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, et al: Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2014, 1:CD001431.

30. Hoffmann TC, Bennett S, Tomsett C, Del Mar C: Brief training of student clinicians in shared decision-making: a single-blind randomized controlled trial. J Gen Intern Med 2014, 29:844-849.

Chapter 5

Systematic review of reporting benefits and harms of surgical interventions in randomized clinical trials

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Abstract

Background

Standardized reporting methods facilitate comparisons between studies. Reporting of data on benefits and harms of treatments in surgical RCTs should support clinical decision-making. Correct and complete reporting of the outcomes of clinical trials is mandatory to appreciate available evidence and to inform patients properly before asking informed consent.

Methods

RCTs published between January 2005 and January 2017 in 15 leading journals comparing a surgical treatment with any other treatment were reviewed systematically. The CONSORT checklist, including the extension for harms, was used to appraise the publications. Beneficial and harmful treatment outcomes, their definitions and their precision measures were extracted.

Results

Of 1200 RCTs screened, 88 trials were included. For the differences in effect size of beneficial outcomes, 68 per cent of the trials reported a *P* value only but not a 95 per cent confidence interval. For harmful effects, this was 67 per cent. Only five of the 88 trials (6 per cent) reported a number needed to treat, and no study a number needed to harm. Only 61 per cent of the trials reported on both the beneficial and harmful outcomes of the intervention studied in the same paper.

Conclusion

Despite CONSORT guidelines, current reporting of benefits and harms in surgical trials does not facilitate clear communication of treatment outcomes with patients. Researchers, reviewers and journal editors should ensure proper reporting of treatment benefits and harms in trials.

Introduction

RCTs are considered the best quality evidence for the effectiveness of therapeutic interventions. Surgeons may use this evidence to inform patients to reach informed consent and facilitate shared decision-making. Surgeons need to communicate clearly the benefits and harms of possible treatments so that patients can understand and weigh these options and express a preference[1]. Surgeons should therefore be able to rely on clear and complete information about trial results.

Interpreting the results of an RCT remains challenging, however, as reporting outcomes may lack transparency. The CONSORT statement[2,3] was developed in the late 1990s to promote complete, clear and uniform reporting of RCTs. An extended version[4], published in 2004, added ten recommendations about harm-related data. Although widely supported, evidence shows there is still inadequate reporting in RCTs[5,6].

The aim of this systematic review was to assess the reporting of data on the benefits and harms in a recent representative sample of surgical RCTs in leading medical journals, in order to appreciate whether reported outcomes were easily interpretable and applicable in clinical practice when treatment decisions have to be made.

Methods

This review was conducted according to the PRISMA statement[7]. Journal Citation Reports was used to identify the top five leading general medical journals and the top ten surgical journals, ranked by impact factors in 2015 (*Table 1*). A literature search was conducted in the MEDLINE database using PubMed. As only RCTs published within the specific journals

Table 1. Characteristics of included journals.

Journal	Impact factor 2015	Consort endorsement	No. of included trials	Modified CONSORT score of included trials (median; range)
Annals of Surgery	8.6	Yes	23	47 (24-59)
American Journal of Transplantation	5.7	Yes	1	40
Journal of the American Medical Association Surgery	5.7	Yes	1	57
The British Journal of Surgery	5.6	Yes	26	50 (31-61)
Journal of Bone and Joint Surgery – American Volume	5.2	No	15	48 (32-56)
Journal of the American College of Surgeons	4.3	Yes	2	61 (59-63)
The New England Journal of Medicine	59.6	Yes	10	54 (39-61)
Lancet	44.0	Yes	6	55 (47-63)
Journal of the American Medical Association	37.7	Yes	4	52 (38-63)

Table 2. Modified CONSORT checklist

Item	Description	No description *n* (%)	Inadequate description *n* (%)	Adequate description *n* (%)
1	Collected data on harms and benefits stated in title and abstract	0 (0)	34 (39)	54 (61)
2	Collected data on harms and benefits stated in the introduction	0 (0)	62 (71)	26 (29)
3	Explicit definition of eligibility criteria for participants	0 (0)	1 (1)	87 (99)
4	Description of settings/locations where data were collected	1 (1)	35 (40)	52 (59)
5	Details of intervention intended for each group and how/when they were administered	3 (3)	6 (7)	79 (90)
6	Specific objectives and hypotheses	0 (0.0)	3 (3)	85 (97)
7	Clearly defined primary and secondary outcome measures, and (when applicable) any methods used to enhance measurements quality	0 (0.0)	20 (23)	68 (77)
8	List addressed adverse events with definitions for each	13 (15)	34 (39)	41 (47)
9	Clarify how harms-related data was collected	17 (19)	21 (24)	50 (57)
10	How sample size was determined and (when applicable) explanation of any interim analyses and stopping rules	12 (14)	0 (0)	76 (86)
11	Method used to generate the random allocation sequence, including details of any restriction	20 (23)	4 (5)	64 (73)
12	Method used to implement the random allocation sequence, clarifying whether sequence was concealed until interventions were assigned	21 (24)	3 (3)	64 (73)
13	Who generated the allocation sequence, who enrolled participants, who assigned participants to their groups	53 (60.2)	4 (4.5)	31 (35)
14	Details of blinding of subjects	49 (56)	0 (0)	39 (44)
15	Details of blinding of treatment providers	55 (63)	0 (0)	33 (38)
16	Details of blinding of assessors	43 (49)	1 (1)	44 (50)
17	Details of blinding of data analysts	64 (73)	0 (0)	24 (27)
18	How the success of masking was assessed	66 (75)	0 (0)	22 (25)
19	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses	0 (0)	7 (8)	81 (92)
20	Describe plans for presenting and analyzing information on harms	23 (26)	11 (13)	54 (61)
21	Flow chart describing patient numbers at different stages	22 (25)	1 (1)	65 (74)
22	Flow of participants described in text, describe protocol deviations from study as planned together with reasons	0 (0)	24 (27)	64 (73)
23	Dates defining the periods of recruitment and follow-up	5 (6)	2 (2)	81 (92)
24	Describe withdrawals due to harms and their experiences with allocated treatment	35 (40)	12 (14)	41 (47)
25	Baseline demographic and clinical characteristics of each group	1 (1)	6 (7)	81 (92)

Item	Description	No description *n* (%)	Inadequate description *n* (%)	Adequate description *n* (%)
26	Number of participants in each group included in each analysis, use of intention-to-treat principle. State results in absolute numbers when feasible	27 (31)	1 (1)	60 (68)
27	Provide the denominators for analyses on harms	11 (13)	20 (23)	57 (65)
28	Complete reporting of results and estimated effect size and its precision	0 (0)	15 (17)	73 (83)
29	Multiple testing and corrections, indicating those prespecified and those exploratory	16 (18)	0 (0)	72 (82)
30	All important adverse events or side-effects in each intervention group/patient	10 (11)	21 (24)	57 (65)
31	Present the absolute risk per arm and per adverse event type, grade, and seriousness, and present appropriate metrics for recurrent events, continuous variables, and scale variables	11 (13)	33 (38)	44 (50)
32	Describe any subgroup analyses and exploratory analyses for harms	69 (78)	2 (2)	17 (19)
33	Balanced discussion of own study results	0 (0)	34 (39)	54 (61)
34	Balanced discussion of generalizability of study results	78 (89)	0 (0)	10 (11)
35	Balanced discussion in comparison with overall evidence	0 (0)	32 (36)	56 (64)

were under consideration, the search did not extend to other databases; all the journals were available and traceable through PubMed.

RCTs including surgical patients and published between January 2005 and January 2017 were eligible. This time interval reflected the publication of the CONSORT extension for harms in 2004. The last search was con- ducted in January 2017. RCTs that compared a surgical treatment with another surgical or non-surgical treatment were sought. The search was limited using RCT as publication type along with the following terms, combined using 'OR': 'Surgical Procedures, Operative'[Mesh], 'excision*'[tiab], 'postoperation*'[tiab], 'postoperative'[tiab], 'resection*'[tiab], and 'surg*'[tiab].

Study selection

It was planned to include a sample of about 100 RCTs. Based on the screening of a pilot sample of 100 eligible RCTs, eight matched the inclusion criteria. Therefore, 1200 RCTs were selected randomly from the initial set of eligible trials to arrive at the intended 100 RCTs. Studies on patients younger than 18 years, non-human studies, pilot studies, non-RCTs, and RCTs in ophthalmology, gynaecology and otorhinolaryngology (being not exclusively surgical specialties) were excluded.

Two reviewers conducted the screening of titles and abstracts of the eligible studies independently. Any disagreements were resolved by a third reviewer. Two reviewers then performed the full-text screening independently. EndNote X7 (https://endnote.com/), Covidence (The Cochrane Collaboration; https://www.covidence.org/home) and Excel® 2010 (Microsoft, Redmond, Washington, USA) were used during the process of study selection.

Critical appraisal

The revised version of the CONSORT statement and the CONSORT extension for harms were used to evaluate completeness of reporting RCTs[2,4,8,9], excluding those unrelated to surgical intervention[10]. The revised CONSORT statement provides a checklist of 22 items, and the CONSORT extension for harms checklist contains ten additional items. The reviewers discussed both check- lists beforehand in order to have the same understanding of each item. This resulted in a combined checklist of 35 items (*Table 2*). Two reviewers independently scored the items. Discrepancies were resolved by discussion.

In addition, the number needed to treat (NNT) and number needed to harm (NNH) were scored, as these numbers are considered as clinically useful measures because of their comprehensibility[11,12]. The 'possible impact of funding on results' was scored as adequate if it was clear from the trial description that it had received unrestricted funding (the sponsor had had no influence on the trial conduct, data collection and analysis, interpretation of the data or writing of the manuscript). Judgement of some items, such as blinding, was given the benefit of the doubt and scored as adequate if this was clear implicitly from the text, even though not stated as such. Similarly, the (in)adequacy of the description of generalizability and comparison with overall evidence was judged with leniency.

Data extraction

A predefined, structured, data extraction form was composed to extract the study characteristics. These were: first author, journal, country of study, year of publication, number of contributing centres, involvement of a statistician or epidemiologist, surgical subspecialty, nature of interventions (surgical versus surgical, or surgical versus non-surgical), patient characteristics, types of intervention, sample size, follow-up period, types and total number of outcomes. One reviewer extracted the data, which was checked by a second reviewer independently. Discrepancies were resolved by discussion.

Only data for up to two 'primary' benefits (desired outcomes as primary outcomes), up to three 'secondary' benefits, up to two 'primary' harms (outcomes to be avoided, used as primary outcomes) and up to three 'secondary' harms were extracted, as these were considered to be the most important ones. Up to ten outcomes were thus extracted for each trial. Outcomes were defined as primary or secondary according to the description in the methods section of each article. Outcomes were considered beneficial or harmful when they were felt to be desired or to be avoided respectively. If a choice had to be made, the selection of harms and benefits for inclusion depended on clinical relevance, as determined by the reviewers. For example, a more patient-relevant or patient-reported outcome measure such as pain was preferred over surgical procedural outcomes such as perioperative pancreatojejunostomy leak. Outcomes, such as wound healing, that were assessed at various time points, were judged as a single outcome.

The various effect measures were recorded, including the accompanying precision measures, difference measures, precision measures of the differences between study arms, whether the outcomes were specifically defined and the time intervals of measurements.

Each extended CONSORT item was scored on a scale from 0 to 2 (0, no description; 1, inadequate description; 2, adequate description). Data were analysed using SPSS® version 22.0 (IBM, Armonk, NewYork, USA). A descriptive analysis was conducted for all available characteristics of the included journals and RCTs.

Results

The search resulted in 9483 potentially eligible articles. Titles and abstracts from a random sample of 1200 articles were examined, from which 121 trials from nine different journals were included for full-text screening. Of these, 88 articles were included in the final sample. An overview of the study selection and inclusion process is shown in *Figure 1*.

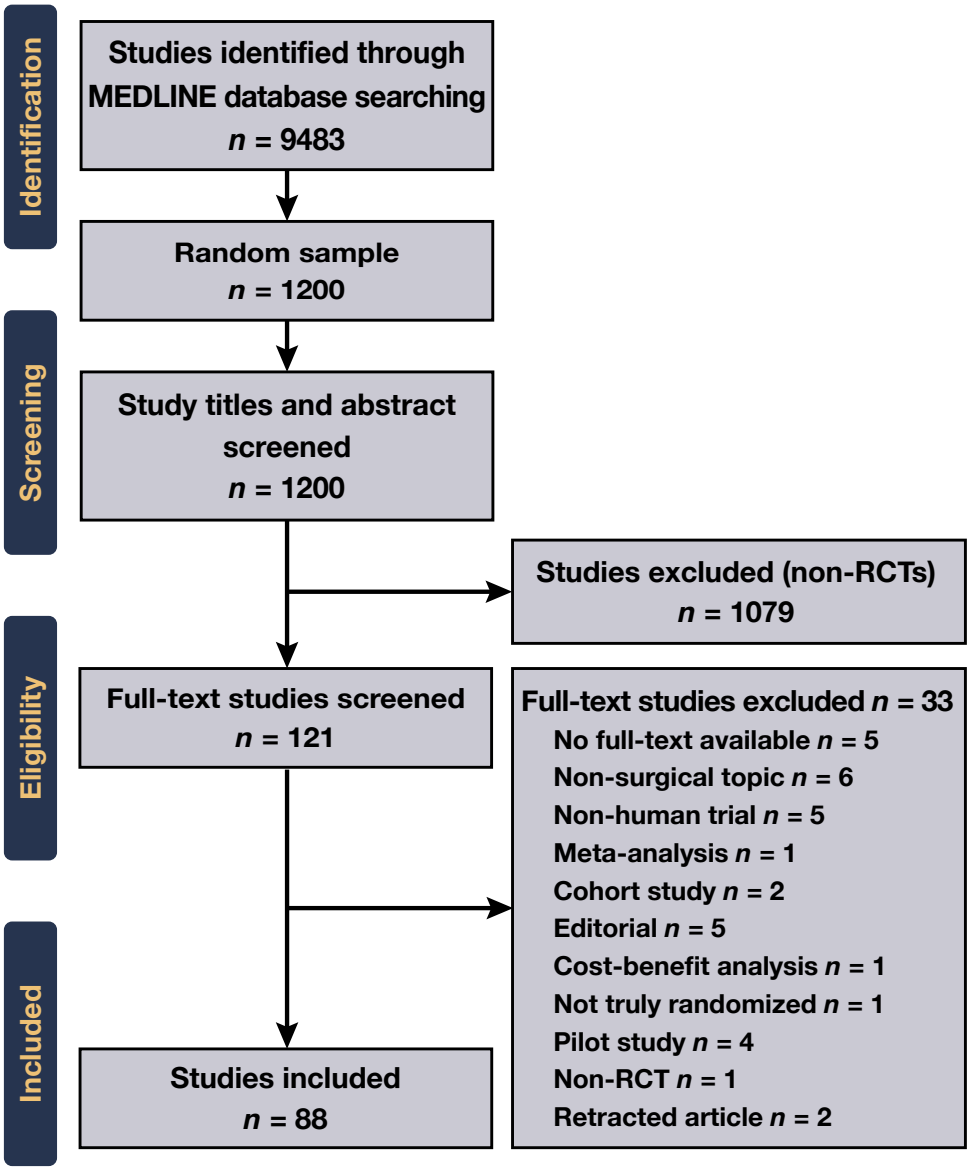

Figure 1. PRISMA flow diagram of the study process.

Characteristics of included journals

The included 88 trials originated from six surgical and three general medical journals. Their characteristics are shown in *Table 1*. Only the Journal of Bone and Joint Surgery did not explicitly endorse the CONSORT statement guidelines. The surgical and medical journals had median impact factors of 5.7 (range 4.3–8.6) and 44 (37.7–59.6) respectively.

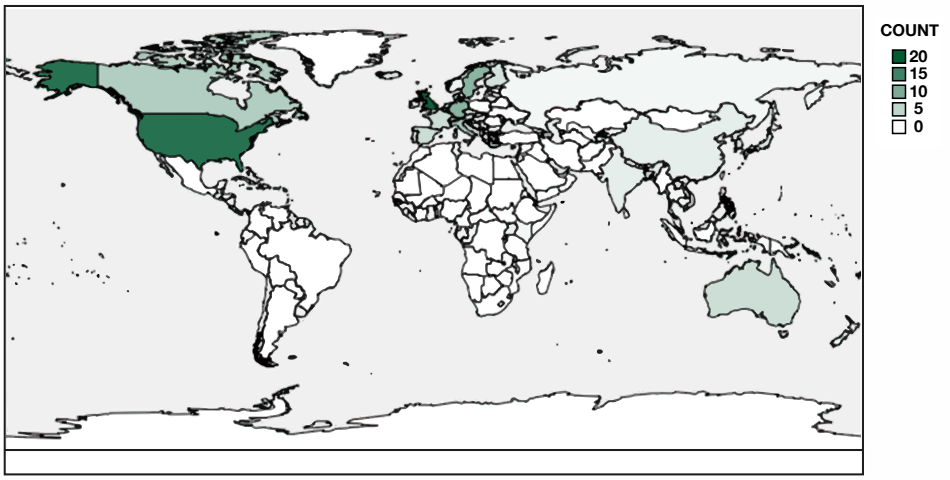

Figure 2. Overview of the demographic distribution of included RCTs
Count indicates the number of articles from each country.

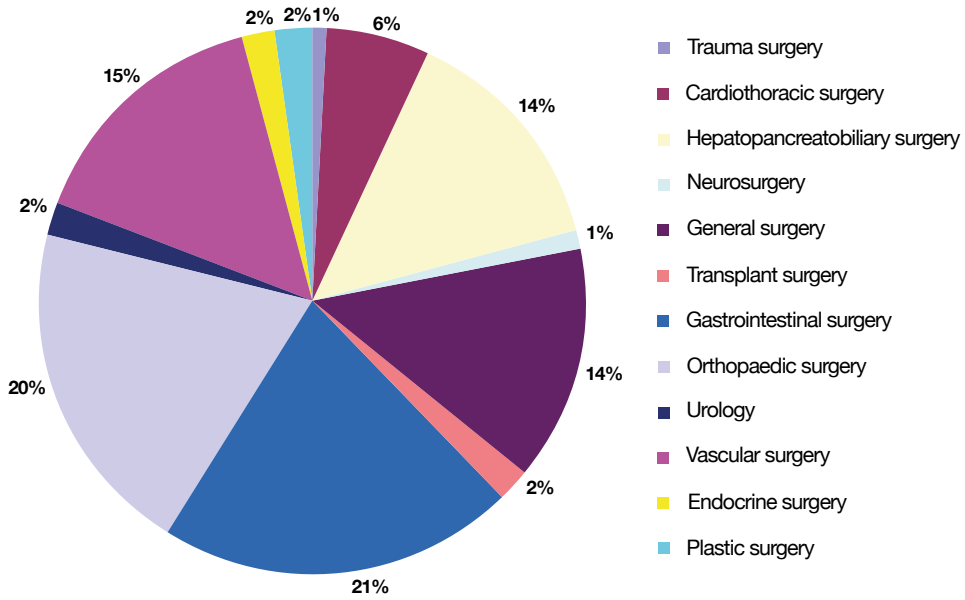

Figure 3. Overview of the subspecialties of included studies.

Table 3. Characteristics of included RCTs.

Characteristic	No. (%) of trials
No. of centers	88 (100)
Single center	44 (50)
Nature of intervention	
Surgical vs. surgical	68 (77)
Surgical vs. non-surgical	20 (23)
Type of RCT	
Initial	70 (80)
Follow-up	18 (20)
Follow-up period	
< 1 month	7 (8)
1-5 months	14 (16)
6-12 months	32 (36)
> 1 year	34 (39)
Missing	1 (1)
Total number of outcomes	
1-3	15 (17)
4-6	9 (56)
7-9	15 (17)
10-12	8 (9)
13	1 (1)
Measurement outcomes	
Primary harm	54 (61)
Primary benefit	39 (44)
Secondary harm	70 (80)
Secondary benefit	37 (42)
Statistician or epidemiologist involvement	
Involvement acknowledged	48 (55)
Funding	
No funding reported	17 (19)
Possible impact funding on results	58 (66)
Unrestricted grant stated	13 (15)
Mentioned adherence to CONSORT statement	
Yes	5 (6)

Characteristics of included trials

Table 3 provides an overview of the trial characteristics. Half of the 88 included trials were multicentre studies, the largest of which involved 177 centres. Of the 88 trials, 68 (77 per cent) compared a surgical intervention with another surgical intervention; the remaining 20 (23 per cent) compared a surgical intervention with a non-surgical intervention.

Nearly 60 per cent of the included trials were conducted in Europe (*Figure 2*). *Figure 3* presents the subspecialties involved; gastrointestinal surgery (21 per cent), orthopaedic surgery (20 per cent) and vascular surgery (15 per cent) were involved most frequently. Adherence to the CONSORT statement was stated in 6 per cent of studies. A median of 6 (range 1 – 13) outcomes were reported in the included trials. A minority (39 of 88, 44 per cent) reported a primary benefit, in contrast to 54 trials (61 per cent) that stated a primary harm. In more than half of the trials (55 per cent) a statistician or epidemiologist was involved (*Table 3*).

Table S1 (supporting information) presents detailed information for the included trials.

Reporting in included trials

The overall CONSORT scores of the included studies are shown in *Table 1*. Median score was 49 (range 24 – 63) of 70. This score was slightly lower for surgical journals (median score 48 (24 – 63)) than for the general medical journals (median score 54 (38 – 63)). CONSORT scores were not significantly higher in more recent publications (median 42 for 2005 – 2011 versus 42.5 for 2012 – 2017 articles).

The metrics referring to harmful outcomes were reported inadequately in 33 of 88 studies (38 per cent) (*Table 2*). Less than half of the studies were scored as adequate regarding the description of loss to follow-up owing to the occurrence of harm. The description of plans for presenting and analysing information on harms was reported adequately in 61 per cent of the studies. The blinding process was poorly described. For example, only 24 trials (27 per cent) described blinding of the data analyst adequately (*Figure 4*). *Table 2* shows that generalizability in the discussion section was reported adequately in only 11 per cent of the studies. In contrast, the definition of eligibility criteria was reported adequately in 99 per cent.

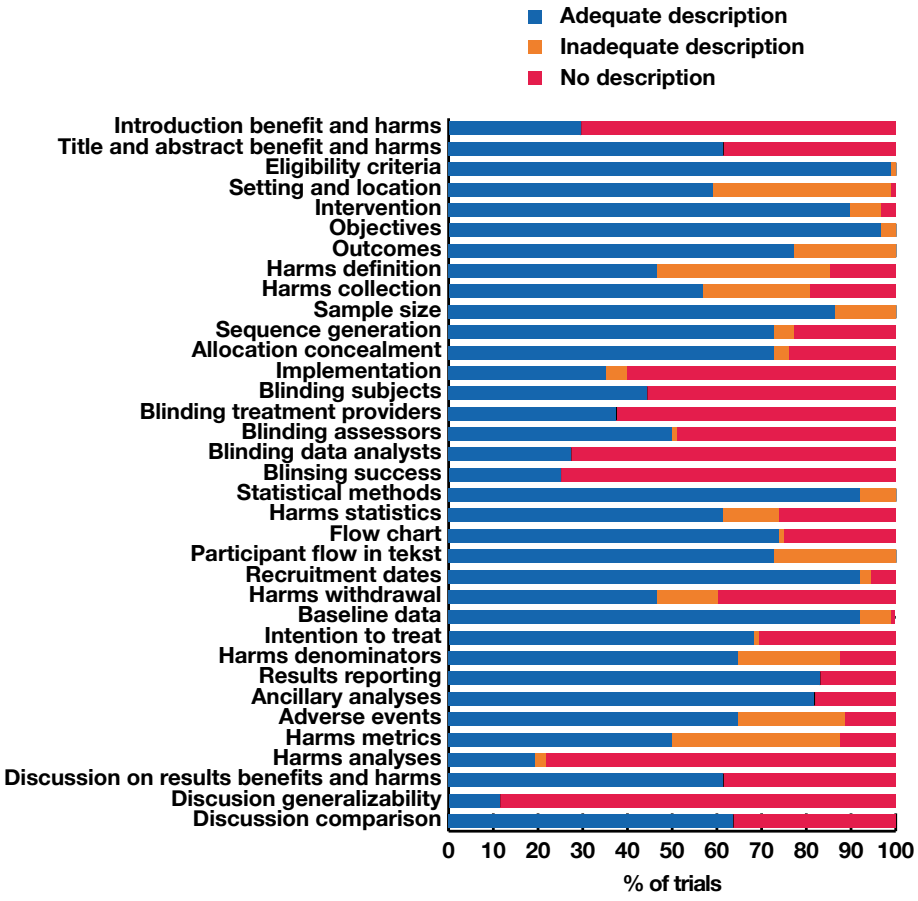

Figure 4. Outcomes of the modified CONSORT checklist.

Reporting of outcome measurements

An overview of the most frequently reported primary beneficial and harmful outcomes is given in *Table 4*. In the 88 studies, a total of 46 primary beneficial outcomes and 63 primary harmful outcomes were reported. Every included study reported at least one discrete outcome. The most frequently reported primary beneficial outcome was a functional outcome measure (15 of 46 reported primary benefits), followed by a measure of the quality of life (10 of 46 benefits). Perioperative characteristics, for example operative blood loss (12 of 63 reported primary harms), complications (12 of 63 harms) and mortality (11 of 63 harms) were the most frequently reported primary harmful outcomes. Overall, 40 of all 280 reported outcomes (14.3 per cent) were not defined clearly. Definitions of primary benefits and harms were lacking in 11 per cent (5 of 46 benefits) and 10 per cent (6 of 63 harms) respectively.

Tables 5 and 6 present the effect and precision metrics for the reported benefits and harms. Overall, more trials reported continuous metrics (expressed as means or medians) than dichotomous measures (such as percentages or absolute numbers). In 29 (63 per cent) of the 46 trials in which primary benefits were described, these were continuous outcomes. Only eight (8 per cent) of the 99 primary and secondary beneficial outcomes were reported as percentages with the corresponding absolute numbers, and 13 per cent (13 of 99) were reported as percentages only (*Table 5*).

A total of 63 primary and 118 secondary harms were reported. In 48 per cent of the trials the primary harm was a continuous outcome. Of the 181 primary and secondary harmful outcomes, 61 (33.7 per cent) were reported as percentages with the corresponding absolute numbers, and 23 (12.7 per cent) were reported as percentages only (*Table 6*).

The precision of the observed differences was usually reported as a *P* value only, and not as a 95 per cent confidence interval. For the differences in effect size of beneficial outcomes, 68 per cent of the trials reported a *p* value only, and not a 95 per cent confidence interval. For harmful effects, this was 67 per cent.

Only five of the 88 studies (6 per cent) mentioned a NNT or NNH. However, a NNT or NNH could be calculated based on the absolute numbers provided for eight of the 46 documented primary benefit outcomes, and for two of the 63 reported primary harm outcomes. Some 39 per cent of the trials did not report on both the beneficial and harmful outcomes of the intervention studied in the same paper.

Table 4. Reporting primary benefits and harms.

Primary Benefits (*n* = 46)	***n* (%)**	**Primary Harms (*n* = 63)**	***n* (%)**
Functional patient-reported outcome measure	15 (33)	Perioperative characteristics	12 (19)
Quality of life	10 (22)	Complications	12 (19)
Survival	5 (11)	Mortality	11 (18)
Intraoperative results	4 (9)	Pain	10 (16)
Technical success	4 (9)	Recurrence	7 (11)
Overall success	4 (9)	Self-reported symptoms	5 (8)
Remission	2 (4)	Hospital stay	5 (8)
Laboratory results	1 (2)	Delay until return to work	1 (2)

Table 5. Frequency of reported outcomes and precision metrics on benefits.

Metrics	Primary benefit 1 (*n* = 39 trials)	Primary benefit 2 (*n* = 7 trials)	Secondary benefit 1 (*n* = 37 trials)	Secondary benefit 2 (*n* = 13 trials)	Secondary benefit 3 (*n* = 3 trials)
Effect measure					
Missing	2.6	-	-	-	-
Mean	48.7	71.4	56.8	69.2	33.3
Median	10.3	14.3	18.9	15.4	66.7
Percentage	15.4	14.3	16.2	-	-
Absolute number	5.1	-	5.4	7.7	-
Absolute number + percentage	15.4	-	2.7	7.7	-
Mean and median	2.6	-	-	-	-
Precision measure of effect					
Missing	33.3	-	27.0	30.8	-
P value	2.6	14.3	-	-	-
95% CI	15.4	-	24.3	23.2	-
SD	38.5	71.4	32.4	30.8	33.3
IQR	5.1	14.3	10.8	15.4	66.7
SD and IQR	2.6	-	-	-	-
Range	2.6	-	5.4	-	-
Difference measure					
Missing	7.7	-	2.7	7.7	-
Risk ratio	2.6	-	-	-	-
Hazard ratio	10.3	14.3	2.7	-	-
Odds ratio	5.1	-	2.7	-	-
Difference in mean	41.0	57.1	48.6	46.2	33.3
Difference in percentage	7.7	-	13.5	-	66.7
Difference in median	10.3	14.3	18.9	15.4	-
Difference in absolute number	-	-	5.4	7.7	-
General effect size	5.1	14.3	2.7	15.4	-
Risk difference	5.1	-	2.7	7.7	-
Relative risk and number needed to treat	2.6	-	-	-	-
Difference in mean and difference in median	2.6	-	-	-	-
Precision measure of difference					
P value	59.0	71.4	73.0	69.2	100.0
95% CI	2.6	14.3	8.1	7.7	-
P value and 95% CI	35.9	14.3	18.9	23.1	-
90% CI	2.6	-	-	-	-

CI: confidence interval; *SD*: standard deviation; IQR: interquartile range

Table 6. Frequency of reported outcomes and precision metrics on harms.

Metrics	Primary harms 1 (*n* = 54 trials)	Primary harms 2 (*n* = 9 trials)	Secondary harms 1 (*n* = 70 trials)	Secondary harms 2 (*n* = 33 trials)	Secondary harms 3 (*n* = 15 trials)
Effect measure					
Missing	1.9	-	-	6.1	-
Mean	35.2	44.4	17.1	24.2	13.3
Median	13.0	-	10.0	9.1	13.3
Percentage	14.8	11.1	10.0	15.2	13.3
Absolute number	5.6	-	17.1	21.2	20.0
Absolute number + percentage	27.8	33.3	42.9	24.2	33.3
Cumulative incidence	1.9	11.1	-	-	-
Absolute number + mean	-	-	1.4	-	-
Ratio	-	-	1.4	-	-
Rate/100 patient-yr	-	-	-	-	6.7
Precision measure of effect					
Missing	42.6	44.4	65.7	63.6	66.7
P value	1.9	-	1.4	3.0	6.7
95% CI	11.1	11.1	8.6	3.0	-
SD	24.1	44.4	12.9	18.2	13.3
IQR	1.9	-	2.9	-	6.7
Range	9.3	-	5.7	12.1	6.7
P value and range	1.9	-	1.4	-	-
SEM	5.6	-	1.4	-	-
Difference measure					
Missing	7.4	11.1	27.1	30.3	26.7
Risk ratio	7.4	11.1	1.4	-	-
Hazard ratio	13.0	-	2.9	3.0	-
Odds ratio	7.4	11.1	2.9	3.0	-
Difference in mean	33.3	44.4	18.6	24.2	13.3
Difference in percentage	13.0	-	37.1	27.3	40.0
Difference in median	13.0	-	7.1	9.1	13.3
Risk difference	5.7	11.1	1.4	3.0	-
Difference in cumulative incidence	-	11.1	-	-	-
Effect size	-	-	1.4	-	-
Difference in rate/100 patient-yr	-	-	-	-	6.7

CI: confidence interval; *SD*: standard deviation; IQR: interquartile range

Table 6 (continued). Frequency of reported outcomes and precision metrics on harms.

Metrics	Primary harms 1 (*n* = 54 trials)	Primary harms 2 (*n* = 9 trials)	Secondary harms 1 (*n* = 70 trials)	Secondary harms 2 (*n* = 33 trials)	Secondary harms 3 (*n* = 15 trials)
Precision measure of difference					
Missing	5.6	11.1	15.7	15.2	13.3
P value	53.7	44.4	72.9	75.8	86.7
95%CI	11.7	-	1.4	-	-
P value and 95% CI	25.9	44.4	8.6	9.1	-
90% CI and 95% CI	1.9	-	1.4	-	-
P value, 95% CI and number needed to treat	1.9	-	-	-	-

CI: confidence interval; *SD*: standard deviation; IQR: interquartile range

Discussion

This systematic review analysed the reporting of data from surgical RCTs published within the past two decades in leading surgical and medical journals. The CONSORT statements have been designed to optimize the reporting of (benefits and harms in) trials, but this review found that current publications still show suboptimal reporting of discrete data. Previous systematic reviews have addressed the suboptimal level of adherence to the CONSORT statement in publications in surgical journals[13]. The present review adds to this in terms of deficiencies in how data on benefits and harms are reported. Few of these outcomes were described as an adequate and easily interpretable effect estimate or difference measure. Measures of precision such as confidence intervals were missing in most trial reports. In combination with effect size, precision measures help the reader to appreciate whether or not a finding is clinically relevant. Besides effect and precision measures, benefits and harms should be defined clearly so that healthcare providers can communicate these with patients.

Most trials included in this review provided P values only, which express statistical significance[14] but do not communicate unequivocally the amount of statistical uncertainty that surrounds the available effect estimate. *P* values can make it more difficult to appreciate results, with risks of misinterpretation and errors in assessing the applicability of an intervention in clinical practice[15].

More trials in the present review reported on harms than on benefits as primary outcomes. This finding is in contrast with a previous review that showed poor reporting of harms[16]. Possibly, trials of surgical interventions pay more (but still insufficient) attention to harmful effects, given the invasive nature of the intervention.

The number of patients who need to be treated to achieve one additional beneficial event, the NNT, has become a well-known measure of treatment benefit[11]. When treatment decisions are to be made, particularly in the surgical outpatient clinic, these parameters may help healthcare providers explain to their patients the expected benefits and risks of interventions. Back in 2001, the CONSORT statement argued that the NNT could be helpful to express the results of an RCT.

Studies assessing reporting quality before the extended CONSORT statement was issued[17,18] showed similar shortcomings. Unfortunately, the publications evaluated here still suffered from the same shortcomings, despite the fact that leading medical journals have

supported the recommendations for standards of reporting[11,17,19], or even extended them[20]. Generalizability of the results was described poorly in most trials. This aspect is crucial for healthcare providers to appreciate whether the results of a trial are relevant and applicable to their own patient population.

The present review has limitations. Of the 88 trials included in the analysis, 18 were follow-up studies, in which some primary reports of trial results were not included. As these follow-up studies often did not describe further details about trial designs and methods, this might have resulted in a lower modified CONSORT score in comparison with the initial RCTs. However, when reporting follow-up data of a study, authors should make clear the main points of the methodology and outcomes of the conducted RCT. The random sample did not yield studies from all initially selected journals, although this seems unlikely to have influenced the findings, as all studies were published in leading journals, nearly all of which endorsed the CONSORT statement. It was, however, unclear in which year the journals in the survey adopted this requirement in their instructions to authors. This study was limited to studies of surgical *versus* surgical *versus* non-surgical interventions. Surgical trials reporting on non-surgical interventions alone might show higher CONSORT scores, because non-surgical (mostly drug) treatments tend to be better scrutinized and monitored before reporting the outcomes. The classification of outcomes as beneficial or harmful was sometimes ambiguous. For example, pain is generally interpreted as harmful and was therefore reported as 'harm', but in one study[21] reduction in pain was scored as a 'benefit'.

The CONSORT statement, along with the extension for harms, provides guidelines that should ensure high reporting quality for RCTs. Current trials, however, reported in leading surgical and medical journals still fail to describe reported benefits and harms in surgical RCTs correctly, despite the fact that the CONSORT statement is sup- ported widely. Interpretation of the provided evidence remains difficult and susceptible to interpretation bias, which, in turn, impedes adoption. Authors, editors, statisticians and peer reviewers should emphasize adherence to CONSORT guidelines to facilitate evidence-based clinical decision-making.

Disclosure

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References

1. Stiggelbout AM, Van der Weijden T, De Wit MP, Frosch D, Legare F, Montori VM et al. Shared decision-making: really putting patients at the centre of healthcare. BMJ 2012; 344: e256.

2. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA 1996; 276: 637 – 639.

3. Freemantle N, Mason JM, Haines A, Eccles MP. An important step toward evidence-based health care. Consolidated standards of reporting trials. Ann Intern Med 1997; 126: 81 – 83.

4. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K et al.; CONSORT Group. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med 2004; 141: 781 – 788.

5. Hopewell S, Dutton S, Yu LM, Chan AW, Altman DG. The quality of reports of randomised trials in 2000 and 2006: comparative study of articles indexed in PubMed. BMJ 2010; 340: c723.

6. Wang JL, Sun TT, Lin YW, Lu R, Fang JY. Methodological reporting of randomized controlled trials in major hepato-gastroenterology journals in 2008 and 1998: a comparative study. BMC Med Res Methodol 2011; 11: 110.

7. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. PLoS Med 2009; 6: e1000100.

8. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D et al.; CONSORT GROUP (Consolidated Standards of Reporting Trials). The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med 2001; 134: 663 – 694.

9. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001; 357: 1191 – 1194.

10. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P; CONSORT Group. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med 2008; 148: 295 – 309.

11. Cook RJ, Sackett DL. The number needed to treat: a clinically useful measure of treatment effect. BMJ 1995; 310: 452 – 454.

12. Tramèr MR, Walder B. Number needed to treat (or harm). World J Surg 2005; 29: 576 – 581.

13. Speich B, Mc Cord KA, Agarwal A, Gloy V, Gryaznov D, Moffa G et al. Reporting quality of journal abstracts for surgical randomized controlled trials before and after the implementation of the CONSORT extension for abstracts. World J Surg 2019; 43: 2371 – 2378.

14. Nuzzo R. Statistical errors: P values, the 'gold standard' of statistical validity, are not as reliable as many scientists assume. Nature 2014; 506: 150 – 152.

15. Baker M. Statisticians issue warning over misuse of P values. Nature 2016; 531: 151.

16. Hodkinson A, Kirkham JJ, Tudur-Smith C, Gamble C. Reporting of harms data in RCTs: a systematic review of empirical assessments against the CONSORT harms extension. BMJ Open 2013; 3: e003436.

17. Nuovo J, Melnikow J, Chang D. Reporting number needed to treat and absolute risk reduction in randomized controlled trials. JAMA 2002; 287: 2813 – 2814.

18. Hildebrandt M, Vervolgyi E, Bender R. Calculation of NNTs in RCTs with time-to-event outcomes: a literature review. BMC Med Res Methodol 2009; 9: 21.

19. Furukawa TA. From effect size into number needed to treat. Lancet 1991; 353: 1680.

20. Legemate DA, Koelemay MJ, Ubbink DT. Number unnecessarily treated in relation to harm: a concept

physicians and patients need to understand. Ann Surg 2016; 263: 855 – 856.

21. Bingener J, Skaran P, McConico A, Novotny P, Wettstein P, Sletten DM et al. A double-blinded randomized trial to compare the effectiveness of minimally invasive procedures using patient-reported outcomes. J Am Coll Surg 2015; 221: 111 – 121

Supplementary Table S1. Detailed charecteristics of included studies.

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Acker, M.A. (32)	NEnglJMed	2014	USA	22	yes	Cardiothoracic	Surg vs. surg	Mitral-valve repair	Chordal-sparing replacement	126	125		Initial	12 months	7	no	possible impact of funding on results
Alifano, M. (33)	AnnSurg	2016	France	22	yes	Cardiothoracic	Surg vs. surg	Fissure opening by non-buttressed staplers alone	Fissure opening with linear cutting staplers buttressed with paired alginate sleeves	187	185		Initial	1 year	7	no	possible impact of funding on results
Arita, J. (34)	BrJSurg	2005	Japan	1	yes	Hepato-biliary-pancreatic	Surg vs. surg	Hepatic resection using a dissecting sealer	Hepatic resection using the clamp crushing method	40	40		Initial	14 days	11	no	possible impact of funding on results
Arora, R. (35)	JBoneJoint SurgAm	2011	Austria	1	no	Trauma	Surg vs. non	Open reduction and internal fixation with volar locking plate	Closed reduction and cast immobilization	36	37		Initial	1 year	6	no	unrestricted grant stated
Arvidsson, D. (36)	BrJSurg	2005	Sweden	7	no	General	Surg vs. surg	Shouldice repair	Laparoscopic transabdominal preperitoneal patch repair	466	454		Follow-up	5 years	1	no	possible impact of funding on results
Aull, M. J. (37)	AmJTransplant	2014	USA	1	yes	Transplant	Surg vs. surg	Laparoendoscopic single site donor nephrectomy	Laparoscopic donor nephrectomy	49	51		Initial	1 year	6	no	possible impact of funding on results
Bagshaw, P.F. (38)	AnnSurg	2012	Australia and New Zealand	31	no	Gastrointestinal	Surg vs. surg	Laparoscopic assisted colon resection	Open colon resection	290	297		Follow-up	5 years	3	no	possible impact of funding on results
Bailey, R.C. (39)	Lancet	2007	Kenya	1	yes	General	Surg vs. non	Circumcision	Delayed circumcision	1391	1393		Initial	2 years	3	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Beaupre, L.A.(40)	JBone-JointSurgAm	2007	Canada	3	no	Orthopaedic	Surg vs. surg	Primary total knee arthroplasty with a hydroxyapatite-coated tibial component	Primary total knee arthroplasty with cemented tibial fixation	40	41		Initial	5 years	5	no	possible impact of funding on results
Bell, S.W. (41)	JBone-JointSurgAm	2016	UK	1	yes	Orthopaedic	Surg vs. surg	Robotic-assisted uni-compartmental knee arthroplasty	Conventional unicompartmental knee arthroplasty	62	58		Initial	3 months	1	no	possible impact of funding on results
Bill-Axelson, A. (42)	NEnglJMed	2014	Sweden, Finland and Iceland	14	yes	Urology	Surg vs. non	Radical prostatectomy	Watchful waiting	347	348		Follow-up	18 years	4	no	possible impact of funding on results
Bingener, J. (43)	JAmCollSurg	2015	USA	1	no	Hepato-biliary-pancreatic	Surg vs. surg	Single port laparoscopic cholecystectomy	Four port laparoscopic cholecystectomy	55	55		Initial	7 days	5	no	possible impact of funding on results
Booth, M.I. (44)	BrJSurg	2008	UK	1	no	Gastrointestinal	Surg vs. surg	Total (Nissen) fundoplication	Partial (Toupet) fundoplication	64	63		Initial	1 year	4	no	no funding reported
Brittenden, J. (45)	NEnglJMed	2014	UK	11	yes	Vascular	Surg vs. surg	Foam Sclerotherapy	Surgery Endovenous laser ablation	286	289	210	Initial	6 months	6	no	possible impact of funding on results
Buchwald, H. (46)	AnnSurg	2010	USA	1	yes	Gastrointestinal	Surg vs. non	Diet plus partial ileal bypass surgery	Diet control only	421	417		Follow-up	25 years	1	no	no funding reported
Bulian, D.R. (47)	AnnSurg	2015	Germany	1	yes	Hepato-biliary-pancreatic	Surg vs. surg	Transvaginal cholecystectomy (TVC)	Needlescopic cholecystectomy (NC)	20	20		Initial	10 days	12	no	possible impact of funding on results
Carradice, D. (48)	BrJSurg	2011	UK	1	no	Vascular	Surg vs. surg	Endovenous laser ablation (EVLA)	Surgery	140	140		Follow-up	1 year	4	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Carradice, D. (49)	BrJSurg	2009	UK	1	no	Vascular	Surg vs. surg	Endovenous laser therapy (EVLT)	Endovenous laser therapy with concomitant ambulatory phlebectomies (EVLTAP)	25	25		Initial	1 year	10	no	possible impact of funding on results
Chalmers, R.T. (50)	BrJSurg	2010	UK and USA	16	no	Vascular	Surg vs. surg	Fibrin sealant in PTFE artial anastomosis	Manual compression in PTFE arterial anastomo-ses	75	72		Initial	5 weeks	5	no	possible impact of funding on results
Chen, J.S. (51)	AnnSurg	2012	Taiwan	1	no	Cardio-thoracic	Surg vs. surg	Apical pleurectomy	Pleural abrasion with minocycline pleurodesis	80	80		Initial	1 year	10	no	possible impact of funding on results
Chung, L. (52)	BrJSurg	2011	UK	1	yes	General	Surg vs. non	Early hernia repair	Observation	80	80		Follow-up	7,5 years	4	no	possible impact of funding on results
Corten, K. (53)	JBone-Joint SurgAm	2011	The Neth-er-lands	1	no	Ortho-paedic	Surg vs. surg	Cementless Mallory-Head total hip re-placement	Cemented Mallory-Head total hip replacement	126	124		Follow-up	20 years	3	no	possible impact of funding on results
Darwood, R.J. (54)	BrJSurg	2008	UK	1	no	Vascular	Surg vs. surg	Endovenous laser ablation with stepwise laser withdrawal	Endovenous laser ablation with continuous laser withdrawal vs. surgery	49	42	45	Initial	1 year	8	no	unrestricted grant stated
De Boer, M.T. (55)	AnnSurg	2012	The Neth-er-lands	7	yes	Hepato-bili-ary-pan-creatic	Surg vs. surg	Prophylactic application of fibrin sealant to resection surface	No application of fibrin sealant	156	154		Initial	30 days	6	no	possible impact of funding on results
Delawi, D. (56)	JBone-Joint SurgAm	2016	Neth-er-lands, France Italy, Spain	9	no	Ortho-paedic	Surg vs. surg	OP-1 combined with local bone	Autologous bone graft from the iliac crest combined with local bone	60	59		Initial	1 year	2	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Dutton, A.Q. (57)	JBone-JointSurgAm	2008	Republic of Singapore	1	no	Orthopaedic	Surg vs. surg	Computer-Assisted Minimally Invasive Total Knee Arthroplasty	Conventional Total Knee Arthroplasty	52	56		Initial	6 months	3	no	unrestricted grant stated
Farges, O. (58)	BrJSurg	2012	China	1	yes	Hepato-biliary-pancreatic	Surg vs. surg	Intermittent Pringle Manoeuvre	No Pringle manoeuvre	63	63		Initial	5 days	6	no	no funding reported
Figueras, J. (59)	AnnSurg	2007	Spain	1	no	Hepato-biliary-pancreatic	Surg vs. surg	Hepatectomy with fibrin glue application	Hepatectomy without fibrin glue application	150	150		Initial	6 months	6	no	possible impact of funding on results
Fischer, C.P. (60)	JAmCollSurg	2013	USA	11	yes	General	Surg vs. surg	Fibrin Pad	Absorbable hemostat	60	30		Initial	30 days	4	no	possible impact of funding on results
Frobell, R.B. (61)	NEnglJMed	2010	Sweden	2	yes	Orthopaedic	Surg vs. non	Structured rehabilita-tion plus early ACL reconstruction	Structured rehabilitation with option of reconstruc-tion if needed	62	59		Initial	2 years	7	no	possible impact of funding on results
Giuliano, A.E. (62)	AnnSurg	2016	USA	177	yes	General	Surg vs. surg	Axillary lymph node dissection after sentinel lymph node dissection	Sentinel lymph node dissection	445	446		Follow-up	10 years	1	no	possible impact of funding on results
Giuliano, A.E. (63)	JAMA	2011	USA	115	yes	General	Surg vs. surg	Axillary lymph node dissection after sentinel lymph node dissection	Sentinel lymph node dissection	445	446		ollow-up	5 years	3	no	unrestricted grant stated
Glazebrook, M. (64)	JBone-JointSurgAm	2014	Canada	3	yes	Orthopaedic	Surg vs. surg	Proximal opening wedge osteotomy	Proximal chevron osteotomy	40	35		Initial	1 year	6	no	unrestricted grant stated
Hessman, O. (65)	BrJSurg	2010	Denmark and Sweden	3	no	Endocrine	Surg vs. surg	Video-assisted parathyroidectomy	Open parathyroidectomy	68	75		Initial	6 months	6	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Hontzsch, D. (66)	JBoneJoint SurgAm	2014	Austria, Germany and Norway	8	yes	Orthopaedic	Surg vs. surg	Intramedullary nailing with the angular stable locking system	Conventional intramedullary nailing	75	67		Initial	1 year	9	no	possible impact of funding on results
Jarvik, J.G. (67)	Lancet	2009	USA	8	yes	Plastic	Surg vs. non	Carpal tunnel surgery	Multi-modality non-surgical treatment	57	59		Initial	1 year	5	no	unrestricted grant stated
Johansson, M. (68)	BrJSurg	2005	Sweden	2	no	Hepato-biliary-pancreatic	Surg vs. surg	Open cholecystectomy	Laparoscopic cholecystec-tomy	35	35		Initial	4 weeks	3	no	no funding reported
Johnston, L. (69)	JBoneJoint SurgAm	2009	UK	34	no	Orthopaedic	Surg vs. surg	Knee arthroplasty with metal backing	Knee arthroplasty with patellar resurfacing / Knee arthro plasty with mobile bearing	409	1715	539	Initial	2 years	6	no	unrestricted grant stated
Jorgensen, L.N. (70)	BrJSurg	2014	Denmark	3	no	Hepato-biliary-pancreatic	Surg vs. surg	Single-incision laparoscopic cholecystectomy	Conventional multi-incision laparoscopic cholecystectomy	59	58		Initial	1 year	13	no	unrestricted grant stated
Kim, J.K. (71)	JBoneJoint SurgAm	2011	South Korea	1	no	Orthopaedic	Surg vs. surg	Volar locking plate fixation alone	Volar locking plate fixation with injection of calcium phosphate bone cement	25	25		Initial	1 year	6	no	unrestricted grant stated
Knebel, P. (72)	AnnSurg	2011	Germany	1	yes	General	Surg vs. non	Open insertion technique	Puncture of subclavian vein under fluoroscopic guidance by radiologists	51	51		Initial	1.5 years	5	no	possible impact of funding on results
Koh, Y.W. (73)	AnnSurg	2008	South Korea	1	no	Endocrine	Surg vs. surg	No-tie technique using the harmonic scalpel	Conventional hand-tied ligation technique	31	34		Initial	6 months	7	no	no funding reported
Kurokawa, Y. (74)	BrJSurg	2015	Japan	27	yes	Gastrointestinal	Surg vs. surg	Abdominal transhiatal total gastrectomy	Left thoracoabdominal total gastrectomy	82	85		Follow-up	10 years	6	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Lederle, F.A. (75)	NEnglJMed	2012	USA	42	no	Vascular	Surg vs. surg	Endovascular repair of abdominal aortic aneu-rysm	Open repair of abdominal aortic aneurysm	444	437		Follow-up	9 years	5	no	possible impact of funding on results
Lee, W.J. (76)	AnnSurg	2005	Taiwan	1	no	Gastrointestinal	Surg vs. surg	Laparoscopic Roux-en-Y gastric bypass	Laparoscopic mini-gastric bypass	40	40		Initial	2 years	6	no	no funding reported
Lehur, P.A. (77)	AnnSurg	2016	France	22	yes	Gastrointestinal	Surg vs. surg	Doppler-guided haemorrhoidal artery liga-tion (DGHAL)	Circular stapled hemorrhoidopexy (SH)	197	196		Initial	1 year	6	no	possible impact of funding on results
Llewellyn-Bennett, R. (78)	BrJSurg	2012	UK	1	no	Plastic	Surg vs. surg	Application of fibrin sealant to the donor-site chest wall	Standard care	54	53		Initial	3 months	10	yes	possible impact of funding on results
Lofgren, J. (79)	NEnglJMed	2016	Uganda	1	yes	General	Surg vs. surg	Use of a low-cost mesh	Use of a commercial mesh	151	151		Initial	1 year	5	yes	possible impact of funding on results
Lorenz, D. (80)	BrJSurg	2007	Germany and Austria	3	no	Vascular	Surg vs. surg	Bipolar coagulating electric vein stripper (EVS)	Conventional stripping	99	101		Initial	4 weeks	7	no	possible impact of funding on results
Lujan, J. (81)	BrJSurg	2009	Spain	1	yes	Gastrointestinal	Surg vs. surg	Open surgery	Laparoscopic surgery	103	101		Initial	5 years	6	no	no funding reported
Lupo, L (82)	BrJSurg	2007	Italy	1	no	Hepato-biliary-pancreatic surgery	Surg vs. surg	Radiofrequency-assisted liver resection	Clamp crushing method for liver resection	24	26		Initial	1,5 years	4	no	no funding reported
Ma, J. (83)	AnnSurg	2011	USA	1	no	Hepato-biliary-pancreatic surgery	Surg vs. surg	Single-port laparoscopic cholecystectomy	Classic 4-port laparoscopic cholecystectomy	21	22		Initial	2 weeks	4	no	unrestricted grant stated

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Mack, M.J. (84)	Lancet	2015	Canada, Germany, USA	25	no	Cardiothoracic	Surg vs. non	Transcatheter aortic valve replacement	Surgical aortic valve replacement	348	351		Follow-up	5 years	8	no	possible impact of funding on results
Malhotra, R. (85)	JBoneJoint SurgAm	2015	India	1	yes	Orthopaedic	Surg vs. surg	Computer-assisted surgery	Conventional total knee arthroplasty	29	28		Initial	1 week	5	no	unrestricted grant stated
Mardani, J. (86)	AnnSurg	2011	Sweden	1	no	Gastrointestinal	Surg vs. surg	Open total fundoplication	Open Toupet partial posterior fundoplication	65	72		Follow-up	18 years	4	no	no funding reported
Martelli, G. (87)	AnnSurg	2005	Italy	1	yes	General	Surg vs. surg	Conservative breast surgery with axillary dissection	Conservative breast surgery without axillary dissection	109	110		Initial	60 months	4	no	no funding reported
Milone, M. (88)	JAMAsurg	2016	Italy	1	no	Gastrointestinal	Surg vs. surg	Minimally invasive treatment	Conventional treatment	76	69		Initial	1 year	7	no	possible impact of funding on results
Mingrone, G. (89)	NEnglJMed	2012	Italy	1	yes	General	Surg vs. non	Conventional medical therapy	Gastric bypass Biliopancreatic diversion surgery	20	20	20	Initial	2 years	7	no	possible impact of funding on results
Mohtadi, N. G. (90)	JBoneJoint SurgAm	2014	Canada	1	yes	Orthopaedic	Surg vs. surg	Open repair	Arthorscopic-repair	98	98		Follow-up	2 years	3	no	possible impact of funding on results
Nicholson, M. (91)	BrJSurg	2010	UK	1	no	Transplant	Surg vs. surg	Laparoscopic donor nephrectomy	Short-incision open donor nephrectomy without rib resection	56	28		Initial	5 years	6	no	possible impact of funding on results
Nocito, A. (92)	BrJSurg	2009	Switzerland	1	yes	General	Surg vs. surg	Venous cutdown	Seldinger technique	76	76		Initial	Missing	4	no	unrestricted grant stated
Nystrom, P. O. (93)	BrJSurg	2010	Denmark, Sweden, UK	18	yes	Gastrointestinal	Surg vs. surg	Anopexy	Milligan-Morgan haemorrhoidectomy	90	90		Initial	1 year	6	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Ogonda, L. (94)	JBone-Joint SurgAm	2005	UK	1	no	Orthopaedic	Surg vs. surg	Minimally invasive incision (<10 cm)	Standard incision (16 cm)	109	110		Initial	6 weeks	6	no	possible impact of funding on results
Pares, J. O. (95)	AnnSurg	2010	Spain	1	yes	Vascular	Surg vs. surg	Conservative hemody-namic management of Varicose veins	Stripping with clinic marking / Stripping with duplex marking	167	167	167	Initial	5 years	4	no	possible impact of funding on results
Park, J.S. (96)	BrJSurg	2012	Korea	1	no	Gastro-intestinal	Surg vs. surg	Robot-assisted colec-tomy	Laparoscopically assisted colectomy	35	35		Initial	30 days	6	no	possible impact of funding on results
Peng, S.Y. (97)	AnnSurg	2007	China	3	no	Hepato-biliary-pancreatic	Surg vs. surg	Binding pancreaticoje-junostomy	Conventional pancreatico-jejunostomy	106	111		Initial	22 days	4	yes	no funding reported
Peterli, R. (98)	AnnSurg	2009	Switzerland	1	yes	Gastro-intestinal	Surg vs. surg	Laparoscopic Roux-en-Y gastric bypass	Laparoscopic sleeve gastrectomy	13	14		Initial	3 months	1	no	possible impact of funding on results
Petrowsky, H. (99)	AnnSurg	2006	Switzerland	1	no	Hepato-biliary-pancreatic	Surg vs. surg	Ischemic precondition-ing with inflow occlu-sion	Intermittent clamping	36	37		Initial	3 months	8	no	no funding reported
Powell, J.T. (100)	BrJSurg	2007	UK	93	yes	Vascular surgery	Surg vs. non	Early elective open surgery	Ultrasound surveillance	563	527		Follow-up	12 years	3	no	possible impact of funding on results
Puzziferri, N. (101)	AnnSurg	2006	USA	1	yes	Gastro-intestinal	Surg vs. surg	Laparoscopic gastric bypass	Open gastric bypass	79	76		Follow-up	3 years	3	no	no funding reported
Reid, K. (102)	BrJSurg	2010	Australia	4	no	Gastro-intestinal	Surg vs. surg	Purse-string closure	Conventional closure	31	31		Initial	1 year	7	no	no funding reported

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Ringleb, P.A. (103)	Lancet	2006	Germany, Austria and Switzerland	35	yes	Vascular surgery	Surg vs. non	Carotid-artery stenting	Carotid endarterectomy	605	595		Initial	30 days	4	no	possible impact of funding on results
Samuel, N. (104)	AnnSurg	2013	UK	1	no	Vascular surgery	Surg vs. surg	Endovenous laser ablation	Conventional surgery	53	53		Initial	1 year	6	no	possible impact of funding on results
Schauer, P.R. (105)	NEnglJMed	2014	USA	1	yes	Gastrointestinal	Surg vs. non	Intensive medical therapy	Intensive medical therapy plus Roux-en-Y gastric bypass / Medical therapy plus sleeve gastrectomy	40	48	49	Follow-up	3 years	11	no	possible impact of funding on results
Seiler, C.M. (106)	AnnSurg	2009	Germany	25	no	General	Surg vs. surg	Interrupted Vicryl	Continuous polydioxanone suture / Continuous Monoplus	210	205	210	Initial	1 year	10	no	possible impact of funding on results
Sihvonen, R. (107)	NEnglJMed	2013	Finland	5	yes	Orthopaedic	Surg vs. non	Arthroscopic partial menisectomy	Sham surgery	70	76		Initial	1 year	6	no	possible impact of funding on results
Stenberg, E. (108)	Lancet	2016	Sweden	12	yes	Gastrointestinal	Surg vs. surg	Closure of mesenteric defects beneath the jejunojejunostomy and at Petersen's space	Non-closure	1259	1248		Initial	3 years	5	no	possible impact of funding on results
Stevenson, A.R. (109)	JAMA	2015	Australia and New Zealand	24	yes	Gastrointestinal	Surg vs. surg	Open laparotomy and rectal resection	Laparoscopic rectal resection	237	238		Initial	30 days	10	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Ulrich, A.B. (110)	BrJSurg	2008	Germany	1	no	Gastrointestinal	Surg vs. surg	Transverse coloplasty pouch	Colon J pouch	76	73		Initial	2 years	7	no	no funding reported
Velazquez, E.J. (111)	NEnglJMed	2011	26 countries, including UK, USA, Poland, India, Russia, Canada, Australia, Italy, Thailand	127	yes	Cardiothoracic	Surg vs. non	Medical therapy plus CABG	Medical therapy alone	610	602		Initial	6 years	3	no	possible impact of funding on results
Venermo, M. (112)	BrJSurg	2016	Finland	2	no	Vascular	Surg vs. surg	Surgery	Endovenous laser ablation (EVLA) Ultrasound guided foam sclerotherapy (UGFS)	65	73	76	Initial	1 year	6	no	no funding reported
Verburg, H. (113)	JBoneJoint SurgAm	2016	The Netherlands	2	yes	Orthopaedic	Surg vs. surg	Mini-midvastus total knee arthroplasty	Conventional total knee arthroplasty	50	50		Initial	5 years	6	no	unrestricted grant stated
Wardlaw, D. (114)	Lancet	2009	Austria, Belgium, France, Germany, Italy, Netherlands, Sweden	21	yes	Orthopaedic	Surg vs. non	Kyphoplasty treatment	Non-surgical care	149	151		Initial	1 year	7	no	possible impact of funding on results

First author	Journal	Year	Country	No. centres	Epidemiologist/ statistician	Surgical subspecialty	Nature of interventions	Intervention 1	Intervention 2 [and 3]	Sample size intervention [1]	[2]	[3]	RCT subtype	Follow-up period	No. outcomes	APPLIED CONSORT	Funding
Weaver, F.M. (115)	JAMA	2009	USA	13	yes	Neurologic	Surg vs. non	Bilateral deep brain stimulation of the subthalamic nucleus	Bilateral deep brain stimulation of the globus pallidus / Best medical therapy	60	61	134	Initial	6 months	5	no	possible impact of funding on results
Willett, K. (116)	JAMA	2016	UK	24	yes	Orthopaedic	Surg vs. non	Surgery	Casting	309	311		Initial	6 months	8	yes	possible impact of funding on results
Willits, K. (117)	JBoneJoint SurgAm	2010	Canada	2	no	Orthopaedic	Surg vs. non	Operative treatment	Nonoperative treatment	72	72		Initial	2 years	5	no	possible impact of funding on results
Wolthuis, A.M. (118)	BrJSurg	2015	Belgium	1	yes	Gastrointestinal	Surg vs. surg	Laparoscopic natural-orifice specimen extrac-tion	Conventional laparoscopic colectomy	20	20		Initial	3 months	6	yes	no funding reported
Wood, K.B. (119)	JBoneJoint SurgAm	2015	USA	6	yes	Orthopaedic	Surg vs. non	Operative treatment (posterior or anterior arthrodesis)	Nonoperative treatment (body cast or orthosis)	24	23		Follow-up	20 years	7	no	possible impact of funding on results
Wyss, T.R. (120)	AnnSurg	2010	UK	41	yes	Vascular	Surg vs. surg	Endovascular aneurysm repair	Open repair	848	594		Follow-up	10 years	4	no	possible impact of funding on results

Part II

New tools for shared decision-making

Chapter 6

Development of three different decision support tools to support shared decision-making in vascular surgery

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Abstract

Background

Shared decision-making (SDM) is known to improve quality of care. Particularly in vascular surgery treatment options are often preference-sensitive. Unfortunately, vascular surgeons infrequently apply SDM. Decision support tools (DSTs) have been shown to be helpful in SDM.

Objective

This article describes the development process of three different DSTs to help vascular surgeons and patients apply SDM. Patient involvement: Patients' information needs were obtained via focus group meetings. Fifty-two patients and eighteen vascular surgeons not involved in the development process evaluated the comprehensibility and usability of the DST-prototypes.

Methods

A multidisciplinary steering group commissioned the development of the three DSTs according to international standards.

Results

Digital decision aids and paper-based consultation cards and decision cards were developed for patients with an abdominal aortic aneurysm, carotid artery disease, intermittent claudication or varicose veins. Patients preferred the use of the decision aids followed by consultation cards, whereas vascular surgeons preferred to use decision cards followed by decision aids.

Discussion

Decision aids, consultation cards and decision cards for four vascular diseases are now available to all vascular surgeons and patients in the Netherlands. The DSTs were well received by both surgeons and patients. English versions are also available.

Introduction

Multiple treatment options are often available to patients with vascular diseases[1]. In these cases the best treatment option is usually the one that best fits the patient's preferences[2]. Shared decision-making is a two-way transfer between clinicians and patients that helps clinicians to elicit these preferences and inform patients about the outcomes of treatment options. Shared decision-making has the ability to improve patient satisfaction and therapy adherence, while also reducing undesired care and increasing desired care with no adverse effects on health-related outcomes[2-5]. Effective use of shared decision-making requires clinicians to share the available treatment options with their patients, including their benefits and harms. Accordingly, they should help patients weigh these benefits and harms in order to arrive at the treatment option that best fits their preferences.

Vascular surgical patients in particular may benefit from shared decision-making, as most treatment decisions are highly preference-sensitive and patients and vascular surgeons may have differing concerns about the benefits and harms of treatment as well as differing views on treatment goals[1]. Unfortunately, many vascular surgeons find it difficult to elicit patients' preferences and to involve them in decision-making[6]. Hence, the need to promote shared decision-making by means of decision support tools (DSTs), as they have proven beneficial in helping clinicians and patients in using shared decision-making[7].

This article presents the development process of three different decision support tools, specifically decision aids, consultation cards and decision cards, in order to help vascular surgeons and patients make shared decisions about the treatment of abdominal aortic aneurysms, carotid artery disease, intermittent claudication and varicose veins. While also studying the differences in how patients and clinicians evaluated the usability of these different decision support tools.

Materials and methods

The systematic development process for patient decision aids as reported by Coulter *et al*.[8] was used to provide a detailed and transparent description of the DST development. Coulter *et al*. describe a model development process that includes all the original International Patient Decision Aid Standards (IPDAS) criteria such as assessing decisional needs, formation of groups to develop and review DSTs, field-testing with patients and appraisal by people not involved in the development process[9]. However, they extended the IPDAS criteria with consideration of format, prototype development and distribution plans, which are all discussed in this article.

Steering group

A steering group was assembled to oversee DST development. This group consisted of a SDM and evidence-based practice expert; two researchers; two representatives of a patient advocacy group (the Heart Council); eight vascular surgeons via the Dutch Society of Vascular Surgery and one phlebologist. The members of the group had no competing interests.

The Netherlands Organization for Health Research and Development provided financial support for the DST development (ZonMw, grant 516022506). This organization was not involved in the development process.

Table 1. *Alpha* testing results

	Patients (*n* = 52)					**Vascular surgeons (*n* = 18)**				
Decision aid										
Claritiy of information	Very unclear		⟷		Very clear	Very unclear		⟷		Very clear
	0%	0%	2%	38%	60%	6%	0%	17,5%	59%	17.5%
Amount of information	Far too much		⟷		Far too little	Far too much		⟷		Far too little
	0%	6%	85%	9%	0%	0%	33%	39%	28%	0%
Presentation of information	Very partial		⟷		Very impartial	Very partial		⟷		Very impartial
	2%	0%	10%	38%	50%	0%	5.5%	39%	50%	5.5%
Clarity of	Very unclear		⟷		Very clear	Very unclear		⟷		Very clear
- animations used	0%	2%	6%	34%	58%	6%	0%	23%	53%	18%
- images used	0%	2%	11%	31%	56%	6%	0%	18%	53%	23%
Usability	Very difficult		⟷		Very easy	Very difficult		⟷		Very easy
	2%	2%	4%	41%	51%	5.5%	11%	28%	39%	17.5%
Satisfaction with decision aid	Very unsatisfied		⟷		Very satisfied	Very unsatisfied		⟷		Very satisfied
	0%	6%	10%	34%	50%	11%	17%	33%	33%	6%
Consultation card										
Clarity of information	Very unclear		⟷		Very clear	Very unclear		⟷		Very clear
	0%	0%	4%	56%	40%	0%	11%	22%	67%	0%
Amount of information	Far too much		⟷		Far too little	Far too much		⟷		Far too little
	0%	6%	85%	9%	0%	0%	33%	39%	28%	0%
Presentation of information	Very partial		⟷		Very impartial	Very partial		⟷		Very impartial
	2%	0%	10%	38%	50%	0%	5.5%	39%	50%	5.5%
Usability	Very difficult		⟷		Very easy	Very difficult		⟷		Very easy
	2%	2%	8%	35%	53%	0%	6%	35%	47%	12%
Satisfaction with consultation cards	Very unsatisfied		⟷		Very satisfied	Very unsatisfied		⟷		Very satisfied
	0%	2%	8%	42%	48%	5.5%	11%	39%	39%	5.5%
Decision cards										
Clarity of information	Very unclear		⟷		Very clear	Very unclear		⟷		Very clear
	2%	8%	10%	37%	43%	6%	23.5%	23.5%	35%	12%
Amount of information	Far too much		⟷		Far too little	Far too much		⟷		Far too little
	2%	8%	74%	16%	0%	0%	17%	50%	33%	0%
Presentation of information	Very partial		⟷		Very impartial	Very partial		⟷		Very impartial
	2%	0%	16%	33%	49%	0%	11%	39%	50%	0%
Clarity of images used	Very unclear		⟷		Very clear	Very unclear		⟷		Very clear
	2%	16%	6%	24%	52%	5.5%	28%	22%	39%	5.5%
Usability	Very difficult		⟷		Very easy	Very difficult		⟷		Very easy
	2%	8%	16%	27%	47%	0%	17%	11%	55%	17%
Satisfaction with decision cards	Very unsatisfied		⟷		Very satisfied	Very unsatisfied		⟷		Very satisfied
	4%	6%	12%	33%	45%	11%	22%	22%	45%	0%

Decision support tools

The steering group decided to develop three different types of DSTs to increase implementation of DSTs as patients and/or clinicians may not respond equally to each type of DST. This allows clinicians to choose the DST that best fits the specific manner in which they inform their patients or the type of DST can be chosen to fit the manner in which the patient wants to be informed. The development of different DSTs also allows clinicians to use combinations of these tools. DSTs developed for patient to use at home prior to the decision-making consultation can be combined with DSTs used during the consultation. This may improve patient understanding due to repetition of the information discussed in both DSTs using similar text and images.

The three different DSTs, that were developed, are decision aids, consultation cards and decision cards. Decision aids are evidence-based applications that inform patients about their disease and its treatment options, preferably using visual aids[10]. Decision aids should preferably contain questions to help patients elicit their preferences regarding treatment options. Patients may use these decision aids at home with their partner or family, prior to the decision-making consultation with their clinician[11,12]. The decision aids developed for our patient population are web-based which allows the use of 3D animations, videos and interactive disease specific knowledge tests.

'Consultation cards', as described in this manuscript, are one page tools that present characteristics and outcomes of available treatment options in table form. This allows clinicians and patients to compare directly treatment options during the consultation. The presented outcomes are based on questions frequently asked by patients. The type of questions patients want to discuss provide insight into what matters most to them. The consultation cards are based on DSTs called Option grids® [13].

Some clinicians and patients do not appreciate these consultation cards due to the large amount of text printed on them. As an alternative, members of the steering group were inspired by the Mayo Clinic's diabetes medication choice DST to develop 'decision cards'[14]. These entail five or six pocket-sized cards presenting information similar to consultation cards. However, decision cards use images to portray the differences between treatment options. Each card focuses on one outcome. This is thought to improve doctor-patient interaction and to help surgeons provide information tailored to patient comorbidity or hospital performance[15,16]. The consultation card or decision cards can be used in combination with the decision aid.

Scope

Shared decision-making is applicable for different diseases and different stages of the disease process. This section specifies the decisions for which the DSTs were developed.

Patients with an intermediate sized abdominal aortic aneurysm, risk aneurysm rupture. Although rupture risk is usually low, mortality is high. Thus, vascular surgeons should help patients decide whether to undergo annual check-ups to monitor aneurysm growth, or to undergo surgery in order to reduce the rupture risk while risking complications from the surgery itself. If patients favour surgery, depending on comorbidities and anatomy, they also need help deciding between endovascular and open repair.

Patients with carotid artery disease, who recently had a stroke, also need help deciding between treatment with medication alone or treatment with medication in combination with

endovascular or open repair. These patients are at risk of a second ischaemic event, which requires intervention. The surgical interventions themselves, however, may also cause a stroke[17].

It is important that surgeons understand the treatment goals of their patients with intermittent claudication. Some may just want to be able to walk to the grocery store, whereas others may want to continue long-distance running. Thus, vascular surgeons should help patients decide whether to start exercise therapy or to also undergo endovascular or open repair.

Also for varicose veins, some patients may just want their symptoms relieved, while others want treatment for cosmetic reasons. Vascular surgeons should help these patients decide whether to wear compression stockings or to undergo one or more interventions.

Prototype development

The Heart Council organized focus group meetings with patients who had previously faced a treatment decision concerning their vascular disease. Patients' information needs and frequently asked questions were obtained during these focus group meetings and complemented with suggestions made by the vascular surgeons and phlebologist from the steering group.

The researchers obtained clinical evidence for abdominal aortic aneurysm from the Cochrane review by Paravastu *et al*.[18] updating their search in October 2016 provided evidence on rupture rates in relation to aneurysm size and long-term results from the Dutch randomised endovascular aneurysm management trial[19,20]. The Dutch Institute for Clinical Auditing, a not-for-profit national registry focussed on presenting transparent healthcare outcome information, provided evidence concerning our Dutch patient population of patients with an abdominal aortic aneurysm or carotid artery disease[21].

Clinical evidence for carotid artery disease was also obtained from the Cochrane review by Bonati *et al*.[17] from 2012. The updated search in October 2016 provided information about the effects of stenting at different ages[22].

In 2015, the Dutch Surgical Society presented a preliminary guideline on the treatment of peripheral artery disease[23]. Publications identified by the systematic reviews performed to support this guideline were used in the DSTs for intermittent claudication, e.g., the endovascular revascularization and supervised exercise trial[24].

For varicose veins, data was mostly used from the 2014 guideline[25], e.g., the meta-analysis from Rigby *et al*.[26] and van der Bos *et al*.[27].

Patients' information needs and clinical evidence were combined with anatomical drawings of surgical procedures to develop 3D animations and videos for the decision aids. These 3D animations, videos and the content management system to run the decision aids were developed by Medify B.V. (Amsterdam, the Netherlands). In addition to decision aid development, the information obtained from patients' information needs and clinical evidence was also moulded into table-form for the consultation cards or presented as colourful decision

Table 2. Preference of decision support tools based on *Alpha* testing

Patients	Vascular surgeons
1. Decision aid (76%)	1. Decision cards (55%)
2. Consultation cards (62%)	2. Decision aid (50%)
3. Decision cards (31%)	3. Consultation cards (33%)

cards using images from the decision aids, from Shutterstock (New York, USA) or images the researchers designed themselves.

Before finalizing prototype development, the hospital's department of patient education checked the DSTs' readability for low literacy patients. The steering group verified the adherence of the decision aids to the IPDAS-criteria (*Appendix A*)[9].

Alpha testing

Patients associated with the Heart Council evaluated the comprehensibility and usability of the DSTs. They received the DST prototypes and an evaluation survey via email. The survey questions were based on the facilitators and barriers survey by Graham *et al*.[28]. Vascular surgeons, invited via the Dutch Society of Vascular Surgery, also received the DSTs, with a similar survey. The feedback received led to final adjustments to the DSTs.

Results

Focus groups

The Heart Council organized four focus groups. Twenty patients participated: 2 for abdominal aortic aneurysm, 8 for carotid artery disease, 6 for intermittent claudication and 4 for varicose veins. These patients first shared their ideas on what they thought a DST should entail. They deemed it necessary that DSTs should include: a clarification that the DSTs are developed to support, but not to replace, the consultation with the surgeon; a detailed description of the disease and its treatment options, preferably using visual aids; information about treatment risks and goals; and information about what they could do themselves in the treatment of the disease.

Patients also provided disease-specific suggestions for the DSTs: the deliberation between risking their current quality of life for a reduced risk of abdominal aortic aneurysm rupture; why an occluded carotid artery does not require intervention, but a stenotic artery may; the facts that atherosclerosis is a systemic disease and that leg pain during exercise therapy for intermittent claudication is not only harmless, but a necessary part of treatment; and information about available treatment options for the different types of varicose veins.

Alpha testing by patients

Fifty-two patients, of whom nineteen had a low educational level, evaluated the comprehensibility and usability of the DSTs. *Table 1* shows the outcomes of their evaluation.

Forty-five patients would recommend the decision aid to others. Forty-eight agreed the decision aid would help them decide what they deem important. Forty-eight patients would recommend the consultation cards. All patients deemed the decision aids and consultation cards to be helpful. Thirty-seven patients would recommend the decision cards. Forty patients preferred the decision aid, followed by thirty-two who preferred the consultation cards, and sixteen who preferred the decision cards (*Table 2*).

Alpha testing by vascular surgeons

Eighteen vascular surgeons with 5–22 years of experience evaluated the DSTs. *Table 1* shows the outcomes of their evaluation.

Seven vascular surgeons would recommend the decision aids to colleagues. Another seven

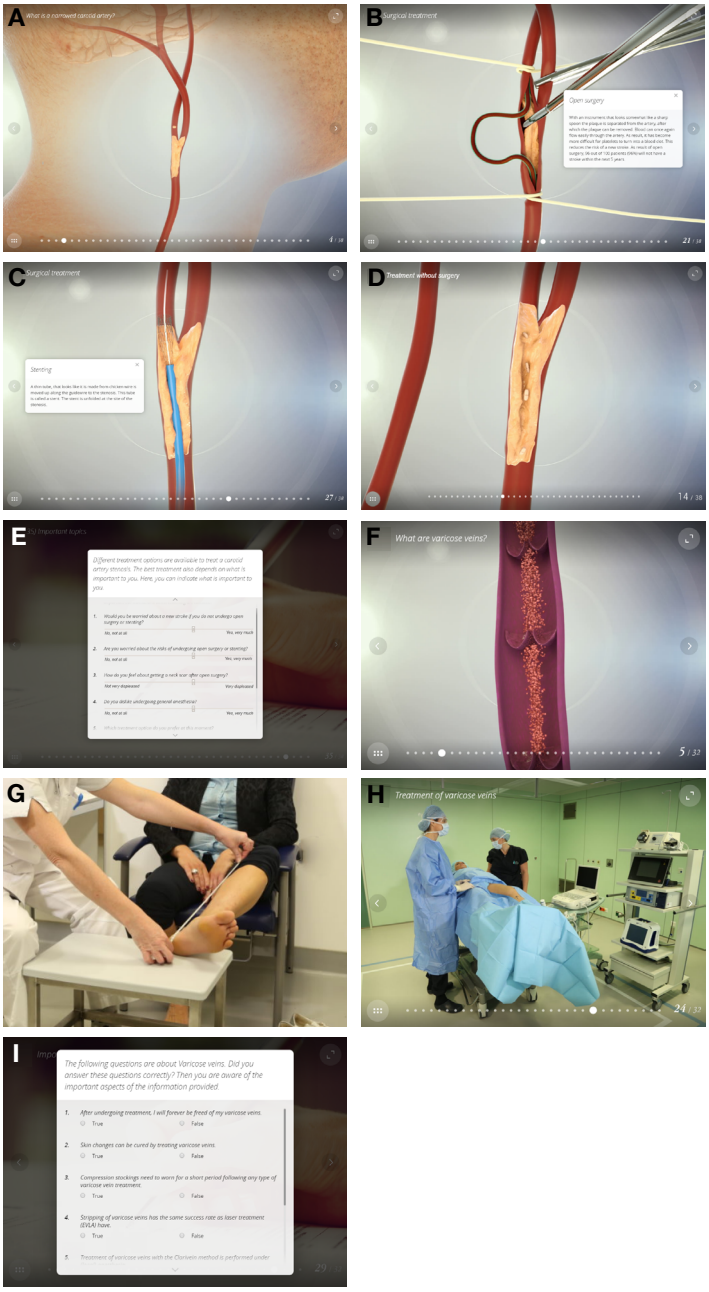

Figure 1. Images of the decision aids for patients with carotid artery disease (A, B, C, D) and varicose veins (E, F, G, H). Panel A: screenshot of a 3D animation informing patients about carotid artery disease, Panel B: screenshot of a 3D animation informing patients about carotid endarterectomy, Panel C: screenshot of a 3D animation informing patients about carotid artery stenting, Panel D: screenshot of a 3D animation informing patients about the effect of medication on carotid artery disease, Panel E: carotid artery disease preference-sensitive items questionnaire, Panel F: screenshot of a 3D animation informing patients about varicose veins, Panel G: screenshot of a video informing patients about compression stocking measurements, Panel H: screenshot of a video informing patients about endovascular laser ablation, Panel I: varicose veins disease-specific knowledge questionnaire.

would consider recommendation. Six vascular surgeons would recommend the consultation cards to colleagues. Eight surgeons considered recommendation. Seven vascular surgeons would recommend the decision cards to their colleagues. Six considered recommendation. Ten vascular surgeons preferred using the decision cards, followed by nine who preferred using the decision aids and six who preferred consultation cards (*Table 2*).

Contrasting alpha testing responses between patients and vascular surgeons

As shown in *Table 2*, patients and vascular surgeons differed in their preference for the different DSTs. Patients preferred the use of the decision aids as it provided them with more information compared to the consultation cards en decision cards. In addition, the use of 3D animation was highly appreciated as it improved their understanding of the information provided. Patients were less enthusiastic about the decision cards, as patients often require additional information from their surgeon to comprehend the images on the cards. Since this information was not provided during alpha testing, six patients said they would not recommend its use. Clarifications were made to patients that both the consultation and decision cards are to be used in the consultation room accompanied by information from the surgeon.

Vascular surgeons preferred the use of the decision cards as these contain less numerical information and text, allowing them to discuss numbers more fitting to the patient's comorbidities and hospital performance. In the comment section, some vascular surgeons also stated that they appreciated the use of colourful cards. Four vascular surgeons stated they would not recommend the decision aids and consultation cards, as they thought it would take too much time to discuss all this information during consultation. In case of the decision aids, the vascular surgeons had wrongly assumed these were to be used during consultation. Clarifications were made to vascular surgeons that decision aids are meant to be used by patients themselves prior to consultation. Both patients and vascular surgeons did agree that using visual aids, such as images and animations, helped transferring information between vascular surgeons and patients.

Patients and vascular surgeons had different opinions about the amount of information presented in the DSTs. Clinicians often think that patients should not be burdened with too much information. However, previous research has shown that patients often want more information than is currently provided[29]. This was also apparent from the comment-section of our survey in which several patients stated they missed a lot of the information provided in the DSTs during their own decision-making process. No changes were made to the amount of information provided.

Although most participants scored the presentation of information in the DSTs as impartial. It is interesting to notice that in the comment-section some of the vascular surgeons deemed that the DSTs favour an endovascular procedure for intermittent claudication. Whereas patients deemed the DSTs to favour exercise therapy. No changes were made to the DSTs, as developers concluded that this is most likely the correct balance for this disease.

Other interesting comments made by patients were that some questioned whether they should even have a say in the decision-making process, since the clinician should know which treatment is best. Likewise, some patients were quite shocked by the evidence presented in the DSTs, for instance that after two years the treatment effect on walking distance of exercise therapy and endovascular treatment are equal and that it is unknown if abdominal aortic aneurysm surgery prolongs life expectancy.

These comments show that there still is a lot to improve in how clinicians inform their patients and in promoting shared decision-making among patients. Implementation of these DSTs may be an important next step.

Final DSTs

Figure 1 shows screenshots of the decision aids for carotid artery disease and varicose veins. English translations of all four decision aids can be accessed via: https://sdmstaging.medify.eu/surgery1/ index_en.html. *Table 3* shows the abdominal aortic aneurysm consultation card. *Figure 2* shows the intermittent claudication decision cards.
The Heart Council has made the Dutch versions of the DSTs available on their webpage: https://www.harteraad.nl/nieuws/ keuzehulpen-vaataandoeningen-op-harteraad-website/.
English versions of the DSTs can be obtained by contacting the corresponding author. All DSTs are available free of charge.

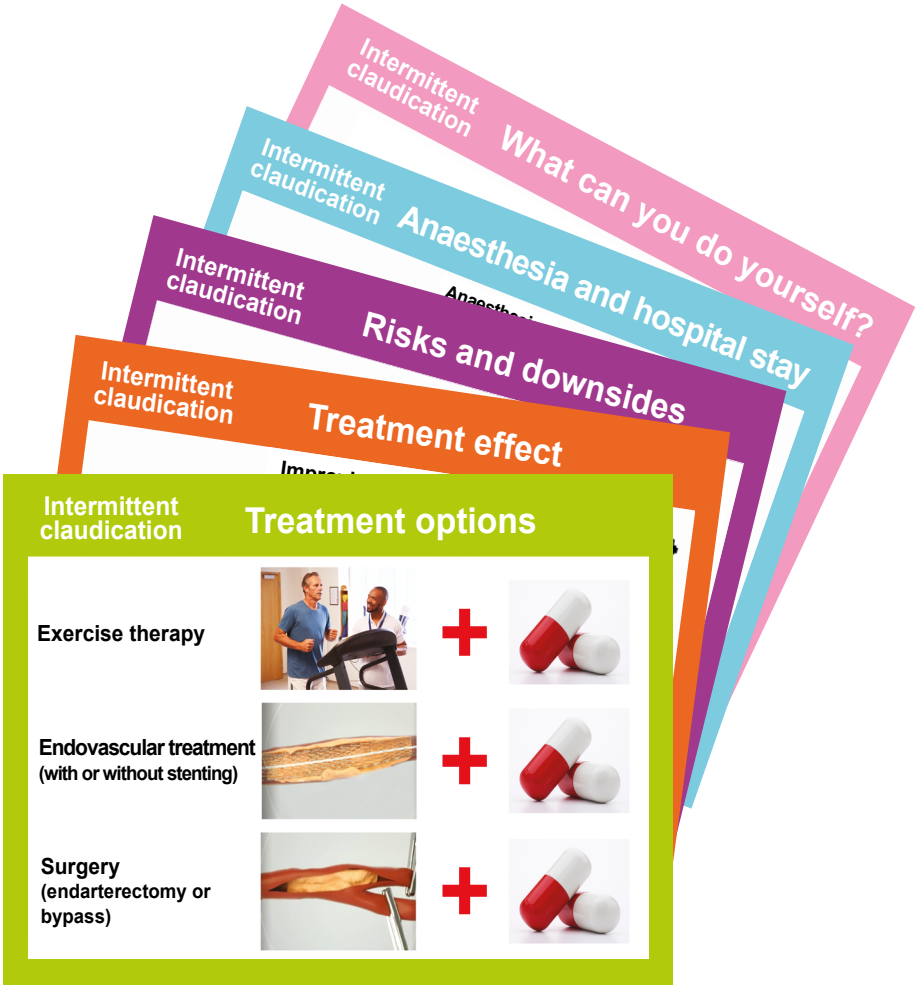

Figure 3. Overview of the subspecialties of included studies.

Table 3. Consultation card for patients with an abdominal aortic aneurysm.

Abdominal aortic aneurysm treatment options			
Use this consultation card to help you and your health care professional talk about how best to treat your abdominal aortic aneurysm.			
Frequently asked questions	**Active surveillance**	**Surgery via the groin**	**Open surgery via the abdomen**
What does this treatment involve?	You will visit the outpatient clinic at least once a year to evaluate the size of your aneurysm.	Via the groin, an expandable stent is inserted into the aneurysm.	The surgeon opens your abdomen and the aneurysm to dplace the stent into the aneurysm.
What are the benefits of this treatment?	You do not have to undergo surgery or recover from surgery.	You will recover faster from this surgery than from open surgery via the abdomen.	You will have less risk of having to undergo additional surgery compared to surgery via the groin.
What are the main risks associated with the treatment?	There is a risk that the aneurysm ruptures. This risk depends on your aneurysm size. Perhaps the fear of aneurysm rupture will negatively affect your daily functioning.	1 to 2 of 100 patients (1-2%) die within 30 days of this surgery. You may also suffer from blood leakage alongside the prosthesis, which means you will require another surgery.	5 to 9 of 100 patients (5-9%) die within 30 days of this surgery. You may also suffer from a pneumonia or after some time from an incisional hernia (bulging underneath the scar).
What is the effect of the treatment?	Depending on the aneurysm size, 70 to 97 of 100 patients (70-97%) are alive after 1 year.	30 to 46 of 100 treated patients (30-46%) are alive after 12 years.	34 to 50 of 100 treated patients (34-50%) are alive after 12 years.
Can my aneurysm still rupture after this treatment?	Yes, because the aneurysm is still there. This risk of aneurysm rupture depends on the size of the aneurysm.	Yes, in 1 to 4 of 100 patients (1-4%) the aneurysm ruptures within six years.	No, this risk aneurysm rupture becomes practically zero.
Will I receive anaesthesia?	No.	Yes, general or local anaesthesia.	Yes, general anaesthesia.
Will I get a scar?	You will not have surgery. Therefore, there is no scar.	You will have a small incision in both groins.	You will have a scar of about 20 cm on your abdomen.
How long do I stay in the hospital?	No hospital stay necessary.	Usually 1 to 3 days.	Usually 7 to 10 days.
How long does my recovery take?	You do not have to undergo surgery. Therefore, there is no recovery necessary.	Several weeks, however many patients will not completely return to their previous health status.	Several months, however many patients will not completely return to their previous health status.
How often do I need check-ups?	At least once a year.	At least once a year.	Usually just once or twice.
Are there things I can no longer do after this treatment?	You can continue to travel, play sports and do other daily activities.	After your recovery, you can continue to travel, play sports and other daily activities.	After you recovery, you can continue to travel, play sports and do other daily activities.
Will I live longer due to the treatment?	It is unknown whether your life is shorter without surgery.	It is unknown whether you live longer due to surgery.	It is unknown whether you live longer due to this surgery.

Discussion and conclusion

Discussion

This article presents the development process of decision aids, consultation cards, and decision cards for four vascular surgical diseases. Despite differences between patients and vascular surgeons concerning which DSTs they preferred to use, in general, the DSTs were well received by both patients and vascular surgeons.

As part of the development process the steering group initiated beta testing of the DSTs in real patient-surgeon encounters via the Operative Vascular Intervention Decision-making Improvement Using Shared decision-making tools (OVIDIUS) stepped-wedge, cluster-randomized trial (trial registry number: NL6312)[30]. Following each step in the stepped-wegde design additional medical centres will start using the DSTs. This ensures that at the end of the trial all centres will have implemented the DSTs. Participating vascular surgeons may themselves decide which of

the three different types of DSTs or which combinations they want to use with their patient. In addition, vascular surgeons are offered to participate in shared decision-making training. Study outcomes include the level of shared decision-making measured using audio-recordings, decisional conflict and disease-specific knowledge. Which DSTs will actually be used is also studied. Results from the OVIDIUS study will become available in 2021.

The steering group encountered several difficulties during the development process. Here, we present six recommendations to assist future DST developers. First, the steering group strongly recommends the development of different formats of DSTs, i.e., consultation cards and decision cards. It does not require developers to gather additional information and it may actually improve implementation of DSTs. Developing different DSTs will allow clinicians to select the DST that best fits the patients preference and level of understanding. As presented in this article, patients and clinicians may have different preferences concerning the DSTs used and some patients may not have access to digital DSTs. Therefore, it is important for clinicians to asses, which DSTs fits best with the patient or which DSTs they themselves are most proficient with. Combinations of different DSTs are also possible, which may further improve a patient's understanding of the information provided.

Second, be aware that patients often want more information than clinicians expect[29]. DSTs should provide the information necessary to help patients weigh the benefits and harms of each treatment option. Thus, we recommend that developers meet the information needs of patients as much as possible within the scope of the decision.

Third, it is crucial to involve the clinicians that will actually be using the DSTs from the start of the development process, for instance by including them in the steering group, as their approval is necessary. In addition, these clinicians can provide information patients may not think of during focus groups but do ask about during consultations.

Fourth, it is not always easy to find patients willing to participate in focus group meetings surrounding their illness. During the development process of the DSTs presented in this article, focus groups for abdominal aortic aneurysm and varicose veins were rather small. In addition, patients who do participate or take part in patient advocacy groups may have received higher education than patients who do not participate. This causes methodological limitations, which is why beta testing of the DSTs in a real-life setting is important.

Fifth, it can be difficult to obtain evidence supporting the information presented in the DSTs. Very few studies present a head-to-head comparison of available treatment options.

Conservative treatment is often excluded. The UK EVAR trials did capture all treatment options[31,32]. Unfortunately, differing patient populations and time points of outcome evaluation were used. In addition, some patient-relevant outcomes have never been studied. Thus, we recommend involving patients in the development process of new trials to ensure that patient-relevant outcomes are included. Decision aid developers are also well situated to advise research funders on study outcomes, as they often come across evidence gaps while trying to find evidence to support patient information needs.

Finally, merely providing patients and surgeons with DSTs will not improve shared decision-making or ensure better health decisions[7]. DSTs can help prepare patients for shared decision-making by providing the necessary information in an understandable manner and by encouraging patients to consider their preferences. However, it also requires surgeons to acquire shared decision-making skills to elicit these preferences. We strongly recommend surgeons to take shared decision-making training.

Developing DSTs remains a continuous process, as DSTs will need updates whenever new clinical evidence becomes available, preferably including patient-relevant outcomes and alongside the development of new clinical guidelines. Future developments are to present tailored information to patients, e.g., based on age and comorbidities, and to incorporate decision aids into electronic medical records.

Conclusion

This manuscript presents the development of decision aids, consultation cards and decision cards for patients with abdominal aortic aneurysm, carotid artery disease, intermittent claudication and varicose veins. These DSTs are available for all Dutch and English-speaking patients and surgeons.

Practical value

We recommend that future developers of DSTs develop different types of DSTs to improve implementation of (at least some of) these DSTs into clinical practice in order to further improve shared decision-making and thereby the quality of care that is provided for patients.

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Authorship contributions

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Category 2: Drafting the manuscript: S.M.L. de Mik. Revising the manuscript critically for important intellectual content: F.E. Stubenrouch, R. Balm, D.T. Ubbink.

Category 3: Approval of the version of the manuscript to be published: S.M.L. de Mik, F.E. Stubenrouch, R. Balm, D.T. Ubbink.

Author statement

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript. Furthermore, each author certifies that this material or similar material has not been and will not be submitted to or published in any other publication before its review process has been completed by Patient Education and Counseling.

Declaration of Competing Interest

The authors report no declarations of interest.

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References

1. D.T. Ubbink, M.J.W. Koelemay, Shared decision-making in vascular surgery. Why would you? Eur. J. Vasc. Endovasc. Surg. 56 (2018) 749–750.

2. A.M. Stiggelbout, T. Van der Weijden, M.P. De Wit, D. Frosch, F. Legare, V.M. Montori, L. Trevena, G. Elwyn, Shared decision-making: really putting patients at the centre of healthcare, Br. Med. J. 344 (2012) 256.

3. A.G. Mulley, C. Trimble, G. Elwyn, Stop the silent misdiagnosis: patients' preferences matter, Br. Med. J. 345 (2012) 6572.

4. E. Oshima Lee, E.J. Emanuel, Shared decision-making to improve care and reduce costs, N. Engl. J. Med. 368 (2013) 6–8.

5. S.A. Ibrahim, M. Blum, G.C. Lee, P. Mooar, E. Medvedeva, A. Collier, D. Richardson, Effect of a decision aid on access to total knee replacement for black patients with osteoarthritis of the knee: a randomized clinical trial, Am. Med. Assoc. Surg. 152 (2017)164225.

6. T.B. Santema, F.E. Stubenrouch, M.J. Koelemay, A.C. Vahl, C.F. Vermeulen, M.J. Visser, D.T. Ubbink, Shared decision-making in vascular surgery: an exploratory study, Eur. J. Vasc. Endovasc. Surg. 51 (2016) 587–593.

7. D. Stacey, F. Legare, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, M. HolmesRovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, Decision aids for people facing health treatment or screening decisions, Cochrane Database Syst. Rev. 4 (2017) CD001431.

8. A. Coulter, D. Stilwell, J. Kryworuchko, P.D. Mullen, C.J. Ng, T. van der Weijden, A systematic development process for patient decision aids, BMC Med. Inform. Decis. Mak. 13 (2) (2013).

9. N. Joseph-Williams, R. Newcombe, M. Politi, M.A. Durand, S. Sivell, D. Stacey, A. O'Connor, R.J. Volk, A. Edwards, C. Bennett, M. Pignone, R. Thomson, G. Elwyn, Toward minimum standards for certifying patient decision aids: a modified delphi consensus process, Med. Decis. Making 34 (2014) 699–710.

10. D.A. Zipkin, C.A. Umscheid, N.L. Keating, E. Allen, K. Aung, R. Beyth, S. Kaatz, D. M. Mann, J.B. Sussman, D. Korenstein, C. Schardt, A. Nagi, R. Sloane, D.A. Feldstein, Evidence-based risk communication: a systematic review, Ann. Intern. Med. 161 (2014) 270–280.

11. W.W. Lam, R. Fielding, P. Butow, B.J. Cowling, M. Chan, A. Or, A. Kwong, D. Suen, Decision aids for breast cancer surgery: a randomised controlled trial, Hong Kong Med. J. 20 (2014) 24–27.

12. G.A. Lin, D.S. Aaronson, S.J. Knight, P.R. Carroll, R.A. Dudley, Patient decision aids for prostate cancer treatment: a systematic review of the literature, CA Cancer J. Clin. 59 (2009) 379–390.

13. G. Elwyn, T. Pickles, A. Edwards, K. Kinsey, K. Brain, R.G. Newcombe, J. Firth, K. Marrin, A. Nye, F. Wood, Supporting shared decision-making using an option grid for osteoarthritis of the knee in an interface musculoskeletal clinic: a stepped wedge trial, Patient Educ. Couns. 99 (2016) 571–577.

14. R.J. Mullan, V.M. Montori, N.D. Shah, T.J. Christianson, S.C. Bryant, G.H. Guyatt, L.I. Perestelo-Perez, R.J. Stroebel, B.P. Yawn, V. Yapuncich, M.A. Breslin, L. Pencille, S.A. Smith, The diabetes mellitus medication choice decision aid: a randomized trial, Arch. Intern. Med. 169 (2009) 1560–1568.

15. M. Breslin, R.J. Mullan, V.M. Montori, The design of a decision aid about diabetes medications for use during the consultation with patients with type 2 diabetes, Patient Educ. Couns. 73 (2008) 465–472.

16. N.D. Shah, R.J. Mullan, M. Breslin, B.P. Yawn, H.H. Ting, V.M. Montori, Translating comparative effectiveness into practice: the case of diabetes medications, Med. Care 48 (2010) 153–158.

17. L.H. Bonati, P. Lyrer, J. Ederle, R. Featherstone, M.M. Brown, Percutaneous transluminal balloon angioplasty and stenting for carotid artery stenosis, Cochrane Database Syst. Rev. (2012)CD000515.

18. S.C. Paravastu, R. Jayarajasingam, R. Cottam, S.J. Palfreyman, J.A. Michaels, S.M. Thomas, Endovascular repair of abdominal aortic aneurysm, Cochrane Database Syst. Rev. (2014)CD004178.

19. F. Parkinson, S. Ferguson, P. Lewis, I.M. Williams, C.P. Twine, N. South East Wales Vascular, Rupture rates of untreated large abdominal aortic aneurysms in patients unfit for elective repair, J. Vasc. Surg. 61 (2015) 1606–1612.

20. T.G. van Schaik, J. de Bruin, M. van Sambeek, H. Verhagen, M. Prinssen, R. Grobbee, K.K. Yeung, J.D. Blankensteijn, Very long-term follow-up (12-15 years) of the dutch randomized endovascular aneurysm repair management (DREAM) trial, J. Vasc. Surg. 63 (2016) 143.

21. Dutch Institute for Clinical Auditing, Annual Reports, (2016) . (Accessed March 26th 2019) https://dica.nl/media/993/DICA-2016-jaarverslag.pdf.

22. J.H. Voeks, G. Howard, G.S. Roubin, M.B. Malas, D.J. Cohen, W.C. Sternbergh 3rd, H.D. Aronow, M.K. Eskandari, A.J. Sheffet, B.K. Lal, J.F. Meschia, T.G. Brott, C. Investigators, Age and outcomes after carotid stenting and endarterectomy: the carotid revascularization endarterectomy versus stenting trial, Stroke 42 (2011) 3484–3490.

23. Dutch society for Surgery, Draft Guideline Diagnostics and Treatment of Patients With Peripheral Ar-

tery Disease of the Lower Extremities, (2015) . http://heelkunde.nl/sites/heelkunde.nl/files/Bijlage-1-ConceptrichtlijnDiagnostiek-en-Behandelingvan-Patienten-met-Perifeer-Arterieel-Vaatlijden. pdf.

24. F. Fakhry, S. Spronk, L. van der Laan, J.J. Wever, J.A. Teijink, W.H. Hoffmann, T.M. Smits, J.P. van Brussel, G.N. Stultiens, A. Derom, P.T. den Hoed, G.H. Ho, L.C. van Dijk, N. Verhofstad, M. Orsini, A. van Petersen, K. Woltman, I. Hulst, M.R. van Sambeek, D. Rizopoulos, E.V. Rouwet, M.G. Hunink, Endovascular revascularization and supervised exercise for peripheral artery disease and intermittent claudication: a randomized clinical trial, J. Am. Med. Assoc. 314 (18) (2015) 1936–1944.

25. Dutch Society for Dermatology and Venereology, Guideline Venous Pathology, (2014) . http://www.nvdv.nl/wp-content/uploads/2014/08/Overkoepelenderichtlijn-veneuzepathologie.pdf.

26. K.A. Rigby, S.J. Palfreyman, C. Beverley, J.A. Michaels, Surgery versus sclerotherapy for the treatment of varicose veins, Cochrane Database Syst. Rev. (2004) CD004980.

27. R. van den Bos, L. Arends, M. Kockaert, M. Neumann, T. Nijsten, Endovenous therapies of lower extremity varicosities: a meta-analysis, J. Vasc. Surg. 49 (2009) 230–239.

28. I.D. Graham, J. Logan, C.L. Bennett, J. Presseau, A.M. O'Connor, S.L. Mitchell, J.M. Tetroe, A. Cranney, P. Hebert, S.D. Aaron, Physicians' intentions and use of three patient decision aids, BMC Med. Inform. Decis. Mak. 7 (2007).

29. T.B.K. Santema, E.A. Stoffer, M. Kunneman, M.J.W. Koelemay, D.T. Ubbink, What are the decision-making preferences of patients in vascular surgery? A mixed-methods study, Br. Med. J. Open 7 (2017).

30. S.M.L. de Mik, F.E. Stubenrouch, D.A. Legemate, R. Balm, D.T. Ubbink, Improving shared decision-making in vascular surgery by implementing decision support tools: study protocol for the stepped-wedge cluster-randomised OVIDIUS trial, BMC Med. Inform. Decis. Mak. 20 (2020) 172.

31. United Kingdom EVAR Trial Investigators, R.M. Greenhalgh, L.C. Brown, J.T. Powell, S.G. Thompson, D. Epstein, Endovascular repair of aortic aneurysm in patients physically ineligible for open repair, N. Eng. J. Med. 362 (2010) 1872– 1880.

32. United Kingdom EVAR Trial Investigators, R.M. Greenhalgh, L.C. Brown, J.T. Powell, S.G. Thompson, D. Epstein, M.J. Sculpher, Endovascular versus open repair of abdominal aortic aneurysm, N. Eng. J. Med. 362 (2010) 1863–1871

Supplementary materials

Appendix A. IPDAS v4.0 Checklist for Patient Decision Aids[14].

No	IPDAS item	Reported	
1	The PDA describes the health condition or problem for which the index decision is required.	✓	Decision aid
2	The PDA explicitly states the decision that needs to be considered.	✓	Decision aid
3	The PDA describes the options available for the index decision.	✓	Decision aid
4	The PDA describes the positive features (benefits) of each option.	✓	Decision aid
5	The PDA describes the negative features (harms) of each option.	✓	Decision aid
6	The PDA describes what it is like to experience the consequences of the options (e.g., physical, psychological, social).	✓	Decision aid
7	The PDA shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information).	✓	Decision aid
8	The PDA (or associated documentation) provides information about the funding source used for development.	✓	This article
9	The PDA (or associated documentation) provides citations to the evidence selected.	✓	This article
10	The PDA (or associated documentation) describes how research evidence was select-ed or synthesized.	✓	This article
11	The PDA (or associated documentation) describes the quality of the research evidence.	✓	Decision aid
12	The PDA (or associated documentation) provides a production or publication date.	✓	Decision aid
13	The PDA (or associated documentation) provides information about the update policy.		Is currently discussed
14	The PDA provides information about the uncertainty around event or outcome probabilities (e.g., ranges or 'our best estimate is…')	✓	Decision aid
15	The development process included a needs assessment with patients.	✓	This article
16	The development process included a needs assessment with health professionals.	✓	This article
17	The development process included review by patients not involved in producing the PDA.	✓	This article
18	The development process included review by health professionals not involved in producing the PDA.	✓	This article
19	The PDA was field tested with patients who were facing the decision.	✓	Study
20	The PDA was field tested with practitioners who counsel patients who face the decision.	✓	Study
21	The PDA includes authors'/developers' credentials or qualifications.	✓	Decision aid
22	There is evidence that the PDA improves the match between the preferences of the informed patient and the option that is chosen.	✓	Study
23	There is evidence that the PDA helps patients improve their knowledge about options' features.	✓	Study
24	The PDA describes the natural course of the health condition or problem, if no action is taken.	✓	Decision aid

No	IPDAS item	Reported	
25	The PDA makes it possible to compare the positive and negative features of the avail-able options.	✓	Decision aid
26	The PDA provides information about outcome probabilities associated with the options (i.e., likely consequences of decisions).	✓	Decision aid
27	The PDA specifies the defined group of patients for whom the outcome probabilities apply.	✓	Decision aid
28	The PDA specifies the event rates for the outcome probabilities.	✓	Decision aid
29	The PDA allows the user to compare outcome probabilities across options using the same time period (when feasible).	✓	Decision aid
30	The PDA allows the user to compare outcome probabilities across options using the same denominator (when feasible).	✓	Decision aid
31	The PDA provides more than one way of viewing probabilities (e.g., words, numbers).	✓	Decision aid
32	The PDA asks patients to think about which positive and negative features of the options matter most to them.	✓	Decision aid
33	The PDA provides a step-by-step way to make a decision.	✓	Decision aid
34	The PDA includes tools like worksheets or lists of questions to use when discussing options with a practitioner.	✓	Decision support tools
35	The PDA (or associated documentation) reports readability levels.	✓	This article

If your PDA helps patients to decide whether or not to undergo a test (e.g., screening), please fill out the checklist for these additional items.

No	IPDAS item	Reported
36	The PDA describes what the test is designed to measure.	NA
37	If the test detects the problem, the PDA describes the next steps typically taken.	NA
38	The PDA describes the next step if the condition is detected.	NA
39	The PDA has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done.	NA
40	The PDA includes information about the chances of having a true-positive test result.	NA
41	The PDA includes information about the chances of having a true-negative test result.	NA
42	The PDA includes information about the chances of having a false-positive test result.	NA
43	The PDA includes information about the chances of having a false-negative test result.	NA
44	The PDA describes the chances the disease is detected with and without the use of the test.	NA

Chapter 7

OPTION[5] versus OPTION[12] instruments to appreciate the extent to which healthcare providers involve patients in decision-making

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Abstract

Objective
The 12-item "observing patient involvement" (OPTION[12]) instrument is commonly used to assess the extent to which healthcare providers involve patients in health-related decision-making. The five-item version (OPTION[5]) claims to be a more efficient measure. In this study we compared the Dutch versions of the OPTION instruments in terms of inter-rater agreement and correlation in outpatient doctor-patient consultations in various settings, to learn if we can safely switch to the shorter OPTION[5] instrument.

Methods
Two raters coded 60 audiotaped vascular surgery and oncology patient consultations using OPTION[12] and OPTION[5]. Unweighted Cohen's kappa (κ) was used to compute inter-rater agreement on item-level. The association between the total scores of the two OPTION-instruments was investigated using Pearson's correlation coefficient (r) and a Bland & Altman plot.

Results
After fine-tuning the OPTION-manuals, inter-rater agreement for OPTION[12] and OPTION[5] was good to excellent (κ range 0.69–0.85 and 0.63–0.72, respectively). Mean total scores were 23.7 (OPTION[12]; SD = 7.8) and 39.3 (OPTION[5]; SD = 12.7). Correlation between the total scores was high (r = 0.71; p = .01). OPTION[5] scored systematically higher with a wider range than OPTION[12].

Conclusion
Both OPTION-instruments had a good inter-rater agreement and correlated well. OPTION[5] seems to differentiate better between various levels of patient involvement.

Practical implication
The OPTION[5] instrument is recommended for clinical application.

Introduction

Shared decision-making (SDM) is the process in which both healthcare providers and patients participate to make decisions about their health management strategies, using the best available evidence[1]. Research has shown that patients desire a more active role in decision-making[2,3]. Besides, patients have a legal right to receive adequate information. This legal imperative should be satisfactorily met in an SDM process, as it includes the presentation of the different treatments strategies that are available, including their benefits and harms. Besides, patients' preferences may differ from the doctors' and when there is equipoise between two or more different options, patients' preferences should be leading[4,5]. An SDM process involves the elicitation and consideration of patients' preferences and helps secure that patients' preferences guide the final choice. Also, evidence shows that involving patients in decision-making increases patients' satisfaction with their care and, thus, improves quality of care[6-9].

Given the increasing interest in SDM among healthcare providers and policy makers[9], it is important to measure the extent to which healthcare providers involve patients in decisions about health management strategies. By doing so, current levels of SDM can be assessed, the effectiveness of interventions introduced to promote SDM can be evaluated[1], and clinical performance can be audited.

In the past decade several instruments have been developed to measure various aspects of the SDM process[10]. Some instruments focus on the patients' subjective perspective[10,11]. The OPTION ("observing patient involvement") 12-item scale measures the extent to which healthcare providers involve patients in decision-making from the perspective of an independent observer, who judges the live conversation or recordings or transcripts of it[1].

However, it has been hypothesized that "a better observable behaviour and more brief measure would have some important benefits, such as improved construct validity, given a focus on a set of behaviours specific to SDM; improved reliability because raters would be required to assess fewer, more relevant, and better defined and observable behaviours; and increased efficiency because of shorter completion time"[12].

For these reasons a revised, shorter version of the OPTION[12] was developed by conflating and adapting some of its items, resulting in the OPTION[5] instrument[12]. Data from a clinical setting suggest that the OPTION[5] instrument has a high internal consistency and discriminative validity, and correlates highly with the OPTION[12] instrument[13].

In this study we aimed at investigating the performance of the Dutch OPTION[5] in terms of inter-rater agreement and its correlation with the OPTION[12] instrument in outpatient doctor-patient consultations in which a treatment decision is made, in multiple clinical settings.

Material and methods

Design

This was a multicentre cross-sectional descriptive validation study. We used audio-recordings from previously conducted studies on the evaluation of communication and decision-making during outpatient doctor-patient consultations in different clinical settings[14-16]. The recordings had all been made to investigate patient involvement in the decision-making process as to treatment choices in usual care situations using the OPTION[12] instrument. In this study these recordings were reviewed and analysed using both OPTION instruments.

The local ethics review boards had approved the original studies, and waived the necessity for further ethical review. In these studies the patients had given informed consent for audiotaping the consultation with their clinician.

Setting

Outpatient departments of three Dutch university hospitals (Academic Medical Center, Maastricht University Medical Center and Leiden University Medical Center) and their affiliated centres.

Observation instruments

The Dutch version of the OPTION[12] instrument was already at hand (see *Appendix A*). The OPTION[5] instrument, including its coding manual, was made available by the developers (see *Appendix B*). The instrument was translated into Dutch following a forward-backward procedure: Investigators who are native Dutch speakers with fluent command of the English language (DU, TW, AP, AS) independently translated the five items into Dutch. Each of these translations was translated back into English by an English speaker with fluent command of the Dutch language (JWMA) and revised until agreement was reached among the translators.

Each item (for example: "The clinician checks that the patient has understood the information") in both instruments was scored on a zero (no effort) to four (exemplary effort) point scale. This score reflected the extent to which the clinician showed a particular behaviour. The English versions of the two measures have been applied and described before in several publications[1,7,12,13].

Participants

We purposively selected participants from existing studies that recruited patients with different medical conditions, i.e., breast cancer, colorectal cancer, and vascular surgical conditions. Hence, the present patient sample represented various disorders and healthcare providers. Except for breast cancer, we also purposively selected an equal number of male and female patients. This was done to appreciate the overall performance of the OPTION instruments in various settings, rather than to explore differences between disorders or specialties.

We eventually included the audio-recordings of a random selection of 15 decision-making consultations of cancer patients with their medical oncologist, 15 with a radiation oncologist, 8 with a surgical oncologist, 7 with a surgical oncology nurse, and 15 vascular patients with their vascular surgeon. The 60 consultations were performed by 37 care providers

Table 1. Interobserver agreement of OPTION[12] and OPTION[5] scores (unweighted Kappa scores (ϰ)) of $n = 60$.

Specialty	*N*	OPTION[12] Kappa (ϰ)	OPTION[5] Kappa (ϰ)
Overall	60	0.76	0.68
Radiotherapy	15	0.85	0.67
Breast surgery	15	0.79	0.63
Medical oncology	15	0.7	0.72
Vascular surgery	15	0.69	0.70

aged 38–66 years and of whom 15 were men. None of the healthcare providers involved had received prior formal SDM training. This allowed us to analyse 60 consultations on preference-sensitive treatment decisions. In case decisions about more than one treatment had been made during the consultation (e.g., about a combination of surgical, hormonal and/or chemotherapy), the raters first selected one main decision for analysis.

Study conduct

Two raters (FES, RF) were trained in applying the coding schemes using the original manuals and seven virtual consultations available on the OPTION instrument website (http://www.optioninstrument.org/). The raters were unaware of the coding results in the previous studies using the OPTION[12] instrument. Then, they independently coded randomly selected consultations (two from each of the medical contexts) using the OPTION[12] and calculated their inter-rater agreement. If agreement was below acceptable levels (i.e., kappa values below 0.6), the raters would discuss discrepancies in their interpretation of the scores and repeat the procedure with another set of eight recordings.

Next, the raters each scored yet another five consultations using OPTION[5]. This was also repeated until their agreement for this instrument was acceptable. In this training phase, agreement was analysed for each specialty separately to detect possible provider- and disease-specific differences, if any, that would need further discussion.

Consultations were not included in the final analysis until the inter-rater agreement was above acceptable levels. There was at least a two-week interval between the OPTION[12] and OPTION[5] ratings to avoid recall bias of the scores previously given. If the patient initiated one of the behaviours to be scored in either OPTION instrument and the clinician or provider responded to this call, for instance when the patient voiced their preference regarding a treatment option without specifically being asked about it and the clinician responded to this, it was scored as if the clinician had initiated the topic.

Data analysis

Inter-rater agreement between the raters for each OPTION instrument was expressed as unweighted Cohen's kappa ($\varkappa$) values. The $\varkappa$ value is a chance-corrected measure of agreement that ranges between -1 and 1. Values above 0.8 are considered excellent, between 0.6 and 0.8 as good, between 0.4 and 0.6 as fair, and between 0.2 and 0.4 as poor[17]. $\varkappa$ values were calculated for each OPTION item separately. The mean value of the total scores by each rater was taken as OPTION score for each consultation. The total scores of both instruments were expressed as percentages of their maximum scores (i.e., 48 and 20 points for the OPTION[12] and OPTION[5], respectively). This percentage represented the mean score of the overall clinicians' behaviour to involve patients in the decision-making process.

The Pearson product moment correlation coefficient (r) was used, after checking for the normality of the distribution, to determine the association between the OPTION[12] and OPTION[5] instruments. Additionally, the relationship between OPTION[5] and OPTION[12] total scores scales was analysed by means of a Bland & Altman plot[18]. This graph plots the differences between both total scores against their mean total scores and offers additional information regarding a possible systematic difference in total scores between the OPTION instruments, including a 95% confidence interval (CI) of this difference, and possible divergences across the range of OPTION scores.

Results

Each patient was included only once in this study. Of the 60 patients, 21 were male and 39 female. Their age ranged between 47 and 77 years. The treatment options discussed were mastectomy, lumpectomy, adjuvant radiotherapy, adjuvant hormonal therapy, adjuvant chemotherapy, rectal cancer resection with or without a permanent stoma and treatment for vascular disorders (claudication, aortic aneurysm, venous insufficiency). The duration of the consultations ranged from 11 to 58 minutes.

After coding the virtual consultations, inter-rater agreement was below acceptable levels. Because of individual differences in the interpretation of the predefined score levels it was not clear, for example, when to score 'minimal' or 'moderate' effort. At this point, the two raters decided to refine the manuals for both instruments to make sure they agreed on how exactly to score the healthcare providers' behaviour. The adapted, more extensive manuals used for the present application of the OPTION instruments are presented in *Appendices A and B*[16].

Subsequently, the two raters reached acceptable levels of agreement using OPTION[12] after the first set of eight recordings ($\varkappa$ = 0.85, 0.74, 0.67, and 0.65 for radiotherapy, surgical oncology, medical oncology, and vascular surgery, respectively). The same was true for the OPTION[5], showing $\varkappa$ values of 0.69, 0.67, 0.69, and 0.72, respectively.

Table 1 shows the inter-observer agreements for the 60 audiotaped doctor-patient consultations. $\varkappa$ values for the OPTION[12] and OPTION[5] instruments were all above 0.6. $\varkappa$ values tended to be higher with the OPTION[12] instrument than with the OPTION[5] instrument.

Mean total OPTION scores for the 60 encounters were 23.7 (*SD* 7.8) and 39.3 (*SD* 12.7) for the OPTION[12] and OPTION[5] instruments, respectively. On the original 0-4 scale, this

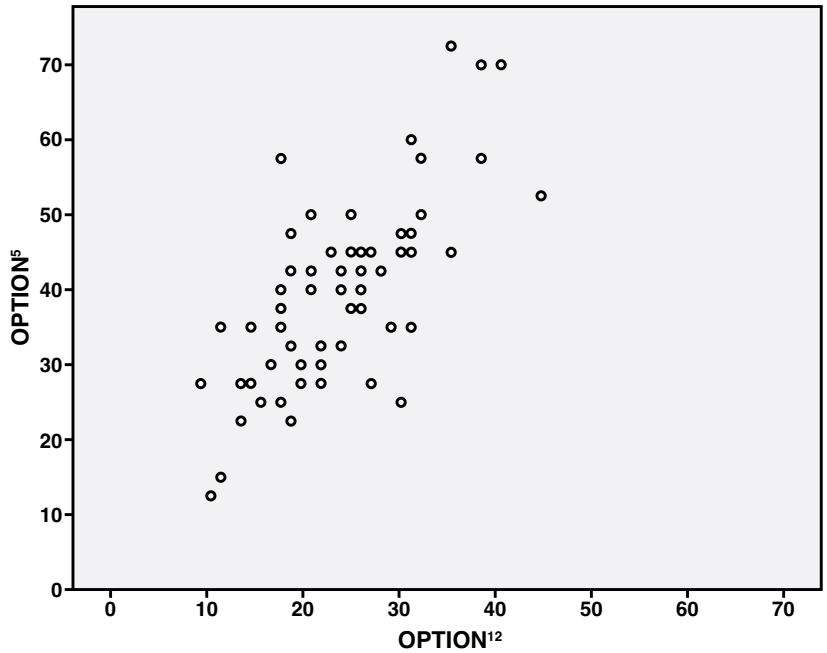

Figure 1. Scatterplot of OPTION[12] and OPTION[5] total scores.

means a mean score of about 1 for the OPTION[12] and 2 for the OPTION[5] instrument. *Figure 1* shows a positive correlation between the OPTION[12] instrument and the OPTION[5] instrument (Pearson $r = 0.71$; $p = .01$). OPTION[12] scores ranged from 9 to 45, whereas OPTION[5] scores varied between 13 and 73. In addition, the Bland &Altman plot (*Figure 2*) shows that the OPTION[5] total scores were consistently, and on average 16 points (95% CI 2–33 points), higher than the OPTION[12] total scores. The difference between both scores clearly increased with increasing mean scores.

Discussion and conclusion

Discussion

This study shows that the two OPTION instruments correlate well and have a good inter-observer agreement at the item level. The OPTION[5] instrument shows consistently higher total scores than the OPTION[12]. Furthermore, the five-item scale seems more sensitive to differentiate between low and high scores for patient involvement. Overall, the OPTION[5] instrument seems a good alternative to the OPTION[12] instrument as it contains less items to be judged. This implies using the OPTION[5] may take less time and be less burdensome, although one still has to appraise the whole conversation, irrespective of the instrument used.

Initially, despite the existing manuals, it was hard to achieve an acceptable inter-observer reliability. Discrepancies in scores between the two raters were likely due to differences in the interpretation of relevant parts of the conversations. We believe the suggested revisions of the manuals are essential for a proper judgment using the OPTION scales, as a clear delineation

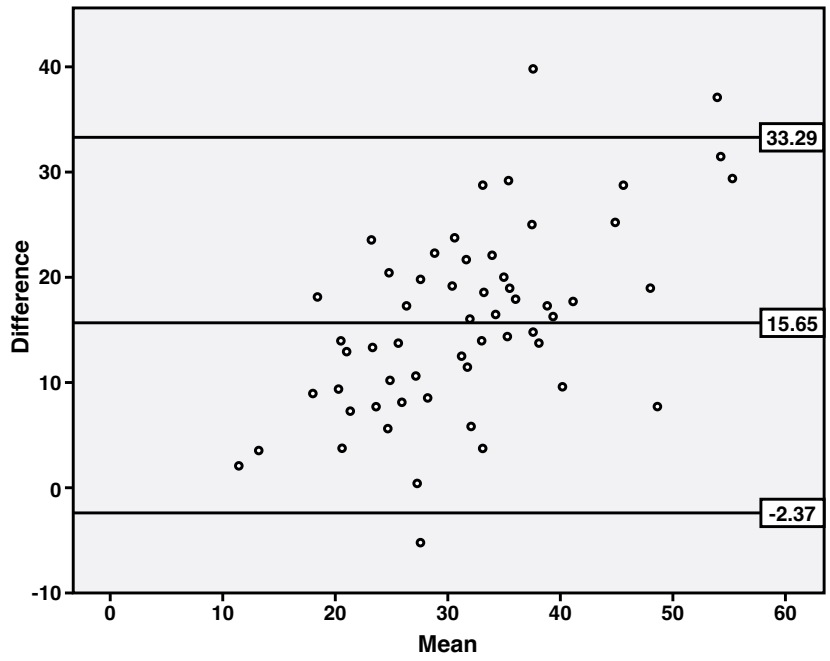

Figure 2. Bland & Altman plot.
The mean of the OPTION[12] and OPTION[5] total scores for each consultation on the X-axis is plotted against the difference between these scores (OPTION[5] minus OPTION[12] total score) on the Y-axis. Horizontal lines indicate the mean difference with its 95% limits of agreement.

of the behaviours to be measured improves inter-rater reliability. There is no reason to assume that these revisions deviate from the interpretation as intended by the original authors.

We eventually achieved a good inter-observer agreement. Barr *et al*.[13] also found that the OPTION[5] can be performed with a good inter-observer agreement. In contrast to what they did, we calculated unweighted κ values, which are more sensitive to inter-observer interpretation differences. Even then, inter-observer agreement was found to be high, indicating that, if raters are properly trained and use the extended manuals, these instruments can be used reliably.

Our findings regarding the total OPTION scores are in agreement with those from a systematic review by Couët *et al*.[1] and the recent study by Barr *et al*.[13]. Couët found a mean OPTION score of 23, which is similar to our mean OPTION[12] score, indicating low levels of patient-involving behaviour. The wider range and systematically higher scores using the OPTION[5] instrument imply that differences observed with each instrument should be interpreted and handled differently. Although the mean total scores for both OPTION instruments were different, the actual levels of patient involvement were obviously the same as they were rated in the same doctor-patient encounters. As there is no reference standard, it is unclear whether the OPTION[5] might overestimate or the OPTION[12] might underestimate actual patient involvement. The OPTION[5], however, might score higher as it leaves out the OPTION[12] items describing that were not deemed to be key steps in an SDM process. Also, some doctors might find these behaviours somewhat artificial, for example gauging how patients want to receive information, and asking patients what their preferred involvement in decision-making is. The presence of items in the OPTION[12] instrument that seemed less relevant to the SDM-process, and therefore received low scores, may have led to a smaller range of scores and may be an explanation for the differences found between both instruments. However, the items deleted in the OPTION[5] version that gauge how patients want to receive information, invite patients to pose questions, and ensure the patient understood the information (i.e., OPTION[12] items 3, 8 and 9), may still support the SDM process. The differences found also have consequences for sample size calculations for studies using (one of) these instruments. Until now, sample sizes for trials employing the OPTION[5] were based on 3.5 to 10-point differences in OPTION[12] scores and their standard deviations[13,19]. For future studies using OPTION[5], these calculations can and should now be based on data known for OPTION[5].

In this study we intentionally introduced variation in disorders and specialties. Although these could obviously not represent all kinds of disorders or specialties, there is no reason to believe that the OPTION instruments would not be valid for other areas in medicine. Finally, the OPTION instruments merely address the provider's behaviour to evaluate patient involvement in the decision-making process. To measure the level of SDM in doctor-patient encounters we are still in need of an instrument that also addresses the SDM behaviour of the patient.

Conclusion

The inter-observer reliability for both OPTION instruments was found to be good, but only after refining their manuals. The OPTION[5] instrument shows a wider range in results and contains fewer items. Hence, it should be better suited to differentiate between various levels of SDM.

Practice implication

The OPTION[5] instrument is recommended for clinical application. It can be applied, for example, to test individual performance and improvement, as well as on an institutional level to test yearly the performance of groups of healthcare providers and give them feedback.

Conflict of interests

There are no conflicts of interest.

Funding sources

There were no funding sources for the current research.

References

1. Couet N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, et al. Assessments of the extent to which health-care providers involve patients in decision-making: a systematic review of studies using the OPTION instrument. Health Expect. 2015;18:542-61.

2. Ubbink DT, Hageman MG, Legemate DA. Shared Decision-Making in Surgery. Surg Technol Int. 2015;26:31-6.

3. Tariman JD, Berry DL, Cochrane B, Doorenbos A, Schepp K. Preferred and actual participation roles during health care decision-making in persons with cancer: a systematic review. Ann Oncol. 2010;21:1145-51.

4. Glasziou P, Moynihan R, Richards T, Godlee F. Too much medicine; too little care. Brit Med J. 2013;347:f4247.

5. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. Brit Med J. 2012;345:e6572.

6. Kiesler DJ, Auerbach SM. Optimal matches of patient preferences for information, decision-making and interpersonal behavior: evidence, models and interventions. Patient Educ Couns. 2006;61:319-41.

7. Pellerin MA, Elwyn G, Rousseau M, Stacey D, Robitaille H, Legare F. Toward shared decision-making: using the OPTION scale to analyze resident-patient consultations in family medicine. Acad Med. 2011;86:1010-8.

8. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg. 2013;257:860-6.

9. Barry MJ, Edgman-Levitan S. Shared decision-making--pinnacle of patient-centered care. N Engl J Med. 2012;366:780-1.

10. Scholl I, Koelewijn-van Loon M, Sepucha K, Elwyn G, Legare F, Harter M, et al. Measurement of shared decision-making - a review of instruments. Z Evid Fortbild Qual Gesundhwes. 2011;105:313-24.

11. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. J Med Internet Res. 2014;16:e2.

12. Elwyn G, Tsulukidze M, Edwards A, Legare F, Newcombe R. Using a 'talk' model of shared decision-making to propose an observation-based measure: Observer OPTION 5 Item. Patient Educ Couns. 2013;93:265-71.

13. Barr PJ, O'Malley AJ, Tsulukidze M, Gionfriddo MR, Montori V, Elwyn G. The psychometric properties of Observer OPTION(5), an observer measure of shared decision-making. Patient Educ Couns. 2015;98:970-6.

14. Snijders HS, Kunneman M, Bonsing BA, de Vries AC, Tollenaar RA, Pieterse AH, et al. Preoperative risk information and patient involvement in surgical treatment for rectal and sigmoid cancer. Colorectal Dis. 2014;16:O43-9.

15. Kunneman M, Marijnen CA, Rozema T, Ceha HM, Grootenboers DA, Neelis KJ, et al. Decision consultations on preoperative radiotherapy for rectal cancer: large variation in benefits and harms that are addressed. Br J Cancer. 2015;112:39-43.

16. Santema TB, Stubenrouch FE, Koelemay MJ, Vahl AC, Vermeulen CF, Visser MJ, et al. Shared Decision-making in vascular surgery. Eur J Vasc Endovasc Surg. 2016; in press.

17. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33:159-74.

18. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1:307-10.

19. Elwyn G, Hutchings H, Edwards A, Rapport F, Wensing M, Cheung WY, et al. The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. Health Expect. 2005;8:34-42.

Supplementary materials

Appendix A. Refined scoring definitions for the OPTION[12] manual[16].

Item	Description	Specification
1	The clinician draws attention to an identified problem as one that requires a decision making process.	0 – not observed 1 – short problem definition 2 – attention the problem, baseline skill 3 – attention the problem, decision should be made 4 – need for a decision
2	The clinician states that there is more than one way to deal with the identified problem ('equipoise')	0 – no options mentioned 1 – listing the options 2 – little explanation of the options 3 – explaining pros and cons of all options 4 – both options are o.k., depends on the preferences of the patient
3	The clinician assesses the patient's preferred approach to receiving information to assist decision making (e.g., discussion, reading printed material, assessing graphical data, using videotapes or other media).	0 – no information 1 – short (do you want a brochure?) 2 – how do you like to receive the information 3 – several options are possible to receive information 4 – listing examples how to receive information and ask the preferences of the patient
4	The clinician lists 'options', which can include the choice of 'no action'.	0 – no options mentioned 1 – listing the options 2 – little explanation of the options (you can choose… or…) 3 – extensively listing options (no action is a possibility) 4 – very detailed explanation of all options
5	The clinician explains the pros and cons op options to the patient (taking 'no action' is an option).	0 – no explanation 1 – explaining pros and cons of some options 2 – explaining pros and cons of all options 3 – explaining pros and cons of all options including the little pros and cons 4 – very detailed explanation of the pros and cons of all options
6	The clinician explores the patient's expectations (or ideas) about how the problem(s) are to be managed	0 – not observed 1 – asking the expectations in passing 2 – asking the expectations (only asking) 3 – asking the expectations 4 – asking the expectations, high standard (discussing the expectations)
7	The clinician explores the patient's concerns (fears) about how problem(s) are to be managed.	0 – not observed 1 – asking about the concerns (in passing) 2 – asking about the concerns (only asking) 3 – asking about the concerns 4 – asking about the concerns, high standard (discussing the concerns)
8	The clinician checks that the patient has understood the information.	0 – not observed 1 – listing the options 2 – is it clear (you can ask questions) 3 – checking if it is clear by asking the patient to repeat the information 4 – high standard
9	The clinician offers the patient explicit opportunities to ask questions during the decision-making process.	0 – not observed 1 – breaks or interruptions 2 – possibility to ask questions (Do you have any questions) 3 – any questions about the options or treatments? 4 – any questions about the options or treatments? High standard
10	The clinician elicits the patient's preferred level of involvement in decision-making.	0 – not observed 1 – short asking 2 – asking explicit (do you want to be involved in decision-making?) 3 – information about the possible options in involvement 4 – easy to understand for the patient

Item	Description	Specification
11	The clinician indicates the need for a decision making (or deferring) stage.	0 – no indication 1 – decision should be made 2 – indicates need for decision 3 – indicates need for decision, good standard 4 – indicates need for decision, high standard
12	The clinician indicates the need to review the decision (or deferment).	0 – not observed 1 – short (follow-up appointment) 2 – follow-up appointment, possible to return the decision 3 – appointment for evaluating the decision, good standard 4 – appointment for evaluating the decision, high standard (explicit)
	Total score 0–20	
	Rescale 0–100	

Appendix B. Refined scoring definitions for the OPTION[5] manual.

Item	Description	Specification
1	The provider draws attention to, or re-affirms, a problem where alternate treatment or management options exist, and which requires the initiation of a decision-making process. If the patient draws attention to the availability of options, and the provider responds by agreeing that the options need consideration, the item can also be scored positively.	0 – not observed 1 – stating that several options exist 2 – listing the options 3 – equality of the options 4 – is it clear / any questions
2	The provider reassures the patient, or re-affirms, that the provider will support the patient to become informed. The provider will support/explain the need to deliberate about the options.	0 – not observed 1 – decide together 2 – mention is it a difficult choice 3 – will support irrespective of the choice of the patient 4 – both options are o.k., depends on the preferences of the patient, provider has a supportive role
3	The provider gives information, or re-affirms/checks understanding, about options that are considered reasonable (including taking 'no action'), to support the patient in understanding/comparing the pros and cons.	0 – no information 1 – explaining pros and cons of one treatment 2 – explaining pros and cons of more than one treatment 3 – is it clear / any questions 4 – ask the patient to repeat the information
4	The provider supports the patient to examine, voice, and explore his/her personal preference in response to the options that have been described.	0 – not observed 1 – exploring one of the following items: preferences, concerns, expectations 2 – exploring two of the following items: preferences, concerns, expectations 3 – exploring all of the following items: preferences, concerns, expectations 4 – integrates preferences / concerns / expectations for recommendation
5	The provider makes an effort to integrate the patient's preferences as decisions are either made by the patient or arrives at by a process of collaboration and discussion.	0 – not observed 1 – indicates need for decision 2 – indicates need for decision based on the preferences of the patient 3 – asking the patient if the patient is in agreement with the decision 4 – provider indicates that the patient can abandon earlier choice
	Total score 0–20	
	Rescale 0–100	

Chapter 8

A web-based application to communicate benefits and risks of surgical treatments

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Abstract

Background

In general, communication is an important aspect during surgeon-patient consultations. However, clear communication of the benefits and risks of the possible treatment options can be challenging. Visual presentation of information may increase patient comprehension. We developed and piloted a web-based application that provides graphical representations of the numerical benefits and risks of surgical treatment options.

Materials and Methods

The app was developed by assessing functional requirements, developing a prototype, pilot-testing and adjusting the prototype, and evaluating the final app. In the app the surgeon enters the benefits and risks of the surgical treatment options as percentages. The app shows the possible outcomes ad libitum as bar charts, icon arrays or natural frequency trees. Subsequently, we investigated clinicians' and patients' satisfaction with the prototype by means of questionnaires, semi-structured interviews and by observing their conversation.

Results

The MAPPING app ("Mapping All Patient Probabilities In Numerical Graphs") was pilot-tested among 5 surgeons and 12 patients with various surgical disorders. Nine patients stated to welcome the app and to better understand the risks and benefits involved when presented as graphs. The surgeons judged the app as simple to use and valuable. The prototype was improved based on their suggestions.

Conclusion

The MAPPING app was developed successfully and has the potential to facilitate surgical risk communication in a more structured and uniform manner. Future research will focus on its validation and promotion of SDM in different types of patients and disorders.

Introduction

Risk communication is an important aspect during doctor-patient consultations. It is essential – and a legal requirement – to inform a surgical patient in detail about the expectations desired, but also the possible undesired outcomes and complications, especially when new surgical techniques are introduced. Apart from communication about available evidence regarding treatment options, the patient's preference needs to be invoked to make sure the surgeon's advice matches the patient's preference.

However, the patient may not always grasp the possible outcomes of the treatment options, even when explained in-depth by the surgeon[1]. Several reasons for this have been postulated. Some of these are a lack of time in the consultation room, innumeracy among clinicians and patients[2], and health illiteracy[3].

To improve risk communication, several supporting tools have been developed. For example, the Mayo Clinic decision aid cards provide a (partly) graphical display of the benefits and risks of different medication options organized around concerns that are important to patients, like the daily implications[4]. Other graphical display tools utilize icon arrays or natural frequency trees[5,6]. Besides, several studies showed evidence that icon arrays and bar charts lead to a better understanding of probabilistic information regarding the benefits and risks of treatments[7-9]. Furthermore, visual aids of the benefits and risks were found to increase patient knowledge and understanding of the benefits and risks and help clinicians to communicate these benefits and risks in an easier and standardized way[10,11]. The addition of visual aids may also reduce the effect of positive framing providing a more honest representation of the risks and benefits[7].

Therefore, the aim of this study was to design, develop, and evaluate a web application, called MAPPING ('Mapping All Patient Probabilities In Numerical Graphs'), to improve risk communication by providing multiple visual representations of numerical benefits and risks of treatment options for surgical disorders for which multiple treatment options are feasible.

Materials and Methods

For the design, development and pilot-testing of the MAPPING app, the 'user-centered design' (UCD) approach was used[12]. This has been applied before in healthcare settings, for example to create a tablet tool for use by patients for primary care visit discussion prioritization[13].

The UCD approach in this project consisted of four steps: 1) assessing functional requirements, 2) developing a prototype, 3) pilot-testing and adjusting the prototype, and 4) evaluating the final app. Thereby, we iteratively improved the design and features available in the app. An overview of the design, development and pilot-testing processes is visualized in *Figure 1* and summarized below.

Assessing functional requirements

To make the idea of MAPPING consistent with the needs in clinical practice and to collect the functional requirements of the app, we conducted individual semi-structured interviews with surgeons from different specialties within the department of surgery at the Academic Medical Center, a university hospital in Amsterdam, the Netherlands. The interviews were conducted until saturation of ideas was reached, (i.e., when two consecutive interviews did not result in any new requirement suggestions).

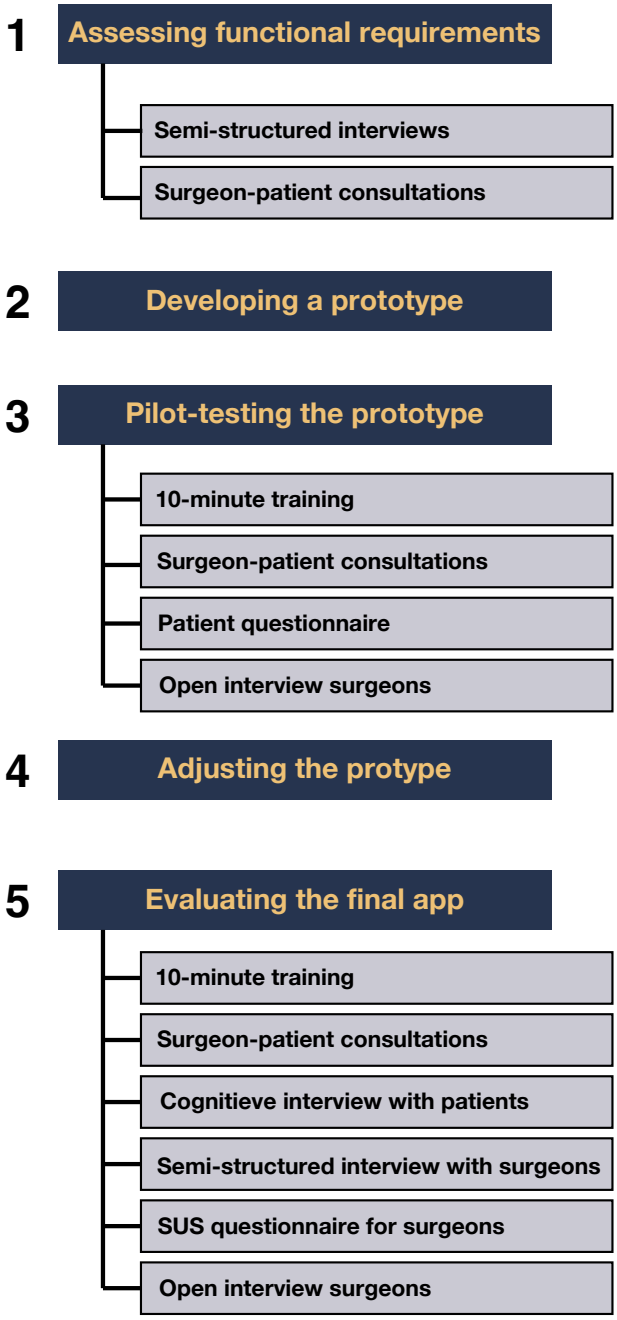


Figure 1. An overview of the design, development and testing processes of the MAPPING app.

In addition, three surgeon-patient consultations were observed in order to determine the information needs regarding (graphical) information during consultation and the current amount of information provided about the different benefits and risks of treatment options.

Developing a prototype

The MAPPING prototype was developed as a Java-EE application. As graphical tools to be displayed in MAPPING we planned to present bar charts, icon arrays and natural frequency trees, based on existing evidence[6,7]. The prototype would allow surgeons to enter the known benefits and risks (as percentages) of the surgical or non-surgical treatment options that were possible and available to the particular patient. Based on these numbers the prototype should generate the graphical displays (*Figure 2*). The app was designed to run on different browsers (i.e., Google Chrome, Mozilla Firefox, and Apple Safari).

Pilot-testing the prototype

For the usability study of the prototype, the app was tested in the outpatient clinic among patients and surgeons from vascular and trauma surgery. Only consultations about surgical disorders for which multiple treatment options are feasible were eligible. In addition, the surgeons should be aware of the numerical data on the benefits and risks of these treatment options.

First, the surgeons received a 10-minute training about how to use MAPPING. One researcher observed the following doctor-patient encounters real-time in the consultation room.

After each consultation the patient received a questionnaire to elaborate on the observation. The questionnaire consisted of 4 questions about: 1) whether the patient was happy with receiving information this way; 2) the understandability of the app; 3) the amount of information received; and 4) which of the graphical representations the patient preferred most. To make sure patients understood the questions, we provided explanation if desired.

At the end of the test period a semi-structured, open-question interview with each surgeon took place to uncover usability issues and missing features. These results were used to further adjust the prototype.

Evaluating the final app

After adjusting the prototype, we tested the final version among surgeons from various surgical specialties during their patient consultations for a period of 3 weeks, in order to have a broader spectrum of different disorders for which more than one treatment option was available. Besides, we tested the willingness of the surgeons to apply the MAPPING app.

Surgeons received the same training as was given during step 2. Two researchers observed the way MAPPING was used in the clinical setting in order to assess if MAPPING provides the functionality the surgeon wanted, and to see how the surgeon and patient would interact with MAPPING. In addition, the following data were recorded: name of surgeon, patient diagnosis, feasible treatment options, and general notes about the course of the conversation. After each consultation a cognitive interview was done with each patient.

After the whole observation period, semi-structured interviews were conducted with the surgeons to identify their opinions about MAPPING. The interview consisted of 7 questions: 1) whether the surgeons were satisfied with presenting information this way;

2) user-friendliness; 3) interaction with the patient; 4) preference regarding the graphical representations, if any; 5) missing features; 6) if they would continue using MAPPING during future consultations; and 7) if they would recommend MAPPING to colleagues.

The interview was completed by asking the surgeons to fill out the System Usability Scale (SUS)-questionnaire[14]. The SUS is a validated 10-item questionnaire for measuring the usability of a system. SUS has become an industry standard in measuring usability, with references in more than 1300 publications[15]. The SUS measures: 1) effectiveness, the ability of users to complete tasks using the system, and the quality of the output of those tasks; 2) efficiency, how long people take to complete the tasks; and 3) satisfaction, how people feel about the design. Each question was evaluated on a scale of 1 ("strongly disagree") to 5 ("strongly agree"). Possible scores range from 0 to 100. A SUS score above 68 is considered "above average" and scores below 68 "below average"16. The Dutch translation of the SUS-score was used, as the translated version was shown to have similar internal validity to the original English version[15].

In addition, the app was evaluated by medical students, medical information students, PhD students, and people working in the hospital without a medical background to test the acceptance and ease of use of the MAPPING app from the patient's perspective.

Table 1. Requirements after semi-structured interviews.

Requirements	Description
FR 1	The tool should have input options for name, success-rate, morbidity, and mortality of a certain treatment.
FR 2	The tool should display more than one visual aid of the risk.
FR 3	The tool should display a sequent arranged icon array, which portrays a risk at the discrete level of measurements as a group of 100 individual icons.
FR 4	The tool should display a bar chart, with success rate, morbidity, and mortality at the x-axis and percentage from 0-100 at het Y-axis.
FR 5	The tool should display a frequency tree.
FR 6	The tool should be able to compare two possible treatments. Treatment x vs. treatment y.
FR 7	The tool should have a button to print the graphs.
FR 8	The tool should have a 'share' button to send the personalized graphs to a certain email-address.
FR 9	The tool should be able to save treatment options with their success-rate, morbidity, and mortality.
FR 10	The tool should be able to alter the saved treatment options.
FR 11	The tool should be able to delete saved treatment options.
NFR 1	The success-rate should be visualized in green, the morbidity-rates orange, and the mortality-rates in red.
NFR 2	The system must be available in Dutch.
NFR 3	The tool should be able to be used by more than one person at the time with a maximum of at least 20 persons.
NFR 4	The tool has to be reachable at the surgical outpatient clinic.
NFR 5	The system should display the graphs within min. 2 seconds.
NFR 6	The System should have an uptime of 99%.

FR: functional requirements; NFR: non-functional requirements.

Clinical example frequency tree

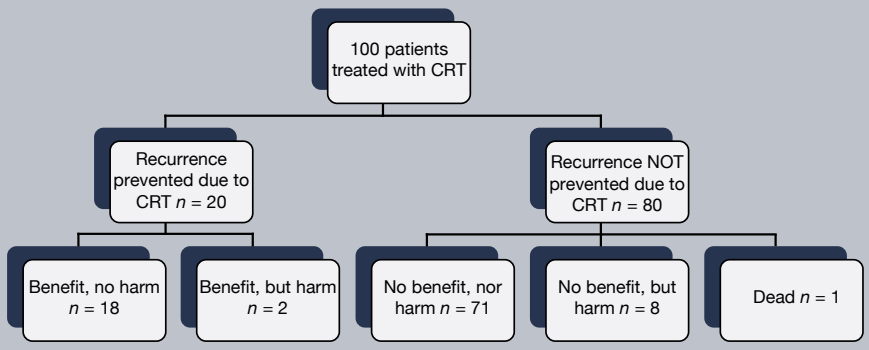
This generic example of how to use the MAPPING app may apply to many patients who need surgery for an arbitrary type of cancer. The numbers used are an approximation and may vary, but the general idea remains the same.

A patient undergoes surgery for cancer. After surgery, the patient's oncologist advises him to undergo additional chemoradiotherapy (CRT) to avoid a local recurrence of the tumor.

The oncologist will explain CRT will be effective to prevent a local recurrence in about 20% of the cases. However, he elaborates, CRT also has side effects, which will occur in roughly one in ten patients. Moreover, about one in a hundred patients will die due to CRT.

The oncologist has learnt his patients may better appreciate these numbers in a visual way. Hence, he uses the MAPPING app to illustrate the possible outcomes of CRT. He just enters the three percentages into the app and names the outcomes for which these percentages stand.

One way of presenting is through a natural frequency tree, which shows the possible outcomes of a virtual number of 100 patients who are treated with CRT as compared to not having CRT:



Because 20% will benefit from CRT, recurrence is prevented in 20 out of 100 patients. Of these, 10% will suffer harm, so two patients will benefit but also suffer from harm. This means only eighteen patients will have the full benefit of CRT.
Of the eighty other patients who may still have a recurrence, one will die and of the remaining 79 10% will suffer harm. So, the great majority (71/100 patients) will have neither benefit nor harm of undergoing CRT, while most of the patients with harm will also have no benefit of CRT[6].

Figure 2. A clinical example.

Results

Assessing functional requirements

The semi-structured interviews were conducted with six surgeons from four specialties: vascular surgery, trauma surgery, hepato-pancreato-biliary (HPB) surgery and general surgery. The first four interviews resulted in 17 requirements (see *Table 1*).

Developing a prototype

Based on these findings, we understood we needed to make the tool as simple as possible, without compromising its functionality. Some of the requirements considered essential in the prototype were a one-screen input and output, consisting of a frame on the left side, in which the outcome data can be entered, and a frame on the right, in which the output is generated.

Second, we matched the colors of each outcome with those of the bars and icon arrays. Third, the outcomes of a single treatment option can be shown, or can be compared with another treatment alternative. All requirements collected were incorporated in the prototype.

Pilot-testing the prototype

Four patients and two surgeons evaluated this prototype during their consultations. They had difficulties to interpret the icon arrays: Surgeons found it hard to understand how to use it and patients found the colors confusing. Also, they stated that the language was not always consistent. The other output screens were found to be clear and understandable. A print and e-mail possibility was also desired. Based on the feedback on the prototype, the app was adjusted so that the icon arrays show the primary outcome, morbidity and mortality in a single graph. Some screenshots are shown in *Figures 3-4*.

Evaluating the final app

A total of five surgeons and eight patients were observed during the doctor-patient consultation.

SUS results

The scores of the SUS-questionnaires showed that the overall satisfaction using MAPPING was above average; Median SUS-score was 80. As you can see in *Figure 5* surgeons appreciated presenting the information about the benefits and risks using MAPPING. Surgeons found this updated version of the MAPPING easy to use and patients liked this way of presenting the information. Four out of five surgeons would continue using MAPPING during consultations and they also would recommend MAPPING to colleagues. One surgeon was still hesitant and stated that more research should be done about MAPPING before using it in clinical practice.

Semi-structured interviews

Some surgeons came up with further suggestions as to the presentation of predefined risks, the possibility to make comments in the printout, to split the complications in major and minor complications, and the possibility of linking to the patient's electronic health record.

For some disorders, surgeons stated that they found it hard to enter exact data due to the lack of numerical data of the benefits and risks of certain treatment options. In these cases, surgeons could still enter their best guess, mostly based on local data.

One surgeon stated that MAPPING did not only help him explain the benefits and risks to the patient. It also forced him to really contemplate the goal of the treatment.

Patient questionnaires

During the development of MAPPING a total of 12 patients filled out the questionnaire. Patients had various treatment proposals, for example for abdominal aortic aneurysm, trauma and endocrine disease. Ten of the patients appreciated using the MAPPING app. Eight of them believed they now better understood the benefits and risks. Overall, they did not find that MAPPING provided too much information to comprehend.

Most of the patients (5 out of 12) preferred the bar chart, although the other graphs were appreciated as well. Two patients stated that MAPPING gave them an easy to understand overview of the benefits and risks. Another two patients expressed they now had a voice in the decision-making process. In contrast, three patients found the frequency tree was difficult

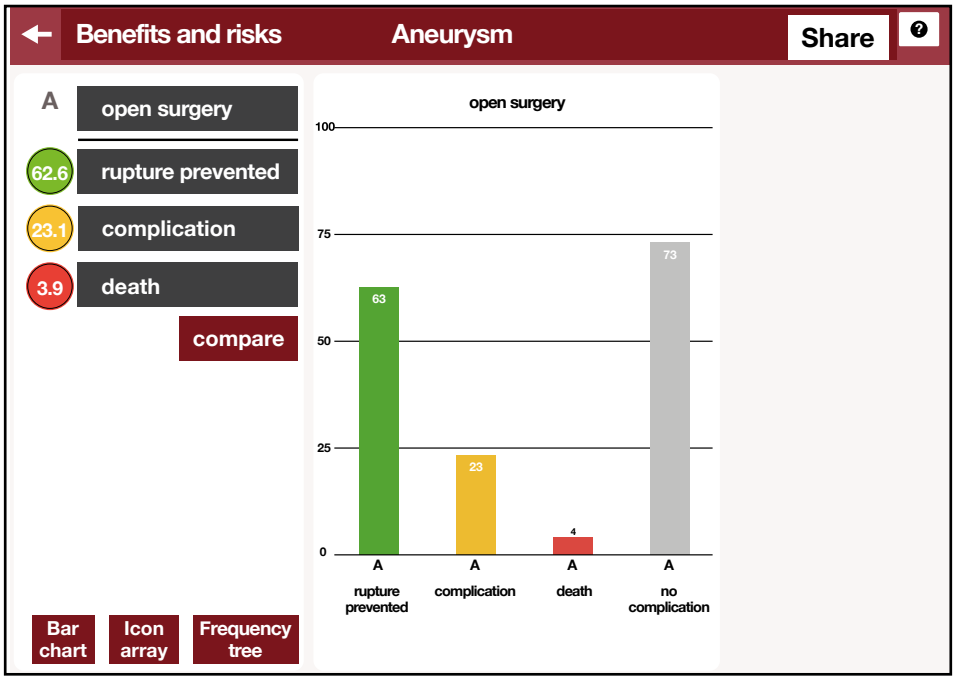


Figure 3. Bar chart showing the possible outcomes of open surgery in patients with abdominal aortic aneurysm.

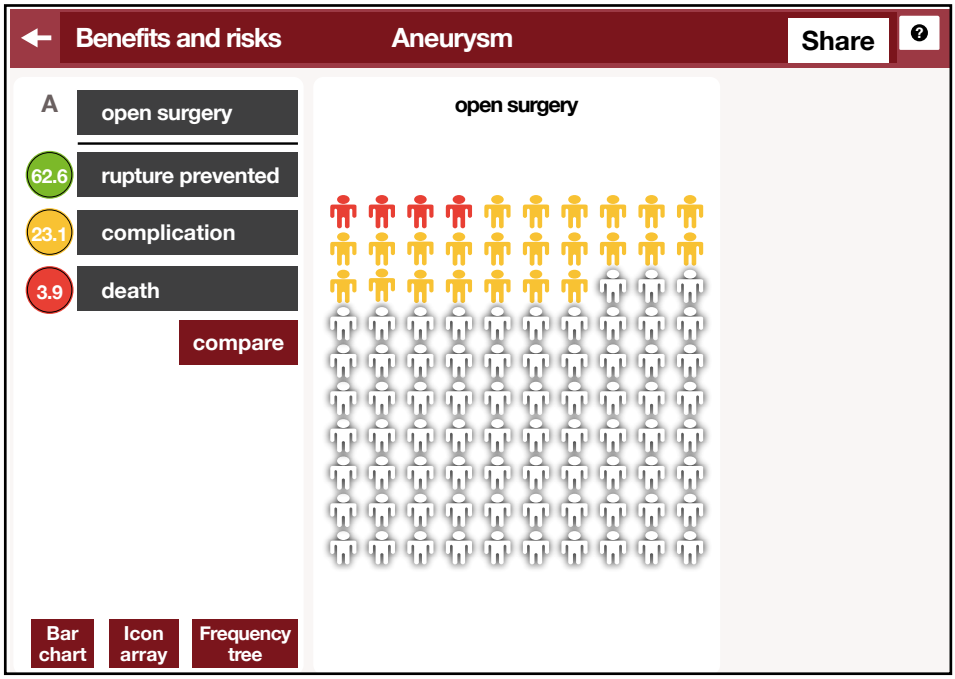


Figure 4. Icon array showing the possible outcomes of open surgery in patients with abdominal aortic aneurysm.

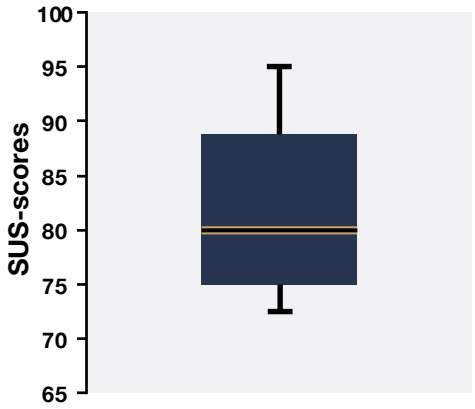


Figure 5. Box-plot of the outcome of the System Usability Scale (SUS)-questionnaire as assessed by the surgeons. SUS measures the usability of a system. Possible scores can range from 0–100. Scores above 68 are considered 'above average', scores below 68 'below average'. All scores were above 72.5.

to understand, whereas three other patients judged the tree as the clearest graph.

Most of the medical students, medical informatics students, PhD students, and people working in the hospital stated that it was useful to have MAPPING to communicate the benefits and risks. They indicated that they preferred the bar chart most. All participants found the icons array and the frequency tree less useful when comparing two treatment options.

Based on the surgeons' and patients' feedback, we added the numbers about the benefits and risks as presets for several disorders, like abdominal aortic aneurysm, carotid stenosis, clavicle fracture, Achilles tendon rupture, ureter stones, based on data from available systematic reviews or guidelines. Surgeons can still adjust these numbers based on the characteristics of their patients or on their local results. For example: if they encounter an elderly patient with substantial comorbidity they can enter a higher complication rate. This version of the app also has the possibility to email or print the graphical output.

Discussion

In this study we developed and piloted a web-based application (the MAPPING app) to better communicate the benefits and risks of surgical treatments. With MAPPING it is possible to show, with the use of various graphs based on the numerical benefits and risks of treatment options, the primary outcome, morbidity, and mortality for each treatment. The first results suggest the app has the potential to improve risk communication and to facilitate the comparison between one treatment with no (surgical) treatment or to compare two different (surgical) treatments so that the patient can better be involved in the decision-making process (shared decision-making)[17].

The most important benefits and risks of surgical interventions to communicate are the primary benefit, morbidity, and mortality of surgery. As opposed to previously developed graphical representations using only one icon array[4], the app developed here provides three graphical options; a bar chart, an icon array, and a frequency three. This feature was appreciated by both surgeons and patients. This is in agreement with a previous study that suggested that patients prefer combined formats[18]. You may experience the MAPPING app yourself at www.mapping.nu. An English version can be made available upon request.

A limitation of this exploratory study is the small number of participants involved. However, interviews were continued until no new insights were obtained. Obviously, further study of the value and applicability of this app in clinical practice is warranted. A second limitation is the fact that only surgeons who showed interest in this study contributed. Most of the participating surgeons were familiar with shared decision-making in their consultations, and therefore receptive to use MAPPING. The positive experiences of both surgeons and

patients with the app are likely to help facilitate its use by other surgeons.

A limitation of the app itself is that the percentages of the benefits and risks are not exactly known for every surgical treatment. In such cases the surgeon can still enter the data known from their own experience or hospital data. Future improvements are the possibility to make comments in the printout, to split the complications in major and minor complications, and a link to the patient's electronic health record.

Conclusion

The MAPPING app was developed successfully and seems a promising tool to facilitate surgical risk communication in a more structured and uniform manner during doctor-patient encounters in which decisions are to be made about treatment options. Future research will focus on its validation and promotion of shared decision-making in different types of patients and disorders.

Authors' disclosure

The authors have no conflicts of interest to disclose.

References

1. Agoritsas T, Heen AF, Brandt L, Alonso-Coello P, Kristiansen A, Akl EA, et al. Decision aids that really promote shared decision-making: the pace quickens. BMJ. 2015;350.

2. Gigerenzer, G. and A. Edwards. Simple tools for understanding risks: from innumeracy to insight." BMJ (2003). 327(7417): 741-744.

3. Nayak, J.G et al. Relevance of graph literacy in the development of patient-centered communication tools. PEC (2016). 99(3): 448-54

4. Montori VM, Breslin M, Maleska M, Weymiller AJ. Creating a conversation: insights from the development of a decision aid. PLoS Med. 2007;4(8):e233.

5. Paling, J. "Strategies to help patients understand risks." BMJ (2003).327(7417): 745-748

6. Legemate, D. A., et al. "Number Unnecessarily Treated in Relation to Harm: A Concept Physicians and Patients Need to Understand." Ann Surg (2016). 263(5): 855-856

7. Zipkin, D. A., et al. "Evidence-based risk communication: a systematic review." Ann Intern Med (2014). 161(4): 270-280.

8. Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. BMJ. 2002;324(7341):827-30.

9. Waldron, C. A., et al. "What are effective strategies to communicate cardiovascular risk information to patients? A systematic review." Patient Educ Couns (2011). 82(2): 169-181

10. Timmermans D, Molewijk B, Stiggelbout A, Kievit J. Different formats for communicating surgical risks to patients and the effect on choice of treatment. Patient Educ Couns. 2004;54(3):255-63.

11. Hawley, S. T., et al. "The impact of the format of graphical presentation on health-related knowledge and treatment choices." Patient Educ Couns (2008). 73(3): 448-455

12. Abras C, Maloney-Krichmar D, Preece J. User-centered design. Bainbridge, W Encyclopedia of Human-Computer Interaction Thousand Oaks: Sage Publications. 2004;37(4):445-56.

13. Lyles, C. R., et al. "User-Centered Design of a Tablet Waiting Room Tool for Complex Patients to Prioritize Discussion Topics for Primary Care Visits." JMIR Mhealth Uhealth (2016). 4(3): e108.

14. Brooke J. SUS-A quick and dirty usability scale. Usability Evaluation in Industry. 1996;189(194):4-7.

15. Brooke J. SUS: a retrospective. JUS. 2013;8(2):29-40.

16. Bangor A, Kortum P, Miller J. Determining What Individual SUS Scores Mean: Adding an Adjective Rating Scale. Journal of Usability Studies. 2009;4(3):114-23.

17. Ubbink, D. T., et al. "Shared Decision-Making in Surgery." Surg Technol Int (2015). 26: 31-36.

18. Dolan JG, Iadarola S. Risk communication formats for low probability events: an exploratory study of patient preferences. BMC Med Inform Decis Mak. 2008;8:14.

Part III

Promoting shared decision-making

Chapter 9

Improving shared decision-making in vascular surgery by implementing decision support tools: study protocol for the stepped-wedge cluster-randomised OVIDIUS trial.

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Abstract

Background

Shared decision-making improves the quality of patient care. Unfortunately, shared decision-making is not yet common practice among vascular surgeons. Thus, decision support tools were developed to assist vascular surgeons and their patients in using shared decision-making. This trial aims to evaluate the effectiveness and implementation of decision support tools to improve shared decision-making during vascular surgical consultations in which a treatment decision is to be made.

Methods

The study design is a multicentre stepped-wedge cluster-randomised trial. Eligible patients are adult patients, visiting the outpatient clinic of a participating medical centre for whom several treatment options are feasible and who face a primary treatment decision for their abdominal aortic aneurysm, carotid artery disease, intermittent claudication, or varicose veins. Patients and vascular surgeons in the intervention group receive decision support tools that may help them adopt shared decision-making when making the final treatment decision. These decision support tools are decision aids, consultation cards, decision cards, and a practical training. Decision aids are informative websites that help patients become more aware of the pros and cons of the treatment options and their preferences regarding the treatment choice. Consultation cards with text or decision cards with images are used by vascular surgeons during consultation to determine which aspect of a treatment is most important to their patient. In the training vascular surgeons can practice shared decision-making with a patient actor, guided by a medical psychologist. This trial aims to include 502 vascular surgical patients to achieve a clinically relevant improvement in shared decision-making of 10 out of 100 points, using the 5-item OPTION instrument to score the audio-recordings of consultations.

Discussion

In the OVIDIUS trial the available decision support tools for vascular surgical patients are implemented in clinical practice. We will evaluate whether these tools actually improve shared decision-making in the consultation room. The stepped-wedge cluster-randomised study design will ensure that at the end of the study all participating centres have implemented at least some of the decision support tools and thereby a certain level of shared decision-making.

Background

Physicians aim to offer the best quality of care to their patients. In recent years it has been acknowledged that the incorporation of the patients' preferences, known as shared decision-making (SDM), improves quality of care by enhancing patient satisfaction and therapy adherence[1,2]. SDM also decreases the number of patients who opt for (major) invasive treatment or who undergo undesired care without adverse effects on health outcomes[1-5].

SDM may especially benefit patients in vascular surgery, because for many patients more than one treatment option is feasible, for example a conservative, endovascular or open surgical treatment, each with their own beneficial and potential harmful effects[6]. It is therefore essential that vascular surgeons are aware of how the patient weighs the benefits and harms of the available options. Unfortunately, studies show that in the Netherlands, the level of SDM is limited among vascular surgeons and that patients are informed inconsistently about their disease and treatment options[7,8]. In order to improve SDM, a set of decision support tools (DSTs) has been developed for both vascular surgeons and patients. When developed and applied correctly, DSTs improve disease-specific knowledge and, more importantly, SDM in the consultation room[1,5,9-12].

DSTs have been developed for Abdominal Aortic Aneurysm (AAA), Carotid Artery Disease (CAD), Intermittent Claudication (IC) and Varicose Veins (VV). These DSTs are designed according to international standards[13] and consist of decision aids, consultation cards, decision cards, and a practical training in SDM for vascular surgeons, physician assistants, and nurse practitioners.

Objectives

The objective of this trial is to evaluate the effectiveness and implementation of DSTs at the individual patient level to improve SDM during vascular surgical consultations in which a treatment decision is to be made for patients with an abdominal aortic aneurysm, carotid artery disease, intermittent claudication and varicose veins.

Methods

The study protocol is designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement and the CONsolidated Standards of Reporting Trials (CONSORT) extension for Cluster Trials[14,15]. A filled out SPIRIT checklist regarding this trial is added as a supplementary file. The trial was registered in The Netherlands National Trial Registry as NTR6487, available at www.trialregister.nl.

Trial design

The Operative Vascular Intervention Decision-making Improvement Using SDM-tools (OVIDIUS) trial design is a 15-center stepped-wedge cluster randomised trial in the Netherlands, as shown in *Table 1*. Each cluster consists of three participating medical centres. The reasons for choosing this design is in the first place that it allows the evaluation of outcomes before and after introduction of the DSTs in the individual centres and limits the influence of any intercurrent changes in protocols on the clinical outcomes. Second, all participating centres will eventually have implemented at least some of the DSTs and thereby a certain level of SDM.

Table 1. Multicentre stepped-wedge cluster-randomised design.

	Month 1-2	Month 3-4	Month 5-6	Month 7-8	Month 9-10	Month 11-12
Cluster 1	–	+	+	+	+	+
Cluster 2	–	–	+	+	+	+
Cluster 3	–	–	–	+	+	+
Cluster 4	–	–	–	–	+	+
Cluster 5	–	–	–	–	–	+

Trial setting

Participating centres are located throughout the Netherlands and must provide care for at least one of the four vascular diseases for which the DSTs have been developed. The list of participating medical centres will be published alongside the trial results and is available upon request by emailing the corresponding author. Patients are to be included between January 1, 2018 and June 30, 2019.

Eligibility criteria

Eligible patients are adults visiting the outpatient clinic of a participating centre who need to decide on a primary treatment for their AAA, CAS, IC or VV. These patients must be eligible for more than one treatment option. *Table 2* shows a more detailed overview of the study's inclusion and exclusion criteria.

Table 2. Eligibility criteria.

Inclusion criteria	Exclusion criteria
Age ≥ 18 years	Patients requiring emergency surgery
> 1 feasible treatment options	Life expectancy less than 1 year
(Newly) diagnosed with an asymptomatic AAA that has grown to ≥ 5 cm in women or ≥ 5.5 cm in men	ASA-IV patients
Newly diagnosed with symptomatic CAD with a >70% stenosis within 6 months since the onset of symptoms, or >50% in men diagnosed within 12 weeks since the onset of symptoms[32]	Insufficient understanding of the Dutch language
(Newly) diagnosed with invalidating IC (Fontaine II)	Cognitively unable to complete Dutch questionnaires
Considering treatment for VV	
Willing to sign an informed consent form	

Interventions

The intervention comprises a set of DSTs, developed to help both vascular surgeons and patients to improve SDM. Use of the DSTs is compared to standard care at the level of individual participants. Standard care may include informative leaflets or websites that participating medical centres already provide to their patients.

The DSTs studied here are decision aids, consultation cards, decision cards and a practical training. The patient advocacy society (Heart and Vascular Group) and the Dutch professional society (Dutch Society for Vascular Surgery) provided intellectual support for the development of the DSTs. The Netherlands Organisation for Health Research and Development provided financial support (ZonMw, grant 516022506). The participating centres may decide which combination of DST they prefer to use.

Decision aids are validated web-based applications that provide patients with information about their disease and treatment options. In addition, it has an interactive section in which the patient is encouraged to consider what he or she believes is important when deciding on a treatment strategy[9,17]. Patients receive the decision aid prior to the decision-making consultation via a personalized web link. The researchers automatically receive the answers given by patients in the decision aid regarding their disease-specific knowledge and treatment preferences. The following link provides access to the English version of the Dutch decision aid used in this study for patients with an AAA: https://sdmstaging.medify.eu/surgery1/index_da-aortic-aneurysm_en.html.

More information about other available decision aids is provided at the website of the Ottawa Hospital Research Institute[18].

Consultation cards are validated tools, also known as Option Grids™ [19]. These are A4-sized paper sheets showing questions -with their answers- that patients most frequently ask about the treatment options, presented in a table format. Vascular surgeon and patient discuss the consultation cards during the consultation. The order in which the patient wants to discuss the questions provides insight into the aspects patients find relevant to them personally when deciding on a treatment strategy[11]. *Table 3* shows the consultation card used in this study by vascular surgeons for patients with symptoms of intermittent claudication. More information about other available decision aids is provided at the website of the Dartmouth Institute[20].

Decision cards are tools designed with the same purpose as consultation cards. Here each question with its answer is presented on a different card. The answers are provided in the form of images, which is supposed to have a beneficial effect on doctor-patient interaction as it leaves room for tailor-made information based on patient comorbidity or hospital performance[10]. *Figure 1* shows the decision cards addressing symptomatic carotid artery disease used in this study by vascular surgeons with their patients. More information about how to use decision cards is provided at the website of the Mayo Clinic Shared Decision-making National Resource Center[21].

The practical training is offered to all vascular surgeons, physician assistants and nurse practitioners in the participating centres. The training allows participants to practice the three important steps of SDM, which are the 'team talk', 'option talk' and 'decision talk'[22]. The participants practice these steps with a patient actor under the guidance of a medical psychologist[12,22]. The practical training takes place just before the vascular surgeons start using the DSTs in their centre.

Table 3. Example of a consultation card for patients with intermittent claudication

Treatment options for intermittent claudication			
Use this consultation card if you want to talk to your health care professional about how to treat your blocked or narrowed leg arteries (medical term: 'intermittent claudication'). This way you can decide with your doctor which option is best for you.			
Frequently asked questions	**(Supervised) exercise therapy**	**Endovascular treatment (with or without stenting)**	**Surgery (Endarterectomy or bypass)**
What does the treatment entail?	You will exercise on a treadmill (supervised by a physical therapist) to increase your overall and pain-free walking distance. You also receive weight training exercises to practice at home. You will also continue to take medication to prevent a heart attack or stroke.	A wire is inserted into the artery in your groin. Attached to this wire is a balloon. The balloon is inflated to reduce the narrowing. Sometimes, a tube is left behind to keep the artery open. You will also continue to take medication to prevent a heart attack or stroke.	- With an 'endarterectomy' the artery is opened and the narrowing surgically removed. - With a 'bypass' either one of your own veins or an artificial tube is used to bypass the narrowed artery. You will also continue to take medication to prevent a heart attack or stroke.
What are the benefits of this treatment?	Your general condition will improve due to exercise therapy. There are no treatment risks.	Your complaints will be less immediately after endovascular treatment.	Your complaints will be less immediately after surgery.
What are the main risks associated with the treatment?	You will not have an immediate effect of exercise therapy. It takes about 3 to 6 months before you experience improvement. Some patients will not be able to walk completely pain-free after exercise therapy.	Two years after endovascular treatment, the walking distance is about the same as after exercise therapy only.	You may suffer from a hematoma (bruise), a wound infection, or the surgery might even worsen your complaints.
What is the effect of the treatment?	After six months of exercise therapy, patients like yourself are able to walk twice as far as before the exercise therapy.	Two years after endovascular treatment, the walking distance is about the same as after exercise therapy only.	Two years after surgery, the walking distance is about the same as after exercise therapy only.
Will I receive anaesthesia?	No.	Yes; local anaesthesia.	Yes; general or local anaesthesia.
How long do I stay in the hospital?	No hospital stay.	Usually, 1 to 2 days.	Usually one week.
What is the risk of losing my leg (amputation)?	1 to 3 of 100 people (1-3%) with intermittent claudication have an amputation within 10 years.	1 to 3 of 100 people (1-3%) with intermittent claudication have an amputation within 10 years.	1 to 3 of 100 people (1-3%) with intermittent claudication have an amputation within 10 years.
What more should I need to know about intermittent claudication?	Exercise therapy does not prevent worsening of the disease. In case of insufficient results, endovascular treatment and surgery are still possible.	Endovascular treatment does not prevent worsening of the disease. Even if you have undergone this treatment, exercise therapy will remain helpful.	Surgery does not prevent worsening of the disease. Even if you have undergone surgery, exercise therapy will remain helpful.
What can I do myself?	The most important things you can do to prevent worsening of the disease is to quit smoking, take plenty of exercise, healthy food, and live a healthy life.	The most important things you can do to prevent worsening of the disease is to quit smoking, take plenty of exercise, healthy food, and live a healthy life.	The most important things you can do to prevent worsening of the disease is to quit smoking, take plenty of exercise, healthy food, and live a healthy life.

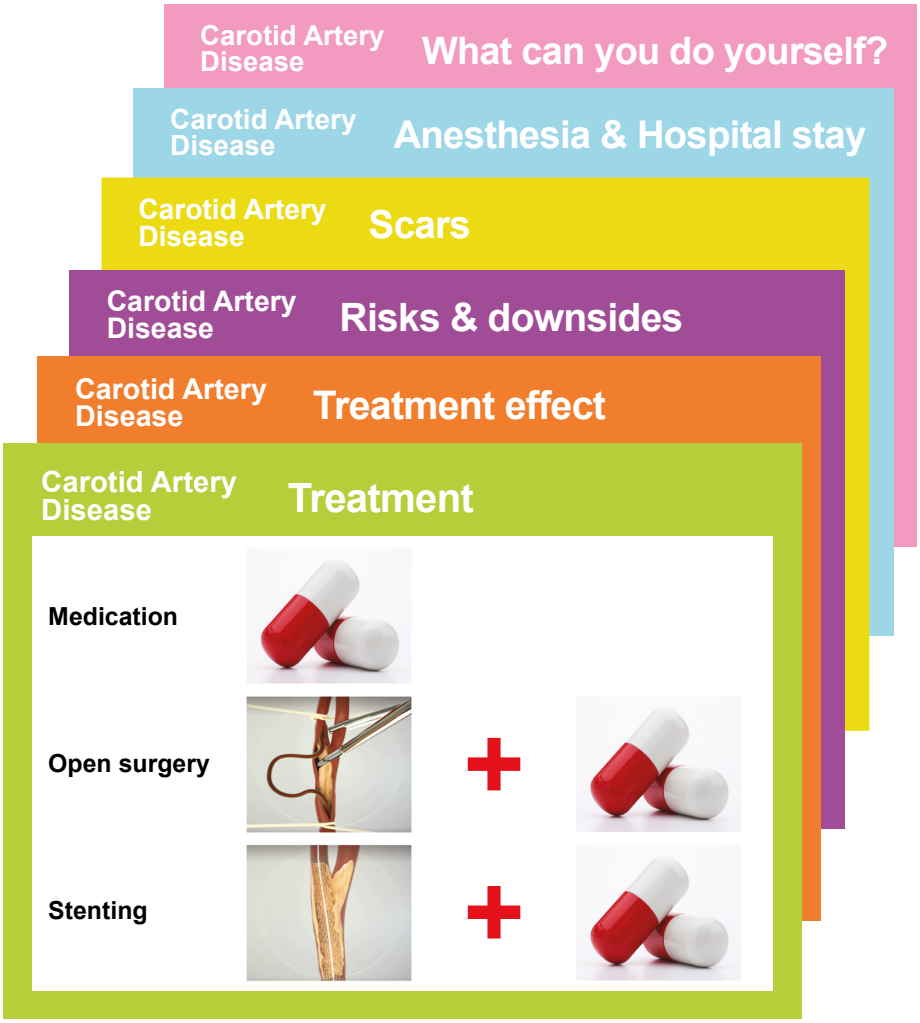

Figure 1. Carotid artery disease decision cards.

Outcomes

The primary outcome is the level of SDM during the consultation as scored with the 5-item Observing patient involvement (OPTION) instrument[23]. The 5-item OPTION instrument allows researchers to objectively assess the level of patient involvement in the decision-making process as scored from audio-recordings of the consultations[24]. If the vascular surgeon and patient need more than one consultation to reach a treatment decision, all consultations are audio-recorded and scored as one consultation. Afterwards, two researchers independently score the five OPTION-items on a five-point scale. The cumulative OPTION-score is expressed on a 100-point scale.

Baseline characteristics, i.e., age, gender, diagnosis, highest level of education, employment status, social status, and ethnicity, are collected from the patients using a questionnaire before consultation.

Secondary outcomes are patients' disease specific knowledge, decisional conflict, quality of life, and SDM as perceived by patients, SDM as perceived by vascular surgeons, the treatment decided upon, the implementation of DSTs, and process measures. The patients' disease-specific knowledge is scored directly after the consultation. The questions test whether patients correctly understood the information presented in the decision aid or received during the consultation. Decisional conflict in patients is scored directly after the consultation and is repeated 4 weeks after consultation in which the treatment decision is made[17]. If an endovascular or open surgical treatment takes place within 4 weeks, decisional conflict is scored just before treatment. The decisional conflict in patients is scored using the 16-item Decisional Conflict Scale (DCS)[25].

Quality of life in patients is scored directly after consultation and again 6 weeks after treatment with the Short Form Health Survey (SF12)[26].

SDM as perceived by patients is scored directly after consultation using the SDM-Q-9 questionnaire, the 3-item CollaboRATE questionnaire, and the one question Control Preference Scale and Control Perception Scale (CPS)[27-29]. The Control Preference Scale documents the desired amount of patient involvement and is scored before the consultation. The Control Perception Scale assesses the actually perceived amount of patient involvement and is scored after the consultation.

SDM as perceived by vascular surgeons is scored after the consultation using the SDM-Q-DOC questionnaire and the Control Perception Scale[29,30]. The treatment decided upon is derived from the audiorecording of the consultation. The actually received treatment is obtained from the participating vascular surgeon or centre.

The extent in which DSTs are implemented is determined by scoring the number of times a specific tool is used as recorded by the audio recording (consultation card and decision cards). Successful use of the decision aid is defined as completion of the decision aid by the patient. Completion and time to complete is recorded automatically when patients access the decision aid via the provided link.

Process measures studied are the number and duration of consultations necessary to decide upon a treatment, as obtained from the audio recording(s) or from the participating vascular surgeon or centre.

All outcomes mentioned above are evaluated at the individual participant level.

Participants' timeline

Figure 2 provides an overview of the participants' timeline. Patients in the intervention group receive the decision aid prior to the appointment at the outpatient clinic. Patient follow-up is finalised after the patient has completed the final questionnaire. Patients receive the final questionnaire 6 weeks after the treatment or, in case of conservative treatment, 6 weeks after the decision-making consultation.

Sample size

Sample size calculations are based on a clinically relevant difference in the use of SDM during consultation before and after introduction of the DSTs. The systematic review of Couët *et al*.[31] found a mean increase from 23 (*SD* 14) to 34 (*SD* 8) of SDM scored with the 5-item OPTION instrument. An 11 out of 100 points increase of the 5-item OPTION instrument seems a meaningful improvement as it means an increase from a 'minimal' to

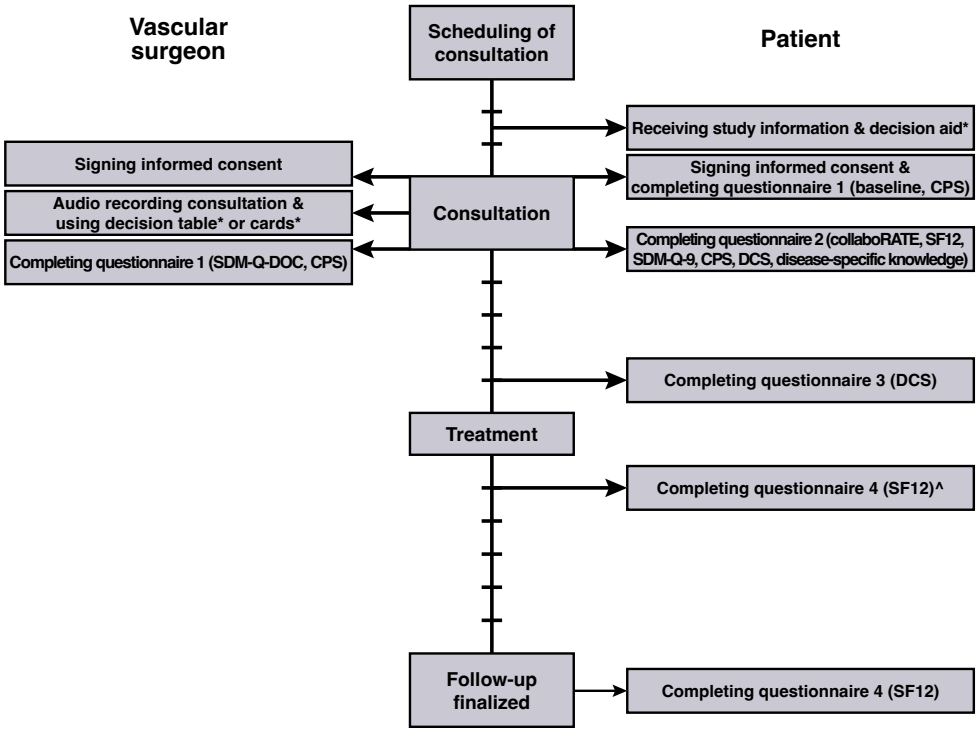

Figure 2. Participants' timeline of actions during the trial.
┼: One week. *: Intervention group. ^: In case of conservative treatment. SF12: Short form health survey. CPS: Control preference or perception scale. DCS: Decisional conflict scale. SDM: Shared decision-making.

a 'moderate' effort to involve patients in the decision-making process[31]. A larger increase would, of course, be even more clinically relevant and would require fewer patients, but this is less likely to reach. With a significance level of .05 and a power of 90%, a total sample size of 58 patients is required.

This number needs correction for the stepped-wedge design with cluster randomisation, as opposed to an individual patient randomisation. The total sample size from the power analysis is to be multiplied by the design effect for a stepped wedge trial. The pre-specified number of 5 steps (i.e., 6 time periods) and 5 clusters results in 58/(6*5) = 2 patients, per cluster per time period. Assuming an intermediate-level intra-cluster correlation of 0.01, the stepped wedge design effect is 1.94432. Thus, the total sample size needed in this trial is 58 * 1.944 = 113 patients per disorder. Since four different vascular diseases are studied, there are actually four trials in one trial. Therefore, a multiplication of the total sample size by 4 is necessary, which leads to 452 patients. To adjust for a loss-to-follow-up of 10%, the study aims to include a total of 502 patients.

Recruitment

All consecutive patients visiting the outpatient clinical of participating medical centres are screened for eligibility. Eligible patients are contacted by the researcher, nurse practitioner or surgeon and informed about the trial via the informed consent materials. The patient is given a minimum of 2 days to consider participation. Next, the patient is asked to participate in the study and to sign the informed consent form.

Allocations

Participating medical centres are randomised into five different clusters, containing three centres. These clusters are again randomised every 2 months thereafter to decide which cluster is next to start applying the DSTs, as shown in *Figure 1*. The researchers evaluate at each randomization instance whether sufficient patients have been included in the trial. If inclusion rate falls behind, randomisation of the next cluster to use the DSTs is delayed for another 2 months. The researchers randomise the participating centres and clusters by drawing lots stating the name of a participating centre or cluster from an opaque container.

Blinding

Due to the nature of this study it is not possible to blind patients or vascular surgeon, since they actively use the intervention. However, the cluster randomisation design does reduce potential contamination of information among the participating vascular surgeons. It is also not possible to blind the researchers scoring the five OPTION items on audio-recordings. The use of consultation cards and decision cards is audible and most vascular surgeons will inquire whether the patient has used the decision aid.

Data collection methods

Trial data are obtained via questionnaires, audio recordings, the decision aid content management system, and participating vascular surgeons. Patients fill out the questionnaires either at their medical centre, at home via email, or on paper accompanied by a stamped selfaddressed envelope.

Data management

All obtained trial data are considered as confidential information and will not be distributed to third parties. Patient data are stored anonymously under a code. Only the principal investigator or researchers authorised by the principal investigator have access to the key file.

Statistical methods

Baseline characteristics are summarised using descriptive statistics. Unevenly distributed outcome measures are expressed as medians and inter-quartile ranges. A differential effect among the four included vascular diseases is not expected, as the primary outcome is SDM. SDM is equally applicable to each of these diseases since multiple treatment options are available. Nevertheless, the sample size is sufficient to analyse the effect on SDM for each disease separately. Differences in mean scores of the 5-item OPTION instrument between consultations in which usual care is provided (control group) and the consultations in which DSTs are used (intervention group), are analysed using the Student *t*-test with Satterthwaite correction for unequal variances. ANCOVA is applied to correct for possible baseline

differences in patients before and after the introduction of the DSTs. Differences in (semi-) continuous variables between the usual care group and the DSTs group (e.g., Likert scales and quality of life scores) are analysed by means of the Student *t*-test or the non-parametric Mann-Whitney U test, depending on the normality of their distribution. Percentages are compared using a Chi-square test (e.g., for the final treatment choice). In particular, before-after differences in DCS at 4 weeks are analysed after correcting for differences between the groups in baseline DCS. Logistic regression analysis is used to determine the individual effect of the different DSTs on our primary outcome. Statistical analyses will be conducted using IBM SPSS version 24 (IBM, Armonk, NY, USA).

Monitoring

Previous studies show that SDM has no adverse effects on health outcomes[1,5,9,12]. Therefore, no monitoring committee was assembled.

Research ethics approval

The Medical Ethics Review Committee of the Academic Medical Center, Amsterdam, reviewed and approved version 2.0, dated 27 September 2017, of our trial protocol and written informed consent procedure.

Protocol amendments

The researchers will notify participating centres, the Medical Ethics Review Committee and the Netherlands trial registry if protocol amendments arise.

Consent or assent

Vascular surgeons, physician assistants, nurse practitioners or researchers inform patients eligible for participation about the OVIDIUS trial. Patients receive this information verbally and on paper, via the informed consent materials.

Access to data

All obtained trial data are considered confidential information and will not be distributed to third parties. Participating vascular surgeons are able to obtain anonymous patient data only on request and when presenting with a relevant question.

Ancillary and post-trial care

After the trial, the DSTs will be made publicly available via the patient advocacy group (Dutch patient organization for people with cardiovascular diseases) and the Dutch professional society (Dutch Society for Vascular Surgery).

Dissemination policy

No restrictions have been placed on the publication of trial outcomes. The trial results are to be published in relevant scientific journals, preferably as open-access to ensure high accessibility. Authorship is granted based on the International Committee of Medical Journal Editors guidelines. The authors also plan to present the trial outcomes at national and international conferences.

Discussion

Vascular surgery is pre-eminently a field in which SDM can enhance quality of care by incorporating patients' preferences in the decision-making process, since there is commonly a conservative, endovascular or open surgical treatment available for most vascular surgical disorders. Unfortunately, the use of SDM is still limited amongst vascular surgeons. We therefore developed DSTs to assist vascular surgeons and their patients in shared decision-making. The OVIDIUS trial was designed to implement these DSTs into the vascular surgical consultation room and to study their effect on SDM.

Strengths of the OVIDIUS trial are first of all that both the patient advocacy group and the Dutch Society for Vascular Surgery were involved in the development of the DSTs, which is a prerequisite for a nationwide implementation of these DSTs to foster SDM. Second, 15 medical centres throughout the Netherlands participate in this study, including university and general hospitals, thus reducing selection bias by including uncomplicated cases only. Third, the stepped-wedge cluster-randomised study design minimizes the influence of any intercurrent changes in local protocols on the clinical outcomes during the trial period and it ensures that at the end of the study all participating centres have implemented at least some of the DSTs and thereby a certain level of SDM.

Limitations of the OVIDIUS trial are, first a potential inclusion bias of patients. Patients who actively want to be involved in the decision-making process may be more willing to participate, whereas patient who prefer the surgeon to make the decision are less inclined to participate. That is why the preferred decision-making strategy is assessed via the CPS questionnaire prior to consultation. Second, the trial is powered for four different diseases, even though their incidences differ. Hence, the researchers must closely monitor the inclusion rates of these different diseases and take appropriate action when one disease is included much more frequently than another.

The OVIDIUS trial will evaluate whether the developed DSTs can be implemented in clinical practice and whether they actually improve the level of SDM by showing an improvement of the 5-item OPTION score measured on audio recordings made in the vascular surgical consultation room. Perhaps even more important is the renewed attention that our trial generates regarding the benefits of using SDM amongst vascular surgeons. Future researchers and developers of DSTs can use this study protocol to set up their own trial for the evaluation and implementation of newly developed DSTs.

Abbreviations

AAA: Abdominal aortic aneurysm; AMC: Academic Medical Center; CAD: Carotid artery disease; CPS: Control preference/perception scale; DCS: Decisional conflict scale; DST: Decision support tools; IC: Intermittent claudication; OPTION: Observing patient involvement; OVIDIUS: Operative Vascular Intervention Decision-making Improvement Using SDM-tools; SD: Standard deviation; SDM: Shared decision-making; SDM-Q-9: Shared decision-making patient questionnaire; SDM-Q-DOC: Shared decision-making physician questionnaire; SF12: Short form health survey; SPIRIT: Standard
Protocol Items: Recommendations for Interventional Trials; VV: Varicose veins

Acknowledgements

We would like to thank Medify B.V., Amsterdam, the Netherlands, for their support in developing the 3D animations, videos and content management system for the decision aids.

Authors' contributions

All authors made substantial contributions to the conception and design of the OVIDIUS trial. SM and FS wrote the manuscript. DL, RB and DU critically revised the manuscript. All authors read and approved the final manuscript.

Funding

This trial is funded by the AMC Foundation. The AMC Foundation not is involved in the study design, manuscript writing or the decision to submit the manuscript for publication. The decision support tools used in this trial were developed with financial support of the Netherlands Organisation for Health Research and Development (ZonMw; grant 516022506).

Availability of data and materials

The decision support tools and datasets used and/or analysed during the OVIDIUS study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The Medical Ethics Review Committee of the Academic Medical Center, Amsterdam, reviewed and approved our trial protocol and written informed consent procedure. The trial is conducted according to the principles of the Declaration of Helsinki in the current version of Fortaleza, Brazil (2013) and in accordance with the Medical Research Involving Human Subjects Act. Principles of good clinical practice will be respected. Written informed consent will be signed by patients who are willing to participate in the OVIDIUS trial after they have received and read the trial information. Study participation is voluntary.

Consent for publication

The study protocol itself does not contain any individual person's data. Thus, consent for publication is not applicable.

References

1. Stacey D, Legare F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017;4:CD001431.

2. Oshima Lee E, Emanuel EJ. Shared decision-making to improve care and reduce costs. N Engl J Med. 2013;368:6–8.

3. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. BMJ. 2012;345:e6572.

4. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg. 2013;257:860–6.

5. Stiggelbout AM, Van der Weijden T, De Wit MP, Frosch D, Legare F, Montori VM, et al. Shared decision-making: really putting patients at the Centre of healthcare. BMJ. 2012;344:e256.

6. Ubbink DT, Koelemay MJW. Shared decision-making in vascular surgery. Why would you? Eur J Vasc Endovasc Surg. 2018;56:749–50.

7. Santema TB, Stubenrouch FE, Koelemay MJ, Vahl AC, Vermeulen CF, Visser MJ, et al. Shared decision-making in vascular surgery: an exploratory study. Eur J Vasc Endovasc Surg. 2016;51:587–93.

8. Knops AM, Ubbink DT, Legemate DA, de Haes JC, Goossens A. Information communicated with patients in decision-making about their abdominal aortic aneurysm. Eur J Vasc Endovasc Surg. 2010;39:708–13.

9. Ubbink DT, Knops AM, Molenaar S, Goossens A. Design and development of a decision aid to enhance shared decision-making by patients with an asymptomatic abdominal aortic aneurysm. Patient Prefer Adherence. 2008;2:315–22.

10. Mullan RJ, Montori VM, Shah ND, Christianson TJ, Bryant SC, Guyatt GH, et al. The diabetes mellitus medication choice decision aid: a randomized trial. Arch Intern Med. 2009;169:1560–8.

11. Elwyn G, Pickles T, Edwards A, Kinsey K, Brain K, Newcombe RG, et al. Supporting shared decision-making using an option grid for osteoarthritis of the knee in an interface musculoskeletal clinic: A stepped wedge trial. Patient Educ Couns. 2016;99:571–7.

12. Legare F, Labrecque M, Cauchon M, Castel J, Turcotte S, Grimshaw J. Training family physicians in shared decision-making to reduce the overuse of antibiotics in acute respiratory infections: a cluster randomized trial. CMAJ. 2012;184:e726–34.

13. Elwyn G, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, et al. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). PLoS One. 2009;4:e4605.

14. Chan AW, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:e7586.

15. Campbell MK, Piaggio G, Elbourne DR, Altman DG, Group C. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661.

16. Beusmans GHMI, Risseeuw NJ, Tjon-A-Tsien MRS, Verstappen WHJM, Burgers JS, Wiersma TJ, et al.: NHG-Standaard Beroerte. 2013. https://www.nhg.org/

standaarden/volledig/nhg-standaard-beroerte#note-27. Accessed 5 Jul 2017.

17. Knops AM, Goossens A, Ubbink DT, Balm R, Koelemay MJ, Vahl AC, et al. A decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm: a randomised clinical trial. Eur J Vasc Endovasc Surg. 2014;48:276–83.

18. The Ottawa Hospital Research Institute (OHRI): Patient Decision Aids. 2015.

https://decisionaid.ohri.ca/index.html. Accessed 24 Aug 2018.

19. Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand MA, et al. Option grids: shared decision-making made easier. Patient Educ Couns. 2013;90:207–12.

20. The Dartmouth Institute: Option Grid™ decision aids. 2017. http://

optiongrids.webfactional.com. Accessed 24 Aug 2018.

21. Mayo Clinic Shared Decision-making National Resource Center: Diabetes

medication choice. 2018. https://shareddecisions.mayoclinic.org/decision- aid-information/decision-aids-for-chronic-disease/diabetes-medicationmanagement/.

22. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision-making: multistage consultation process. BMJ. 2017;359:j4891.

23. Stubenrouch FE, Pieterse AH, Falkenberg R, Santema TK, Stiggelbout AM, van der Weijden T, et al. OPTION(5) versus OPTION(12) instruments to appreciate the extent to which healthcare providers involve patients in decision-making. Patient Educ Couns. 2016;99:1062–8.

24. Barr PJ, O'Malley AJ, Tsulukidze M, Gionfriddo MR, Montori V, Elwyn G. The psychometric properties of observer OPTION(5), an observer measure of shared decision-making. Patient Educ Couns. 2015;98:970–6.

25. O'Connor AM. Validation of a decisional conflict

scale. Med Decis Mak. 1995;15:1.

26. Ware J Jr, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996;34:220–33.

27. Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M. The 9-item shared decision-making questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient Educ Couns. 2010;80:94–9.

28. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. J Med Internet Res. 2014;16:e2.

29. Lavelle K, Sowerbutts AM, Bundred N, Pilling M, Degner L, Stockton C, et al. Is lack of surgery for older breast cancer patients in the UK explained by patient choice or poor health? A prospective cohort study. Br J Cancer. 2014;110:573–83.

30. Scholl I, Kriston L, Dirmaier J, Buchholz A, Harter M. Development and psychometric properties of the shared decision-making questionnaire-physician version (SDM-Q-doc). Patient Educ Couns. 2012;88:284–90.

31. Couet N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, et al. Assessments of the extent to which health-care providers involve patients in decision-making: a systematic review of studies using the OPTION instrument. Health Expect. 2015;18:542–61.

32. Woertman W, de Hoop E, Moerbeek M, Zuidema SU, Gerritsen DL, Teerenstra S. Stepped wedge designs could reduce the required sample size in cluster randomized trials. J Clin Epidemiol. 2013;66:752–8.

Supplementary materials

Supplementary table S1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*.

Section/item	Item No	Description	Page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	1-19
Protocol version	3	Date and version identifier	14
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1 & 20
	5b	Name and contact information for the trial sponsor	NA
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)	6
Methods: participants, interventions, and outcomes			
Study design	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists)	6-7

Section/item	Item No	Description	Page No
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)	7-10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
Participant timeline	13	Time schedule of enrolment, interventions (including any runins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10-11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11-12
Methods: assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interven-tions	12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a

Section/item	Item No	Description	Page No
Methods: data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-14
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	13-14
	20c	Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	NA
Methods: monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21a	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14

Section/item	Item No	Description	Page No
Consent or assent	26a	Who will obtain informed consent or assent from potential trial partici-pants or authorised surrogates, and how (see Item 32)	14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclo-sure of contractual agreements that limit such access for investigators	14-15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial partici-pation	15
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the pub-lic, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrange-ments), including any publication restrictions	15
	31b	Authorship eligibility guidelines and any intended use of professional writers	15
	31c	Plans, if any, for granting public access to the full protocol, partici-pant-level dataset, and statistical code	NA
Appendices			
Informed con-sent materials	32	Model consent form and other related documentation given to partici-pants and authorised surrogates	Omitted due to author instruc-tions
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

* It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elabo-ration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoD-erivs 3.0 Unported" license.

Chapter 10

Improving shared decision-making in vascular surgery by implementing decision support tools: a stepped-wedge cluster-randomised trial.

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Abstract

Objective

Different treatment options are available and feasible for various vascular surgical disorders. Hence, vascular surgery seems an area par excellence for shared decision-making (SDM), in which clinicians incorporate the patient's preferences into the final treatment decision. However, current SDM levels in vascular surgical outpatient clinics are below expectations. To improve this, different decision support tools (DSTs) have been developed: online patient decision aids, consultation cards, and decision cards.

Methods

This stepped wedge cluster randomised trial was conducted in 13 Dutch hospitals. Besides the developed DSTs, training on how to apply SDM during the clinician patient encounter was used in this study. Data were obtained via questionnaires and audio recordings. The primary outcome was the OPTION^5 score, an objective tool to assess the level of SDM, expressed as a percentage of exemplary performance. Main secondary outcomes were patients' disease specific knowledge, consultation duration, and treatment choice. Factors influencing OPTION^5-scores were studied using linear regression analysis.

Results

Included in the study were 342 patients with an abdominal aortic aneurysm (AAA; $n = 87$), intermittent claudication (IC; $n = 143$), or varicose veins (VV; $n = 112$). Audiotapes of 395 consultations were analysed. Overall, the mean OPTION^5 score significantly improved from 28.7% to 37.8% (mean difference 9.1%, 95% CI 6.5–11.8%) after implementation of the DSTs. Also, patient knowledge increased significantly (median increase: 13%, effect size: 0.13, $p = .025$). The number of patients choosing non-surgical treatment choices increased, with 21.4% to 28.8% for patients with AAA and doubled (16.0% to 32.0%) among patients with IC. For surgeons, the SDM training and for patients the decision aid significantly and independently increased OPTION^5 scores ($p < .001$ and $p = .047$, respectively).

Conclusion

Introducing DSTs improves the level of shared decision-making in vascular surgery, improves patient knowledge, and shifts their preference towards more non-surgical treatments. The SDM training for clinicians and the decision aid for patients appeared the most effective means of improving SDM

What this study adds

Decision-making support tools improved the level of shared decision-making (SDM) for three vascular diseases (abdominal aortic aneurysm, intermittent claudication, and varicose veins), as measured by the OPTION^5 instrument. For patients the online decision aid, and for clinicians the SDM training appear the most effective means of improving SDM. Improving SDM fosters the choice for less invasive and non-surgical treatments.

Introduction

Shared decision-making (SDM) is the approach in which clinicians and patients collaborate to choose the most suitable treatment option for the patient, taking the best available evidence into account[1]. Both clinicians and patients appear to gradually be welcoming SDM and want more patient involvement in the decision-making process[2].

SDM enhances a patient's satisfaction with the care process, improves their knowledge about their disease and treatment options, decreases anxiety, improves therapy adherence[3-5], and increases the number of patients who decide on less invasive treatment[6,7]. Besides these beneficial effects, there are also legal and ethical obligations to correctly inform patients about their disease and treatment options[8]. In addition, it is known that SDM has no harmful effects such as increased anxiety, decisional conflict, or poorer health outcomes[9,10].

SDM is particularly relevant in surgery as surgical interventions are irreversible and complications can be life changing[11]. In vascular surgery multiple treatment options with similar effectiveness, but different side effects, are available for various vascular diseases. In addition, treatment option preferences of patients with abdominal aortic aneurysm (AAA) vary widely[12]. Hence, vascular surgery seems an area par excellence in which patients' preferences should be incorporated in the final treatment decision[8].

Despite this evidence, SDM is not very common and patients are informed inconsistently about their disease and possible treatment options[13,14]. To help patients improve their disease specific knowledge, elicit their preferences, and help clinicians apply SDM, various decision-making support tools (DSTs) have been developed[10,15,16].

However, the mere availability of DSTs does not guarantee more SDM in the consultation room. In this trial the effectiveness and implementation of tools (decision cards, consultation cards, online patient decision aids, and SDM training) developed in vascular surgical practice to improve the level of SDM among vascular surgeons and their patients were evaluated.

Methods

Study design

The OVIDIUS (Operative Vascular Intervention Decision-making Improvement Using SDM tools) study, a stepped wedge cluster randomised trial, was conducted in the outpatient clinics of 13 Dutch hospitals. The study protocol of this trial was registered at www.trialregister.nl, NTR6487, and has been published previously[17]. Therefore, only the essentials of the study protocol are described here. This trial was reported along the CONSORT guidelines with an extension for stepped wedge cluster randomised trials[18].

The Medical Ethics Review Board of the Amsterdam University Medical Centres, location University of Amsterdam, and the local site investigators approved the protocol. All participants provided written informed consent.

Patients

Patients were eligible when visiting the outpatient clinics for their abdominal aortic aneurysm (AAA), varicose veins (VVs), carotid artery stenosis (CAS), or intermittent claudication (IC) and for whom more than one treatment option was possible (including the option not to treat). Patients had to be newly diagnosed with an asymptotic AAA (women: ≥ 5.0 cm, men: ≥ 5.5 cm). For patients with IC, CAS, and VVs (minimally) invasive treatments had to be considered.

Patients were excluded when requiring emergency surgery, younger than 18 years, having a life expectancy less than one year, having insufficient understanding of the Dutch language, cognitively unable to complete Dutch questionnaires, or diagnosed with American Association of Anesthesiologists (ASA)-IV.

Interventions

DSTs were developed for patients with AAA, IC, CAS, and VVs according to international standards[17,19], in co-creation with patient representatives and the Vascular Surgical Society[20]. For these patients, online patient decision aids, which they could use prior to the consultation, were developed that informed about the treatment options, elicited patient preferences, and tested the patient's knowledge. The consultation cards (*Table 1*) and decision cards (*Figure 1*) were developed for use by the clinician during the consultation, to support patient involvement. Furthermore, practical consultation trainings were deployed for this trial. In this three-hour SDM training, clinicians practised the typical communication steps in the SDM process[1] and the use of DSTs with a simulation patient led by an experienced medical psychologist.

All hospitals started with their regular way of consulting with their patients (control group). Every three months, two to three hospitals were allotted randomly to start applying the DSTs they had chosen to deploy (intervention group). The choice of the DSTs also depended on the preference of the individual clinicians. Patients were included consecutively and were unaware of group allocation.

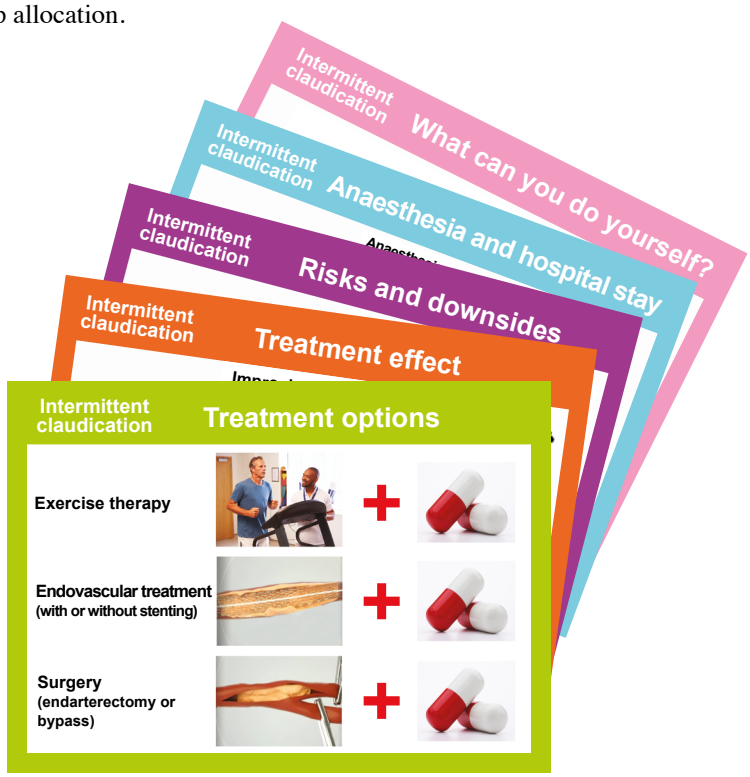

Figure 1. Decision cards for intermittent claudication developed for use by the clinician during the consultation, to support patient involvement.

Table 1. Consultation card for intermittent claudication to help the patient and clinician talk about how best to treat the patient's blocked or narrowed leg arteries.

Frequently asked questions	(Supervised) exercise therapy	Endovascular treatment (with or without stenting)	Surgery (Endarterectomy or bypass)
What does the treatment entail?	You will exercise on a treadmill (supervised by a physical therapist) to increase your overall and pain-free walking distance. You also receive weight training exercises to practice at home. You will also continue to take medication to prevent a heart attack or stroke.	A wire is inserted into the artery in your groin. Attached to this wire is a balloon. The balloon is inflated to reduce the narrowing. Sometimes, a tube is left behind to keep the artery open. You will also continue to take medication to prevent a heart attack or stroke.	- With an 'endarterectomy' the artery is opened and the narrowing surgically removed. - With a 'bypass' either one of your own veins or an artificial tube is used to bypass the narrowed artery. You will also continue to take medication to prevent a heart attack or stroke.
What are the benefits of this treatment?	Your general condition will improve due to exercise therapy. There are no treatment risks.	Your complaints will be less immediately after endovascular treatment.	Your complaints will be less immediately after surgery.
What are the main risks associated with the treatment?	You will not have an immediate effect of exercise therapy. It takes about 3 to 6 months before you experience improvement. Some patients will not be able to walk completely pain-free after exercise therapy.	Two years after endovascular treatment, the walking distance is about the same as after exercise therapy only.	You may suffer from a hematoma (bruise), a wound infection, or the surgery might even worsen your complaints.
What is the effect of the treatment?	After six months of exercise therapy, patients like yourself are able to walk twice as far as before the exercise therapy.	Two years after endovascular treatment, the walking distance is about the same as after exercise therapy only.	Two years after surgery, the walking distance is about the same as after exercise therapy only.
Will I receive anaesthesia?	No.	Yes; local anaesthesia.	Yes; general or local anaesthesia.
How long do I stay in the hospital?	No hospital stay.	Usually, 1 to 2 days.	Usually one week.
What is the risk of losing my leg (amputation)?	1 to 3 of 100 people (1-3%) with intermittent claudication have an amputation within 10 years.	1 to 3 of 100 people (1-3%) with intermittent claudication have an amputation within 10 years.	1 to 3 of 100 people (1-3%) with intermittent claudication have an amputation within 10 years.
What more should I need to know about intermittent claudication?	Exercise therapy does not prevent worsening of the disease. In case of insufficient results, endovascular treatment and surgery are still possible.	Endovascular treatment does not prevent worsening of the disease. Even if you have undergone this treatment, exercise therapy will remain helpful.	Surgery does not prevent worsening of the disease. Even if you have undergone surgery, exercise therapy will remain helpful.
What can I do myself?	The most important things you can do to prevent worsening of the disease is to quit smoking, take plenty of exercise, healthy food, and live a healthy life.	The most important things you can do to prevent worsening of the disease is to quit smoking, take plenty of exercise, healthy food, and live a healthy life.	The most important things you can do to prevent worsening of the disease is to quit smoking, take plenty of exercise, healthy food, and live a healthy life.

Data collection and outcome measures

Data were obtained via questionnaires, audio recordings of the consultations, and the decision aid's content management system.

The primary outcome measure was the level of SDM during the consultation, measured using the five item Observing patient involvement (OPTION) instrument[20] and scored by two observers independently. The five OPTION items are shown in Supplementary *Table S1*.

Secondary outcomes were factors influencing SDM level; SDM as perceived by patients (SDM-Q-9[21], CollaboRATE[22]) and by clinicians (SDM-Q-Doc[23]); the degree of desired patient involvement (CPS[24]); disease specific knowledge; treatment choice; consultation duration; decisional conflict (DCS[25]); and patient's quality of life (QoL; SF-12[26]).

Sample size

As described in the study protocol[17], a sample size of 113 patients for each disease was sufficient to detect an 11-point difference in OPTION-scores. This difference was considered clinically relevant based on the systematic review of Couët, where a mean increase of 11% (*SD*:14) in OPTION[5] score was found in nine studies after the implementation of DSTs[2]. During the trial it became clear that it was logistically impossible to inform patients with CAS about the study and introduce DSTs, due to the small time window between detection and treatment. Therefore, the sample size was adjusted to include only three vascular diseases (113 * 3 = 339 patients).

Statistical analysis

Differences in OPTION[5] scores and continuous secondary outcome measures between the control and intervention groups were analysed using the independent *T*-test or Mann-Whitney tests. Differences between repeated measures for QoL and decisional conflict were compared with the paired *t*-test or the Wilcoxon Matched-Pairs Test. Categorical variables were compared using the Chi-squared test.

The impact of the different tools on the level of SDM were investigated with a multivariable linear regression analysis. Variables with a $p < .10$ in the univariable analysis were included stepwise. Predictors were considered significant if $p < .050$. Consultation duration was not linear and therefore stratified into four categories: 0 = lowest – 10 minutes, 1 = 10–20 minutes, 2 = 20–30 minutes, 3 = 30 minutes – highest. The use of the decision aid was stratified into two categories: 'not used' (neither sent nor opened), or 'used' (opened or completed). The β coefficient shows the degree of change in the OPTION[5] score for every unit of change in the independent variable. The *R* squared of the regression models shows the proportion of the variation in outcome variable the model explained.

Results

The patient inclusion process is shown in *Figure 2*. Between January 2018 and February 2021, 342 patients were included, of which 44.2% in the control group and 55.8% in the intervention group. Of the initial 15 participating hospitals, two withdrew from the trial due to logistical limitations.

Table 2 shows patient characteristics for each disease. Baseline patient characteristics were similar between control and intervention groups. Mean age was 62 years (*SD* 13.3) in the control group and 65 years (*SD* 12.9) in the intervention group. Education levels did

not significantly differ between both groups (p = .83). In the control group 3.6% and in the intervention group 6.6% of the patients marked their ethnicity as non-Dutch. Median AAA-diameter was 5.7 cm (interquartile range [IQR] 5.5, 6.2) and did not differ between the two groups.

Table 2. Characteristics of 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), and varicose veins (VVs) analysed for 395 clinician-patient consultations for shared decision-making.

	AAA (n = 87)	IC (n = 143)	VV (n = 112)	Total (n = 342)
Age – y	73 ± 6.8	67 ± 8.6	52 ± 13.2	66 (56, 73)
Female sex	14 (16)	39 (27)	84 (75)	137 (40)
Education level				
Primary education	19 (24)	22 (17)	1 (1)	42 (13)
Secondary education	42 (52)	79 (59)	68 (62)	189 (59)
Higher education	19 (24)	32 (24)	40 (37)	91 (28)
Marital status				
Single	29 (36)	47 (35)	14 (13)	90 (28)
Living together	51 (64)	87 (65)	95 (87)	233 (72)
Ethnicity				
Dutch	78 (98)	125 (94)	102 (93)	305 (95)
Non-Dutch*	2 (2)	8 (6)	7 (7)	17 (5)

Data are presented as mean ± standard deviation, median (interquartile range), or n (%). * Surinamese, Indonesian, Dutch Antillean/Aruban, Turkish, and other ethnicities who sufficiently understood the Dutch language.

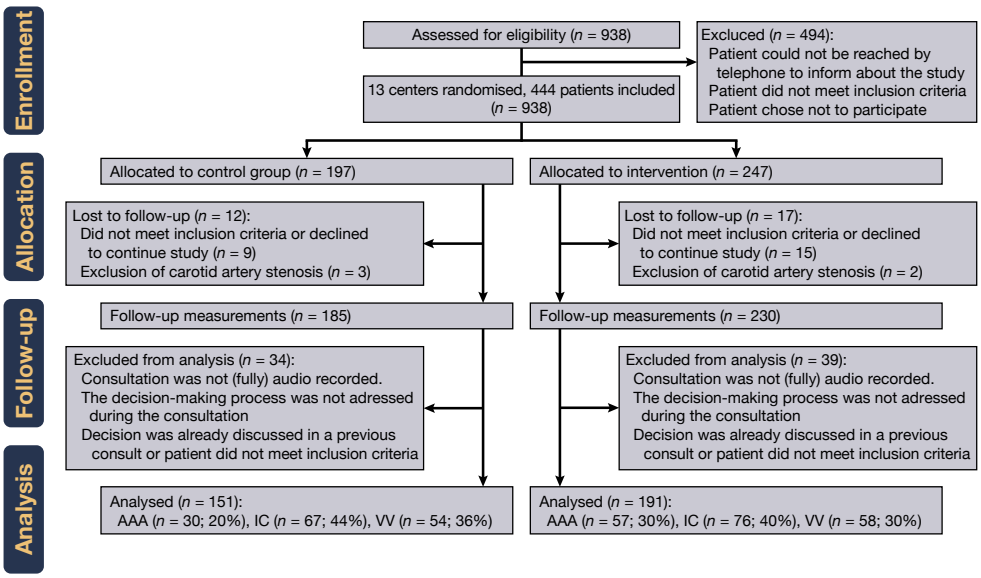

Figure 2. Flow diagram of patient enrollment with abdominal aortic aneurysm (AAA), intermittent claudication (IC), and varicose veins (VVs) to study the effect of decision-making support tools (DSTs) on the level of shared decision-making.

Implementation process

The online decision aid had been sent to 80% of the patients in the intervention group, as 20% did not have an email address and was not able to receive it electronically. They were predominantly patients with AAA (55%) or IC patients (33%), older (76 years *vs*. 66 years), and lower educated (26% *vs*. 10%).

Of the patients who received the decision aid, 70% had actually used it, of which 59% completely finished it by answering all questions. In general, patients who actually used the online decision aid were better educated (33% *vs*. 19%).

Decision cards were used during 29.5% of the consultations, mostly for patients with AAA: AAA: 48% *vs*. CI 21% and VV 31%.

Clinicians in six of the 13 contributing hospitals had followed the SDM-training. Consequently, 71% of the consultations analysed were performed by a trained clinician. The remaining hospitals mentioned a lack of time and financial reasons for not being trained.

Primary outcome: OPTION[5] scores

After scoring the first 10 audio recordings using the OPTION[5] instrument, the raters reached a $\varkappa$ value of 0.82 (95% CI 0.63–1.00). An unweighted Cohen's kappa ($\varkappa$) between 0.6 and 0.8 is considered as good interobserver agreement[27].

Table 3 shows the OPTION scores for the control and intervention groups for each disease. Overall, the mean OPTION-score after implementation of the DSTs was significantly higher (37.8%, *SD* 12.4) than before (28.7%, *SD* 12.4); mean difference 9.1%, 95% CI 6.5–11.8% ($p < .001$). This increase in OPTION scores was observed for each of the three diseases, being statistically significant ($p < .001$) for patients with IC and VVs. Of the five OPTION items, item 2 ("offering help") scored lowest and item 3 ("explaining the options") the highest, while "preference elicitation" (item 4) showed the largest improvement (*Supplementary Figure S1* and *Supplementary Table S2*).

Secondary outcomes

Factors influencing the level of SDM

Significant independent factors influencing the OPTION[5] score were the DST intervention, consultation duration, type of disease and type of hospital (*Table 4*). Access to the DSTs, longer consultation duration (especially, > 30 minutes), having an AAA (vs. IC and VVs), and consultations in general hospitals (vs. university clinics) led to higher OPTION[5] scores. β values indicated that for instance consultations with patients with IC and patients with VV scored, respectively, 10.3 and 10.7 (of 100 points) lower OPTION[5] scores than patients with AAA.

Another model (*Table 5*) shows the separate effects of the various DSTs and hospitals. Both the SDM training and the decision aid significantly improved SDM. Consultations with clinicians who had attended the SDM training, scored 8.1 (of 100 points) higher OPTION[5] score than consultations without prior training. In addition, consultations scored 3.16 (of 100 points) higher when patients had used the decision aid. The influence of the decision cards did not reach statistical significance.

Table 3. The five item Observing patient involvement (OPTION[5]) scores in 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), and varicose veins (VVs) analysed for 395 clinician-patients consultationsfor shared decision-making.

	Control group		Intervention group		Mean difference in OPTION[5] score (95% CI)	*p* value
Patient group	**Patients**	**OPTION[5] score**	**Patients**	**OPTION[5] score**		
Total	151	28.7 ± 12.4	191	37.8 ± 12.4	9.1 (6.5–11.8)	<.001
AAA	30	41.0 ± 12.9	57	44.3 ± 13.97	3.3 (-2.8–9.4)	.29
IC	67	24.5 ± 10.6	76	33.8 ± 10.6	9.3 (5.8–12.8)	<.001
VV	54	27.0 ± 9.6	58	36.7 ± 10.2	9.7 (6.0–13.4)	<.001

Data are presented as *n* or as mean ± standard deviation, unless stated otherwise.

Table 4. Factors associated with five item Observing patient involvement (OPTION[5]) scores in 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), and varicose veins (VVs) analysed for 395 clinician-patient consultations.

Independent variable	β*	95% CI	*p* value
(Constant)	36.9	32.9 to 41.0	
IC patients	-10.3	-13.5 to -6.97	<.001
VV patients	-10.7	-14.2 to -7.21	<.001
Group, control *vs*. intervention	7.67	5.17 to 10.2	<.001
Type of hospital†	-4.35	-7.52 to -1.18	.007
Duration of consultation‡			
10–20 min	1.87	-1.17 to 4.91	.23
>20–30 min	3.13	-0.90 to 7.15	.13
>30 min	7.22	2.23 to 12.2	.005

Variables with a $p < .10$ in the univariable analysis were included stepwise. Predictors were considered significant if $p < .050$. This model was corrected for age, gender, education level, number of participants during the consultation, number of consultations per patient, and ethnicity. *R* square = 0.30. Dependent variable = OPTION[5] scores.

* β coefficient. The degree of change in the OPTION[5] score for every 1 unit of change in the independent variable.

† Categories: 0 = general hospital, 1 = university hospital.

‡ Reference: 0–10 min.

Table 5. Association between the use of seperate decision-making support tools (DSTs) and five item Observing patient involvement (OPTION[5]) scores in a study population of 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication, or varicose veins, analysed for 395 clinician-patient consultations.

Independent variable	β*	95% CI	*p* value
(Constant)	21.9	18.6 to 25.1	
Online decision aid †	3.16	0.038 to 6.29	.047
SDM training	8.07	4.46 to 11.7	<.001
AAA patiens	12.4	8.97 to 15.8	<.001
Contributing hospitals‡			
Hospital 1 (academic)	1.76	-2.92 to 6.43	.46
Hospital 2 (general)	1.89	-20.2 to 24.0	.87
Hospital 3 (general)	11.0	5.47 to 16.4	<.001
Hospital 4 (general)	14.2	3.85 to 24.5	.007
Hospital 5 (general)	2.41	-2.87 to 7.68	.37
Hospital 6 (general)	8.66	4.27 to 13.0	<.001
Hospital 7 (general)	0.98	-6.73 to 8.70	.80
Hospital 8 (academic)	4.66	-1.69 to 11.0	.15
Hospital 10 (general)	7.49	2.96 to 12.0	.001
Hospital 11 (general)	1.88	-6.46 to 10.2	.66
Hospital 12 (general)	3.71	-3.10 to 10.5	.28
Hospital 13 (general	9.38	-1.96 to 20.7	.11

Variables with a $p < .10$ in the univariable analysis were included stepwise. Predictors were considered significant if $p < .05$. This model was corrected for the type of condition and the contributing hospitals (both shown in table) and additionallye for age, gender, education level, number of participants during the consultation, number of consultations per patient, and ethnicity. *R* square = 0.33. Dependent variable = OPTION[5] scores.

* β coefficient. The degree of change in the OPTION[5] score for every unit of change in the independent variable.

† Categories: 0 = not used/not sent, 1 = used/completed.

‡ Reference: hospital 9 (academic).

SDM-Q-9, CollaboRATE and SDM-Q-Doc scores

The perceived level of SDM by patients (SDM-Q9 and CollaboRATE) and clinicians (SDM-QDoc) is shown in *Supplementary Table S3*. No significant differences were found for SDM-Q9 and CollaboRATE scores between the control and intervention groups.

Only the median SDM-Q-Doc score among clinicians was significantly higher in the intervention group (80.0%; IQR 71.1%, 86.7%, 4.5% top score) compared with the control group (73.3%: IQR 64.4%, 84.4%, 2.8% top score).

Control preferences scale and control perception scale

Control preferences scores for patients (before the consultation) and the control perception scores for patients and clinicians (after the consultation) are shown in *Supplementary Figure S2A–C*. Significantly (p = .006) more patients stated "I prefer to make the final selection of my treatment after seriously considering my doctor's opinion" in the intervention group (20.8%) than in the control group (12.1%). The control perception scores did not differ significantly after the implementation of DSTs.

Patient knowledge

Patient knowledge scores are shown in *Supplementary Table S4*. Knowledge scores were significantly higher after introduction of the DSTs (median difference 13.3%, effect size 0.13, p = .025). Patients with AAA and IC in the intervention group who had completed the online decision aid before receiving information from their clinician had a significantly higher knowledge score about their disease and treatment options before the consultation (AAA median difference 40%, effect size: 0.42, p = .003; IC median difference 20%, effect size 0.30, p = .006) than patients in the control group after the consultation, who only received information from their clinician.

Treatment choice

In the intervention group, 81% of the patients made the decision during the first consultation vs. 84% in the control group.

Patients with AAA and IC more often preferred non-surgical treatment options when DSTs were used. The percentage of AAA patients who chose conservative treatment increased significantly from 7.4% to 28.8% (difference 21.4%, 95% CI 5.6 to 37.2). The percentage of endovascular aneurysm repair and open repair decreased, but not significantly, from 59% to 52% (difference -7.0%, 95% CI -28.3 to 15.3) and from 26% to 17% (difference -8.6%, 95% CI -28.4 to 10.4), respectively.

IC patients showed similar results: preferences for percutaneous transluminal angioplasty treatment significantly decreased from 70% to 47% (difference -24%, 95% CI -38.3 to -7.2) in the group that had access to the DSTs. On the other hand, preferences for continued supervised exercise training and conservative treatment increased significantly from 16% to 32% (difference 16%, 95% CI 2.0 to 29.5) and (not significantly) from 8% to 17% (difference 9%, 95% CI -2.0 to 20.6), respectively.

No significant differences were observed in treatment choices for patients with VVs before and after the intervention.

Duration of consultations

Median consultation duration in the control group was 12:30 (minutes:seconds; IQR 08:55, 17:18) and in the intervention group 16:30 (IQR 11:15, 22:17; difference: 04:00, $p < .001$). Generally, consultations for patients with AAA were longer than for patients with IC and VVs (*Supplementary Table S5*).

Decisional conflict scale and quality of life

Median Decisional Conflict score (*Supplementary Table S6*) and quality of life scores (*Supplementary Table S7*) did not change significantly after implementation of DSTs.

Discussion

This multicentre stepped wedge trial shows that the application of DSTs in vascular surgery promotes patient involvement in the decision-making process for their vascular disease. Of the four intervention tools offered, the SDM training for clinicians and the decision aid for patients most effectively enhanced SDM. As a result of using these DSTs, patients were more knowledgeable about their disease and treatment options and less often chose invasive treatment options, without any adverse effects in terms of a higher decisional conflict or reduced QoL.

The 9% increase in OPTION[5] score found here reached statistical significance, even though an 11% difference was required according to the sample size calculation, probably due to the inclusion of slightly more patients and the smaller standard deviation observed around the mean difference. The OPTION[5] score of 37.8% found after the implementation of DSTs is slightly better than reported in a systematic review for similar studies[2], showing a mean of 34%. The baseline scores were also higher than in this review, especially among patients with AAA, suggesting that SDM is already better applied for this disease. Even so the level of SDM also increased in these patients, although not significantly, after implementing the DSTs.

The clinical relevance of the finding is a change from a "minimal" to a "moderate" effort to involve patients in two of five aspects of the decision-making process. Supporting treatment choice deliberation needs special effort. Clinicians can attain a "skilled effort" level by ensuring patients get more information about the relevant options and by working together with the patient to consider those options. Incorporating SDM in the guidelines for vascular (surgical) diseases will probably motivate clinicians to put more effort into involving patients in the decision-making process. However, only the recently revised European Society for Vascular Surgery guidelines for chronic venous disease of the lower limbs explicitly encourage SDM[28]. Therefore SDM should be included in future revised guidelines for AAA and peripheral arterial diseases as well[29,30].

For clinicians, a single, three hour SDM training session was the most effective intervention. Multiple studies have indeed recommended SDM training as it improves SDM behaviour and can positively change clinician's attitudes towards SDM in a wide range of specialties[31-33]. For patients, the online decision aid most effectively stimulates the patients to get involved in the decision-making process, leading to more knowledge about their disease and possible treatment options. Also, patients preferred a more dominant role in the decision-making process after receiving the decision aid, which was confirmed by clinicians. For this reason, how to continue with these DSTs in routine clinical practice was discussed with contributing

hospitals after the trial was completed and the tools are available for free.

Overall, the DSTs were well received and used, except for the consultation cards. Probably due to the large amount of text and lack of visuals, which may be less appealing to use during the consultation. The use of the decision aid depended on whether the patient had an email address, which was more likely among the younger patients with VVs than among more elderly patients with AAA. Hence, a paper version for use at home or the presence of a digital device at the outpatient clinic to present the decision aid is recommended.

In concordance with previous research within surgery, patients more often chose non-surgical treatment options after the intervention[6,34]. This also implies that application of SDM could prevent overtreatment and reduce healthcare costs[4]. Decision aids possibly better enable patients to weigh the pros and cons of the different treatment options and prefer QoL over the risks associated with surgical interventions. Patients with IC, in particular, more often chose continued supervised exercise training. This suggests that applying SDM may also lead to better adherence to current guidelines, which primarily advise conservative treatment for IC.

Finally, longer consultation duration was found to be associated with higher OPTION[5] scores. However, studies also suggest that SDM, or application of DSTs, does not increase consultation duration and may save time in the long term[35]. In addition, nearly twice as many patients with AAA were included in the intervention group, which could explain the observed longer consultation duration.

Study strengths and limitations

The strength of this trial is the stepped wedge cluster randomised trial design, which corrects for the potential influence of other interventions and changes in treatment modalities throughout the trial period.

On the other hand, some limitations should be highlighted. First, the three types of diseases with different severity and patient characteristics in the trial could have affected the overall OPTION[5] scores. However, this trial mainly addressed the principle of SDM and clinician behaviour, independent of the different diseases. Moreover, the sample size was sufficient to detect differences in each disease separately.

Second, several intervention tools were studied, not all of which were used by every hospital or even by individual clinicians. This could have obscured the effects that were found for the separate interventions. However, to facilitate implementation of the tools, a pragmatic choice was made to leave it to the discretion of the hospitals which combination of tools they saw fit to implement. Nevertheless, the impact of the individual tools could still be investigated through multivariable regression analysis.

Third, clinicians were probably aware of the study design, which could have affected their behaviour and SDM-Q-Doc-scores, even before applying the DSTs. In addition, performance bias might occur by knowing that their consultation was audiotaped. However, research shows that clinicians quickly return to their habits[36]. Similarly, participating clinicians may have been inclined towards SDM in the first place. However, this did not seem to lead to an overestimation of the level of SDM, as the results still show ample room for improvement.

Fourth, in two hospitals the diagnosis was immediately followed by a treatment choice, which precluded the deployment of a decision aid. This also was true for patients with CAS, as they were often seen in a semi-acute setting instead of the outpatient clinic.

Conclusion

Introducing DSTs promotes SDM between vascular surgical patients and clinicians, improves patient knowledge, and increases the choice for non-surgical treatment. In particular, the SDM training for clinicians and the online decision aid for patients appear effective means for promoting SDM. However, there is still room for improvement. More awareness of the concept of SDM and better use of the tools are necessary for successful implementation.

Conflict of interest statement and funding

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Data availability statement

The data of this study are available upon request.

References

1. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision-making: multistage consultation process. bmj. 2017;359:j4891.

2. Couët N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, et al. Assessments of the extent to which health-care providers involve patients in decision-making: a systematic review of studies using the OPTION instrument. Health Expectations. 2015;18:542-61.

3. Stacey D, Hill S, McCaffery K, Boland L, Lewis KB, Horvat L. Shared decision-making interventions: theoretical and empirical evidence with implications for health literacy. Stud Health Technol Inform. 2017;240:263-83.

4. Oshima Lee E, Emanuel E. Shared decision-making to improve care and reduce costs. The New England journal of medicine. 2013;368:6-8.

5. Bekker HL, Hewison J, Thornton JG. Understanding why decision aids work: linking process with outcome. Patient education and counseling. 2003;50:323-9.

6. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Annals of surgery. 2013;257:860-6.

7. Stiggelbout AM, Van der Weijden T, De Wit MP, Frosch D, Légaré F, Montori VM, et al. Shared decision-making: really putting patients at the centre of healthcare. Bmj. 2012;344:e256.

8. Ubbink DT, Koelemay MJ. Shared Decision-making in Vascular Surgery. Why Would You? Eur J Vasc Endovasc Surg. 2018;56:749-50.

9. Knops A, Goossens A, Ubbink D, Balm R, Koelemay M, Vahl A, et al. A decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm: a randomised clinical trial. European Journal of Vascular and Endovascular Surgery. 2014;48:276-83.

10. Elwyn G, Pickles T, Edwards A, Kinsey K, Brain K, Newcombe RG, et al. Supporting shared decision-making using an Option Grid for osteoarthritis of the knee in an interface musculoskeletal clinic: A stepped wedge trial. Patient Education and Counseling. 2016;99:571-7.

11. De Mik S, Stubenrouch F, Balm R, Ubbink D. Systematic review of shared decision-making in surgery. Journal of British Surgery. 2018;105:1721-30.

12. Faggioli G, Scalone L, Mantovani L, Borghetti F, Stella A, Group PS. Preferences of patients, their family caregivers and vascular surgeons in the choice of abdominal aortic aneurysms treatment options: the PREFER study. Eur J Vasc Endovasc Surg. 2011;42:26-34.

13. Santema T, Stubenrouch F, Koelemay M, Vahl A, Vermeulen C, Visser M, et al. Shared decision-making in vascular surgery: an exploratory study. European Journal of Vascular and Endovascular Surgery. 2016;51:587-93.

14. Knops A, Ubbink D, Legemate D, de Haes J, Goossens A. Information communicated with patients in decision-making about their abdominal aortic aneurysm. European Journal of Vascular and Endovascular Surgery. 2010;39:708-13.

15. Ubbink DT, Knops AM, Molenaar S, Goossens A. Design and development of a decision aid to enhance shared decision-making by patients with an asymptomatic abdominal aortic aneurysm. Patient preference and adherence. 2008;2:315.

16. Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand M-A, et al. Option Grids: shared decision-making made easier. Patient education and counseling. 2013;90:207-12.

17. de Mik S, Stubenrouch F, Legemate D, Balm R, Ubbink D. Improving shared decision-making in vascular surgery by implementing decision support tools: study protocol for the stepped-wedge cluster-randomised OVIDIUS trial. BMC medical informatics and decision-making. 2020;20:1-10.

18. Hemming K, Taljaard M, McKenzie JE, Hooper R, Copas A, Thompson JA, et al. Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. BMJ. 2018;363:k1614.

19. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards AG, Coulter A, et al. International Patient Decision Aids Standards (IPDAS) Collaboration. Developing a quality criteria framework for patient decision aid: online international Delphi consensus process. British Medical Journal. 2006;333:417-9.

20. Stubenrouch FE, Pieterse AH, Falkenberg R, Santema TKB, Stiggelbout AM, van der Weijden T, et al. OPTION5 versus OPTION12 instruments to appreciate the extent to which healthcare providers involve patients in decision-making. Patient education and counseling. 2016;99:1062-8.

21. Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. The 9-item Shared Decision-making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient education and counseling. 2010;80:94-9.

22. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. Journal of medical Internet research. 2014;16:e3085.

23. Scholl I, Kriston L, Dirmaier J, Buchholz A, Härter M. Development and psychometric properties of the Shared Decision-making Questionnaire–physician version (SDM-Q-Doc). Patient education and counseling. 2012;88:284-90.

24. Degner LF, Sloan JA, Venkatesh P. The control preferences scale. Canadian Journal of Nursing Research Archive. 1997:21-44.

25. O'Connor AM. Validation of a decisional conflict scale. Medical decision-making. 1995;15:25-30.

26. Ware Jr JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical care. 1996:220-33.

27. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977:159-74.

28. De Maeseneer MG, Kakkos SK, Aherne T, Baekgaard N, Black S, Blomgren L, et al. European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. European Journal of Vascular and Endovascular Surgery. 2022;63:184-267.

29. Wanhainen A, Verzini F, Van Herzeele I, Allaire E, Bown M, Cohnert T, et al. Editor's choice–European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. European Journal of Vascular and Endovascular Surgery. 2019;57:8-93.

30. Halliday A, Bax JJ. The 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European Society for Vascular Surgery (ESVS). European journal of vascular and endovascular surgery. 2018;55:301-2.

31. Geiger F, Liethmann K, Reitz D, Galalae R, Kasper J. Efficacy of the doktormitSDM training module in supporting shared decision-making– Results from a multicenter double-blind randomized controlled trial. Patient education and counseling. 2017;100:2331-8.

32. Henselmans I, van Laarhoven HW, de Haes HC, Tokat M, Engelhardt EG, van Maarschalkerweerd PE, et al. Training for medical oncologists on shared decision-making about palliative chemotherapy: A randomized controlled trial. The oncologist. 2019;24:259.

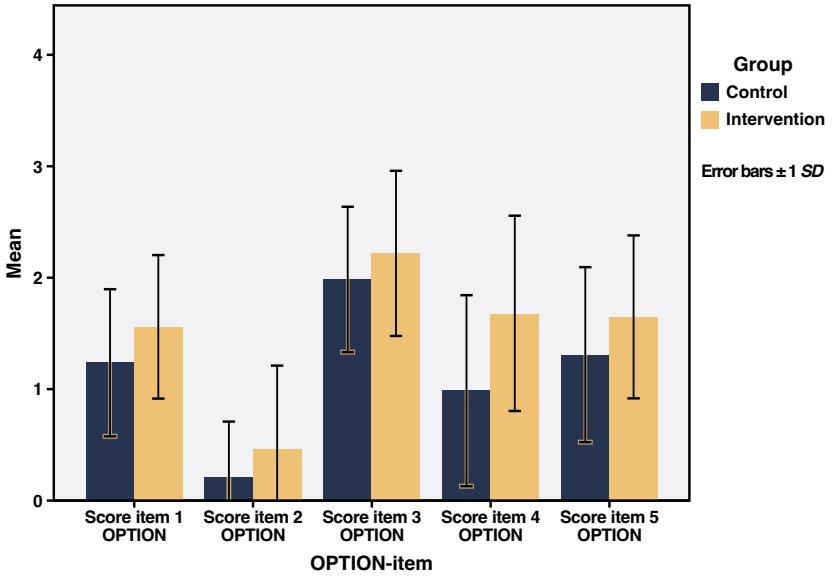
33. Légaré F, Stacey D, Turcotte S, Cossi MJ, Kryworuchko J, Graham ID, et al. Interventions for improving the adoption of shared decision-making by healthcare professionals. Cochrane database of systematic reviews. 2014;9:CD006732.

34. Arterburn D, Wellman R, Westbrook E, Rutter C, Ross T, McCulloch D, et al. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. Health Affairs. 2012;31:2094-104.

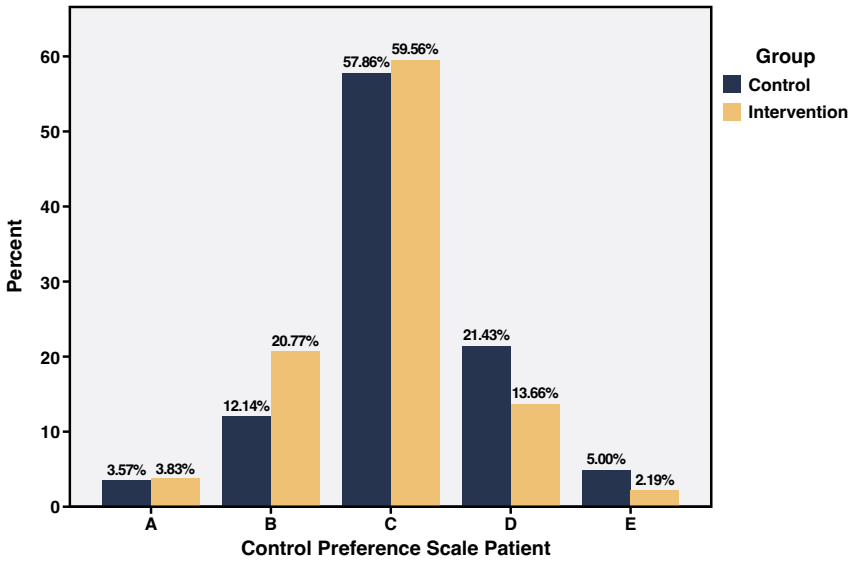
35. Scalia P, Durand M-A, Berkowitz JL, Ramesh NP, Faber MJ, Kremer JA, et al. The impact and utility of encounter patient decision aids: systematic review, meta-analysis and narrative synthesis. Patient education and counseling. 2019;102:817-41.

36. Coleman T. Using video-recorded consultations for research in primary care: advantages and limitations. Family practice. 2000;17:422-7.

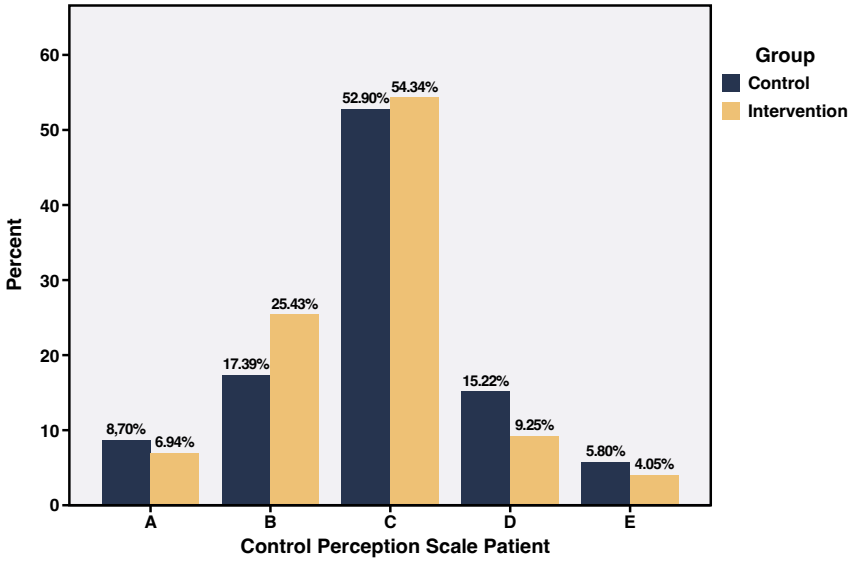
Supplementary materials



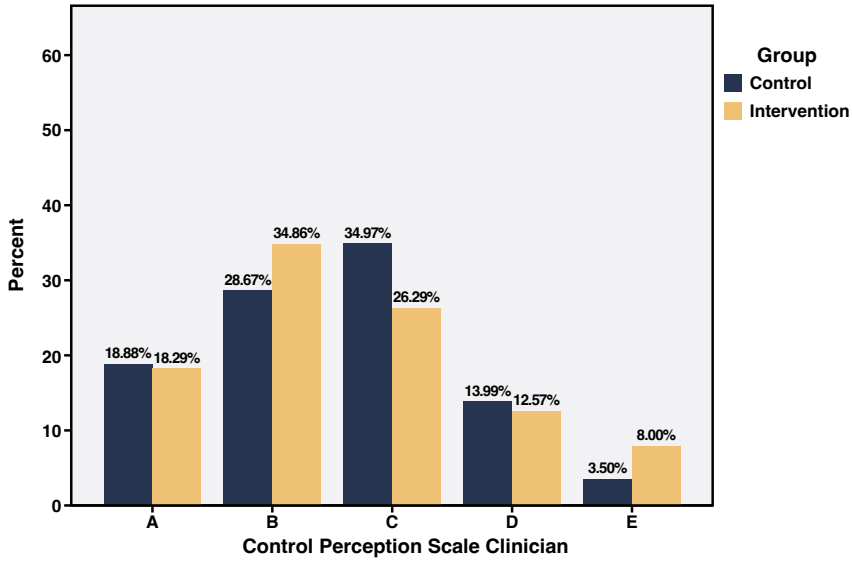
Supplementary Figure S1. OPTION-score per item.
Mean SDM scores per item are presented as bars. Each item is scored between 0 (no effort) and 4 (exemplary effort).
Item 1: Option talk: alternate options; item 2: Team Talk: support deliberation / forming a partnership; item 3: Option Talk: information about options; item 4: Decision Talk: eliciting preferences; item 5: Decision Talk: integrating preferences.



Supplementary Figure S2A. Control Preference Scale Patients.
A: I prefer to make the final decision about what treatment I will receive;
B: I prefer to make the final selection of my treatment after seriously considering my doctor's opinion;
C: I prefer that my doctor and I share responsibility for deciding which treatment is best for me;
D: I prefer that my doctor makes the final decision about which treatment will be used, but considering my opinion;
E: I prefer to leave all decisions regarding my treatment to my doctor.



Supplementary Figure S2B. Control Perception Scale Patients.
A: I made the final decision about what treatment I will receive;
B: I made the final selection of my treatment after I seriously considered my doctor's opinion;
C: I shared the responsibility with my doctor for deciding which treatment is best for me;
D: My doctor made the final decision about which treatment will be used, but considered my opinion;
E: I left all decisions regarding my treatment to my doctor.



Supplementary Figure S2C. Control Perception Scale Clinicians.
A: The patient has made the final treatment decision himself;
B: The patient has made the final treatment decision himself, after first thinking carefully about my advice;
C: I have shared responsibility with the patient in choosing the right treatment;
D: I made the final treatment decision myself, taking the patient's preferences into account in the decision;
E: I have made the final treatment choice myself.

Supplementary Table S1. The observer OPTION[5] measure.

Item 1	For the health issue being discussed, the clinician draws attention to or confirms that alternate treatment or management options exist or that the need for a decision exists. If the patient rather than the clinician draws attention to the availability of options, the clinician responds by agreeing that the options need deliberation.
Item 2	The clinician reassures the patient or re-affirms that the clinician will support the patient to become informed or deliberate about the options. If the patient states that they have sought or obtained information prior to the encounter, the clinician supports such a deliberation process.
Item 3	The clinician gives information or checks understanding about the options that are considered reasonable (this can include taking no action), to support the patient in comparing alternatives. If the patient requests clarification, the clinician supports the process.
Item 4	The clinician makes an effort to elicit the patient's preferences in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive.
Item 5	The clinician makes an effort to integrate the patient's elicited preferences as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician makes an effort to do so.
	0 = No effort 1 = Minimal effort 2 = Moderate effort 3 = Skilled effort 4 = Exemplary effort
	Total Score 0-20 Rescale 0-100

Supplementary Table S2. The observer OPTION[5] measure.

OPTION[5] item	Control	Intervention	Mean difference (95% CI), *p*-value
Item 1	1.2	1.6	0.3 (0.18, 0.46), < .001
Item 2	0.2	0.5	0.3 (0.12, 0.38), < .001
Item 3	2.0	2.2	0.2 (0.08, 0.38), .002
Item 4	1.0	1.7	0.7 (0.51, 0.88), < .001
Item 5	1.3	1.7	0.3 (0.18. 0.50), < .001

Each item is scored between 0 (no effort) and 4 (exemplary effort). Item 1: Option talk: alternate options; item 2: Team Talk: support deliberation / forming a partnership; item 3: Option Talk: information about options; item 4: Decision Talk: eliciting preferences; item 5: Decision Talk: integrating preferences.

Supplementary Table S3. Subjective involvement measures (SDM-Q-9, SDM-Q-Doc, CollaboRATE) in the control and intervention group.

	Control	Intervention	
	Median, IQR, top score	Median ICR, top score	*P*-value, 95% CI
SDM-Q-9 (*n* = 138, 171)	93.3% (79.4%, 100%), 31.2%	93.3% (82.2%, 100%), 27.2%	.71
CollaboRATE (*n* = 137, 171)	86.7% (80.0%, 90.0%), 6.6%	83.3% (80.0%, 90.0%), 7.5%	.61
SDM-Q-Doc (*n* = 143, 175)	73.3% (64.4%, 84.4%), 4.5%	80.0% (71.1%, 86.7%), 2.8%	.002

Supplementary Table S4. Patient knowledge in the control and intervention group per condition

	Control (N = 138) Median % (IQR)	Intervention (N = 173) Median % (IQR)	P-value
AAA patients (median %, IQR) $N_{control}$ = 27, $N_{intervention}$ = 49	60.0 (60.0-80.0)	80.0% (60.0-80.0)	.39
IC patients (median %, IQR) $N_{control}$ = 61, $N_{intervention}$ = 71	80.0 (60.0-100.0)	80.0 (80.0-100.0)	.15
VV patients (median %, IQR) $N_{control}$ = 50, $N_{intervention}$ = 53	50.0 (33.0-66.7)	66.7 (50.0-66.7)	.025
Total score	66.7 (50.0-80.0)	80.0 (60.0-91.7)	.025

AAA = abdominal aortic aneurysm; IC = intermittent claudication, VV = varicose veins.

Supplementary Table S5. Duration of consultations in the control and intervention group per condition.

	Control (N = 151) Median (IQR)	Intervention (N = 191) Median (IQR)	P-value
AAA $N_{control}$ = 30, $N_{intervention}$ = 57	17:40 (14:18, 25:40)	21:24 (14:22, 29:50)	.28
IC $N_{control}$ = 67, $N_{intervention}$ = 76	10:29 (08:30, 14:09)	14:43 (08:52, 20:04)	.009
VV $N_{control}$ = 54, $N_{intervention}$ = 58	11:31 (08:11, 17:13)	16:08 (11:15, 21:44)	.001
Total	12:30 (08:55-17:18)	16:30 (11:15-22:17)	< .001

AAA = abdominal aortic aneurysm; IC = intermittent claudication, VV = varicose veins. Duration in min:sec.

Supplementary Table S6. Decisional Conflict Scale scores in the control and intervention group directly and 2-4 weeks after the consultation.

	Directly after consultation Median (IQR)			After 2-4 weeks Median (IQR)		
	Control (n = 138)	Intervention (n = 171)	P-value	Control (n = 98)	Intervention (n = 145)	P-value
Total score	13.3 (0.0, 26.6)	14.1 (1.6, 26.6)	.058	20.3 (6.3, 26.6)	23.4 (10.9, 29.7)	.072

Supplementary Table S7. Quality of Life in the control and intervention group directly and 6 weeks after the consultation.

	Directly after consultation Median (IQR)			After 6 weeks Median (IQR)		
	Control (n = 138)	Intervention (n = 174)	P-value	Control (n = 98)	Intervention (n = 145)	P-value
Mental QoL	52.7 (41.8, 57.6)	54.6 (45.3, 58.6)	.064	52.5 (43.4, 56.0)	52.3 (44.8, 57.0)	.81
Physical QoL	35.1 (27.3, 48.2)	38.6 (27.9, 49.4)	.67	45.6 (33.9, 53.5)	44.0 (34.3, 51.0)	.54

Chapter 11

Predictors of the level of shared decision-making in vascular surgery: a cross sectional study.

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Abstract

Objective

Although patients with vascular diseases often face multiple treatment options with different risks and benefits, the application of shared decision-making (SDM) remains low. In SDM, clinicians and their patients work together to decide upon the treatment option that best fits the patient's situation and preference. This study aimed to reveal predictors of the extent to which the SDM process occurs in vascular surgery.

Methods

This was a cross sectional cohort substudy of the OVIDIUS trial, a multicentre, randomised, stepped wedge trial on the effect of implementing SDM supporting tools. The data of outpatients visiting university and general hospitals and suffering from abdominal aortic aneurysms (AAAs), intermittent claudication (IC), or varicose veins (VV) were used. Consultations were audio recorded. SDM levels were scored independently by two evaluators, using the OPTION[5] instrument, on a scale from 0% (no SDM effort) to 100% (exemplary SDM effort). Possible associations between the OPTION[5] scores and patient, clinician, and consultation characteristics were investigated using multivariable linear regression analysis.

Results

Of the 342 patients included (AAA, n = 87; VV, n = 143; IC, n = 112), 60% were male and mean age was 64 years. Overall, the SDM score was relatively low; mean ± *SD* 33.8% ± 13.2%, mainly due to insufficient support for the patient in deliberating their options. Regression analysis showed that the mean SDM scores in consultation with patients with IC and patients with VV were -9.9 (95% confidence interval [CI] -13.2 – -6.5; $p < .001$) and -12.7 (95% CI -17.3 – -8.0; $p < .001$) points lower than in patients with AAA, respectively. Consultations by a resident in training or nurse practitioner resulted in a -8.6 (95% CI -13.1 – -4.0; $p < .001$) and -4.2 (95% CI -7.9 – -0.42; $p = .029$) point lower SDM score than by a surgeon, respectively. A consultation longer than 30 minutes resulted in a 5.8 (95% CI 1.3 – 10.3; $p = .011$) point higher SDM score than consultations lasting fewer than 10 minutes.

Conclusion

In this study, it was found that SDM can still be improved, especially by helping patients understand and deliberate about their options. Spending time weighing up the options, notably with patients with IC and VV, will help improve the SDM process. Training in SDM consultations is important, particularly for junior clinicians.

Introduction

Over the last 20 years, the concept of shared decision-making (SDM) has been advocated as the preferred communication model in doctor–patient encounters. In contrast to classical approaches, SDM advocates for a more engaged and proactive role for the patient in the decision-making process when facing different treatment options, while clinicians should assume more of a coaching role[1,2].

Vascular surgery in particular lends itself to SDM, as these patients often face multiple treatment options with different risks and benefits[3]. In addition, three of four patients with peripheral artery disease or abdominal aortic aneurysms (AAAs) have inadequate health literacy[4]. Therefore, it is important that patients are able to make an informed decision and are supported in understanding the pros and cons of each option, bearing in mind that some treatment options are irreversible.

Moreover, SDM and the use of SDM supporting decision aids have beneficial effects on patient satisfaction, treatment adherence, and disease specific knowledge, without raising anxiety levels[5-7]. Surgical patients more often choose less invasive treatment options when involved in the decision-making process, showing the potential of SDM to reduce healthcare costs and over treatment[7,8].

However, the current level of SDM remains below expectations[9], which is also true for vascular surgery[10]. Therefore, the association between SDM level and patient, clinician and consultation characteristics has been studied for several diseases[11-16]. These studies have shown that patient education level and employment status are associated with higher patient perceived SDM levels[11,12], and longer duration of consultation with higher objectively measured SDM levels[12-14,16]. However, studies that examine this association in secondary or tertiary care, specifically in vascular surgery, are lacking. In addition, patient and clinician perceived subjective SDM levels are often overestimated in vascular surgery[10]. Relating patient and consultation characteristics to objective SDM scores might yield more reliable predictors of the actually achieved level of SDM. Therefore, the main objective of this study was to reveal significant independent predictors of the level of SDM in vascular surgery.

Materials and methods

Design

This cross sectional cohort study was performed as a substudy of the Operative Vascular Intervention Decision-making Improvement Using SDM tools (OVIDIUS) trial, a multicentre, randomised, stepped wedge trial examining the effect of decision-making support tools on the level of SDM[17]. Data from both the control group (without the application of SDM tools) and the intervention group (with the application of SDM tools) were obtained from the OVIDIUS trial to have a wider range of SDM levels that would help find possible predictors.

The association between the objectively measured SDM scores and the following independent variables, as derived from the literature[12,15,18], were investigated: education level; type of disease; length of consultation; number of consultations; and patient employment status. The following possibly predictive variables were also added: age and sex of the patient; the number of participants in the consultation; and the profession and sex of the clinician. Additionally, the use of decision-making tools and the contributing hospital were adjusted for. For examples of the different tools, the OVIDIUS trial was referred to[19]. The English versions of the online decision aids are accessible at https://keuzehulp.medify.eu.

Setting

Data were collected from the vascular surgery or dermatology outpatient clinics of 13 Dutch hospitals that were considered to be representative of the vascular surgical care provided in the Netherlands as they comprise university, teaching, and general hospitals.

Participants

Adult patients eligible for more than one treatment option, including the option not to treat (yet), were informed of the study by one of the researchers one week before the consultation and were included consecutively. Clinicians were also informed about the study and were asked to audio record the consultations with eligible patients in which a decision was to be made. Patients were included for three different vascular diseases: AAA; varicose veins (VV); or intermittent claudication (IC) Fontaine stage IIb. Patients were included if diagnosed with an asymptomatic AAA with a diameter of 5.0 cm or more in women and 5.5 cm or more in men; patients with IC who had undergone supervised exercise training according to the current guideline but with unsatisfactory effect; and patients with VV for whom minimally invasive treatment was considered. All patients gave written informed consent to participate in the OVIDIUS trial. The trial was approved by the medical ethics review board of the Amsterdam University Medical Centre.

Table 1. Characteristics of 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), or varicose veins (VV) studied for shared decision making.

	AAA (*n* = 87)	**IC (*n* = 143)**	**VV (*n* = 112)**	**All (*n* = 342)**
Age	73 ± 7	67 ± 9	52 ± 13	64 ± 13
Sex				
Male	72 (84)	104 (73)	28 (25)	204 (60)
Female	14 (16)	39 (27)	84 (75)	137 (40)
Education level				
Low	19 (24)	2 (6)	1 (1)	43 (13)
Medium	42 (52)	20 (61)	68 (62)	189 (59)
High	19 (24)	11 (33)	40 (37)	91 (28)
Employment status				
Working	12 (15)	46 (34)	82 (75)	140 (43)
Retired	68 (85)	88 (66)	27 (25)	183 (57)
Marital status				
Single	29 (36)	47 (35)	14 (13)	90 (28)
Living together	51 (64)	87 (65)	95 (87)	233 (72)
Use of SDM intervention				
No	30 (35)	67 (47)	54 (48)	151 (44)
Yes	57 (65)	76 (53)	58 (52)	191 (56)

Data are presented as *n* (%) or as mean ± standard deviation.

Study conduct

Patient characteristics

Prior to the consultation, patients completed a questionnaire (*Supplementary Table S1*) about demographic data, including age, sex, ethnicity, education level (low, medium, high), employment status (employed, unemployed), and marital status (living alone, living together). Education levels were categorised into three groups: participants who had received "primary education" were grouped as "low"; those with "secondary education" as "medium"; and "higher professional" or "scientific education" as "high".

Clinician characteristics

Researchers registered the profession (in training, nurse practitioner/specialist, or vascular surgeon) and sex of the clinicians. None of the clinicians had any previous training in SDM.

Consultation characteristics

Clinicians audio recorded their consultations in which a treatment decision was to be made. Being audio recorded does not influence clinician or patient behaviour[20]. If multiple consultations were necessary to reach a treatment decision, subsequent consultations were also audio recorded, combined, and scored as one consultation. The observers registered the length of the consultation (in minutes), the number of consultations needed to reach a decision (1 or > 1), and the number of participants, including the clinician, in the consultation (2 or > 2).

Table 2. Characteristics of consultations for shared decision making for 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), or varicose veins (VV).

Consultation	AAA (*n* = 87)	IC (*n* = 143)	VV (*n* = 112)	All (*n* = 342)*
Duration – min:sec†	19:22 (14:24–27:13)	12:04 (8:45–17:09)	13:41 (9:41–18:42)	14:31 (10:04–20:06)
Participants				
2	19 (22)	73 (51)	90 (80)	182 (53)
>2	67 (78)	70 (49)	22 (20)	159 (47)
Number of consultations prior to decision				
1	56 (65)	123 (86)	101 (90)	280 (82)
>1	30 (35)	20 (14)	11 (10)	61 (18)
Profession of the clinician				
In training	6 (8)	10 (8)	16 (15)	32 (10)
Nurse practitioner	1 (1)	44 (33)	21 (19)	66 (20)
Vascular surgeon	74 (91)	77 (59)	73 (66)	224 (70)

Data are presented as n (%) or median (interquartile range).
* In total, 356 consultations were audio recorded of 342 individual patients.
† If a patient had more than one consultation audio recorded, the duration of all consultations were added together.

Table 3. Five item observing patient involvement (OPTION[5]) instrument item scores to measure the level of shared decision making for 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), or varicose veins (VV).

OPTION item	AAA	IC	VV	All
Item 1	1.8 ± 0.7 (0–3)	1.2 ± 0.6 (0–3)	1.4 ± 0.5 (1–3)	1.4 ± 0.7 (0–3)
Item 2	0.7 ± 0.9 (0–4)	0.2 ± 0.5 (0–2)	0.2 ± 0.6 (0–3)	0.4 ± 0.7 (0–4)
Item 3	2.5 ± 0.7 (1–4)	2.0 ± 0.7 (0–4)	2.0 ± 0.7 (0–4)	2.1 ± 0.7 (0–4)
Item 4	1.9 ± 0.9 (0–4)	1.1 ± 0.9 (0–3)	1.3 ± 0.8 (0–3)	1.4 ± 0.9 (0–4)
Item 5	1.8 ± 0.8 (0–3)	1.3 ± 0.8 (0–3)	1.5 ± 0.7 (0–3)	1.5 ± 0.8 (0–3)
Total score (%)	43.2 ± 13.6 (15–75)	29.4 ± 11.5 (10–60)	32.1 ± 11.0 (10–55)	33.8 ± 13.2 (10–75)

Data are presented as mean ± standard deviation (range) of score items. Scores per item could range from 0 (no effort) to 4 (exemplary effort). Total scores are converted into 0–100% scale.
Item 1 = option talk (alternate options); item 2 = team talk (support deliberation/forming a partnership); item 3 = option talk (information about options); item 4 = decision talk (eliciting preferences); item 5 = decision talk (integrating preferences).

Measuring SDM level

The five item "observing patient involvement" (OPTION) instrument was used to score the extent to which the clinician involves the patient in the decision-making process during consultations, according to the observer manual[21]. This instrument is frequently used to reliably assess SDM behaviour across multiple clinical settings and diseases[13,22]. The five items comprise: 1, option talk (alternate options); 2, team talk (support deliberation); 3, option talk (information about options); 4, decision talk (eliciting preferences); and 5, decision talk (integrating preferences). Definitions are shown in *Supplementary Table S2*. Each item is given a score between 0 (no effort) and 4 (exemplary effort), with a maximum total score of 20. Audiotapes were analysed twice by two of the three evaluators (L.P., F.S., and J.T.) independently. Before analysing audiotapes individually, 10 audiotapes were analysed by more than one evaluator to test inter-rater reliability, expressed as unweighted Cohen's kappa (κ)[23]. If items were scored differently, scores were discussed until consensus was achieved.

Data analysis

Descriptive statistics were applied for patient and consultation characteristics and SDM scores. Patients and consultation characteristics are presented as mean ± standard deviation (*SD*), or median (interquartile range [IQR]), when appropriate, for continuous variables and as percentages for categorical variables. The total SDM OPTION[5] score was converted from a 0 to 20 point scale into a 0% to 100% scale and presented as mean ± *SD*. Continuous variables were tested for normality and linearity.

Univariable and multivariable linear regression analyses were used to find significant independent predictors of the level of SDM, as assessed using the OPTION[5] score. First, univariable linear regression analysis was performed to check for correlations between patient or consultation characteristics, and the observed OPTION[5] score. Variables were selected for multivariable linear regression analysis if the p value was < .20. Subsequently, the backward method was used to exclude non-significant variables in the multivariable model. Possible differences in SDM level among the contributing centres as potential confounders were adjusted for. A p value < .050 was considered statistically significant. All statistical analyses were performed using SPSS version 26 (IBM, Armonk, NY, USA).

Results

Characteristics

The observers analysed 356 audiotapes from 342 unique patients of the OVIDIUS cohort[19]. The patient and consultation characteristics for each disease are shown in *Table 1 and 2*. Patient characteristics were representative for the three vascular diseases: compared with patients with AAA and IC (mostly older males), patients with VV were more often younger women. Mean patient age was 64 ± 13 years; 204 (59.6%) of them were men. The median duration of the consultations was 14 minutes and 31 seconds (IQR 10 minutes 4 seconds – 20 minutes 6 seconds) and ranged from three minutes to 58 minutes and 52 seconds. Because the duration of consultations was not normally distributed, it was stratified into four categories (< 10 minutes, 10–20 minutes, 20–30 minutes and > 30 minutes). In total, 42 clinicians (23 men, 19 women) participated in this study; 69% were (vascular) surgeons, 19% were residents in training; and 12% were nurse practitioners/nurse specialists. Of all the included patients, 47% were accompanied by their partner or family member and in 54% of the consultations SDM tools were used to improve the SDM process.

Shared decision-making level

A $\varkappa$ of 0.82 (95% confidence interval [CI] 0.63–1.00) was found among the evaluators, representing good inter-rater reliability. OPTION[5] items and scores are shown in *Table 3* and *Figure 1*. Mean total SDM score was 33.8% ± 13.2% (range 10–75%). The lowest scoring

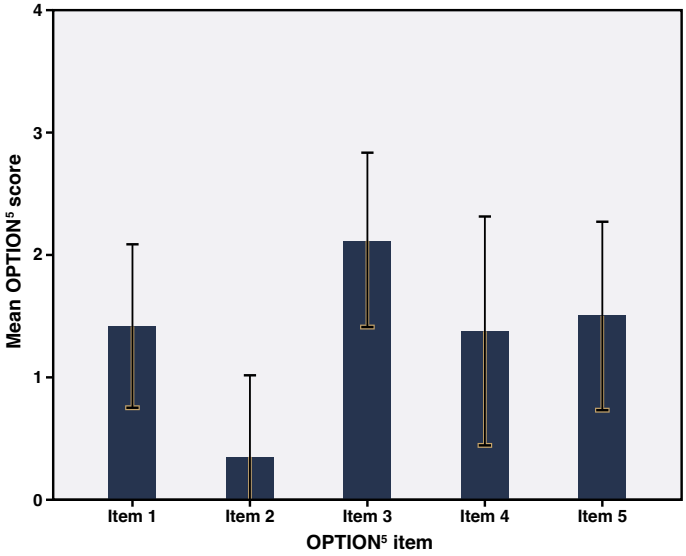

Figure 1. Mean shared decision making (SDM) scores with standard deviations (*SD*) per five item observing patient involvement (OPTION[5]) in 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), or varicose veins (VV). Each item is scored between 0 (no effort) and 4 (exemplary effort). Item 1= identifying a problem needing a decision making process (option talk); 2 = clinician will support the need to deliberate about the options (team talk); 3 = clinician provides information about the options with their pros and cons (option talk); 4 = clinician explores the patient's preferences (decision talk); 5 = clinician integrates the patient's preference in the final decision (decision talk).

Table 4. Factors associated with the five item observing patient involvement (OPTION[5]) scores to measure the level of shared decision-making in univariable and multivariable regression analyses for 342 patients with abdominal aortic aneurysm (AAA), intermittent claudication (IC), or varicose veins (VV).

	Univariable*		Multivariable†	
Indepedent variable	**β‡ (95% CI)**	***p* value**	**β (95% CI)**	***p* value**
Patient characteristics				
Age	0.13 (0.0–0.02)	.013		
Male *vs*. female sex	2.6 (–0.1–5.2)	.061		
Diagnosis				
IC *vs*. AAA		.061	–9.9 (–13.2 – –6.5)	<.001
VV *vs*. AAA	–10.0 (–13.2 – –6.8)	<.001	–12.7 (–17.3 – –8.0)	<.001
Education level				
Medium *vs*. low	2.1 (–2.0–6.2)	.32		
High *vs*. low	2.2 (–2.3–6.7)	.35		
Employed *vs*. unemployed	–2.9 (–4.6 – –0.1)	.040		
Marital status living together vs. single	1.1 (–1.9–4.2)	.46		
Clinician characteristics				
Male *vs*. female sex	4.5 (1.8 to 7.3)	.001		
Function				
Clinical nurse specialist *vs*. surgeon	–9.4 (–12.6 – –6.1)	<.001	–4.2 (–7.9 – –0.42)	.029
Clinical doctor in training *vs*. surgeon	–8.8 (–13.3 – –4.3)	<.001	–8.6 (–13.1 – –4.0)	<.001
Consultation characteristics				
Length of consultation – min§				
10–20 *vs*. 0–10	4.8 (1.7–8.0)	.003		
20–30 *vs*. 0–10	7.3 (3.1–11.4)	.001		
>30 *vs*. 0–10	11.6 (6.4–16.7)	<.001	5.8 (1.3–10.3)	.011
Participants during consultation				
>2 *vs*. 2 people	3.5 (0.9 to 6.1)	.009		
Number of consultations prior to decision				
>1 *vs*. only 1	6.1 (2.7–9.5)	<.001		
Use of SDM intervention				
Yes *vs*. no	9.1 (6.5–11.8)			

* Variable "length of consultation" was categorised.
† All multivariable regression analyses were additionally corrected for contributing centres.
‡ β indicates the regression coefficient.
§ All univariable regression analyses were corrected for the use of decision-making support tools.

item was item 2 (team talk: support deliberation/forming a partnership; 0.4 ± 0.7 [range 0–4]) and the highest scoring item was item 3 (option talk: information about options; 2.1 ± 0.7 [range 0–4]).

Associations between patient, clinician, and consultation characteristics and shared decision-making level

The non-standardised β, 95% CI, and *p* values from the univariable analysis are shown in *Table 4*. The age, sex, diagnosis, and employment status of the patient; the sex and profession of the clinician; consultation duration; number of participants in the consultation; and number of consultations prior to decision were included in the multivariable analysis, as these provided a *p* value < .20 after univariable analysis. Based on evidence from previous research, education level was also included. All univariable regression analyses were adjusted for the use of decision-making support tools, being part of the intervention in the OVIDIUS trial.

Multivariable regression analysis showed that diagnosis, clinician profession, and duration of consultation were significant factors ($p < .050$) in explaining the variation in SDM levels. The model was adjusted for all contributing centres and use of decision-making support tools. The final model included IC diagnosis (95% CI -13.2 – -6.5; $p < .001$), VV diagnosis (95% CI -17.3 – -8.0; $p < .001$), clinician profession (nurse practitioner 95% CI -7.9 – -0.42, $p = .029$; clinical doctor in training 95% CI -13.1 – -4.0, $p < .001$), and consultation duration (> 30 minutes; 95% CI 1.3 – 10.3, $p = .011$) (*Table 4*). The β values presented in *Table 4* indicate that consultations with patients with IC and VVs resulted in a 9.9 and 12.7 of 100 point lower SDM score, respectively, compared with consultations with AAA patients. Consultations with nurse practitioners or residents in training showed 4.2 and 8.6 point lower SDM scores, respectively, compared with consultations with surgeons. In addition, consultations taking > 30 minutes led to a 5.8 point higher OPTION score compared with consultations of < 10 minutes. No significant differences were found for consultations of 10–20 or 20–30 minutes. The final model explained 34% (adjusted R^2) of the variance.

Discussion

In this study the associations between patient, clinician, and consultation characteristics, and the level of SDM, were investigated in vascular surgical consultations, as measured by using the OPTION[5] instrument.

The mean SDM scores found in this study (33%) were slightly better than in other studies using the OPTION instrument, but still show ample room for improvement. A review performed in 2013 that compared 33 studies found a mean SDM score of 23% for consultations without, and 34% for consultations with, SDM improving interventions[13]. However, SDM might have gained ground in vascular surgery since then. Another study in vascular surgery, published in 2016, found a mean OPTION score of 31% without SDM improving interventions[10]. However, these studies assessed SDM behaviour using the 12 item instead of the five item OPTION instrument, which generally leads to lower scores[22].

To improve the implementation of SDM, vascular surgeons should first be aware of the importance of SDM and how to integrate it in decision-making with patients[18,24]. If surgeons pay sufficient attention to each of the five OPTION items (i.e., a score of at least 3 out of 4), a desirable OPTION total score would be 75 out of 100. To achieve this, clinicians should

make a specific effort in supporting patients to become informed and deliberate about their options, as shown in this study. In addition, clinicians should make an effort to elicit the patient's preferences before making the decision, as other studies in vascular surgery and oncology have shown previously[10,25]. Decision-making support tools, such as patient decision aids, choice cards, or option grids, may foster this process[6,26-29].

In addition, this study revealed several predictors for a better SDM performance.

First, consultations with patients with AAA showed higher SDM levels than those with IC and VV. An explanation for this could be that patients with AAA more often face equally effective treatment options according to current guidelines[30]. This facilitates clinicians in recognising the equipoise of these treatment options, and to share them with their patients. For IC and VVs the guidelines nudge towards one of the options. For example, patients with IC are often advised to take supervised walking exercise[31], and patients with VV to wear compression stockings[32], particularly as insurance companies do not always reimburse surgery. As a consequence, clinicians are less inclined to initiate the weighing of the pros and cons of all options and to elicit the patient's preferences. This corresponds with reports from clinicians' perspectives, as 'clinical situation' has been mentioned as the main barrier.18 Guidelines fostering SDM by presenting the pros and cons of more than one treatment option may be an effective means of overcoming this barrier[33]. In addition, AAA consultations were more often conducted by vascular surgeons than IC and VV consultations, which also might explain the higher SDM scores.

Second, it was found that consultations with surgeons led to significantly more SDM compared with consultations with nurse practitioners or residents in training. This is in agreement with a recent study showing that residents in training prefer a more paternalistic role in the decision-making process than medical specialists[34]. In addition, surgeons' preferences for SDM seem to be related to their years of experience, which also could explain the difference found[35]. Although nurse practitioners showed less SDM behaviour than surgeons, studies show the potential of the meaningful and supportive roles that nurses could play in the process of SDM[36]. Offering more guidance and training seems necessary to prepare nurses for this supportive role[36,37]. However, the small numbers of nurse practitioners and residents in training included in this study made it difficult to generalise the results. Nevertheless, the overall OPTION[5] scores, including among surgeons, show room for improvement.

Third, the study found that longer duration of consultations (specifically, longer than 30 minutes) was associated with higher SDM levels, which is also suggested by previous research outside the surgical realm[13,15,16]. As often stated, strategies for improving SDM should address the duration of consultations, as the standard duration for outpatient consultations in many European countries is about 10 minutes[38]. However, the use of patient decision aids may better inform and prepare patients before their visit to the surgeon, which would reduce the time needed to explain treatment options and their possible (un)desired effects during the consultation[39,40].

Study limitations

Subsequent consultations were not always audio recorded if multiple consultations were required to decide on treatment. This may have resulted in an underestimation of all aspects of SDM, as multiple consultations could provide more room for patients to reflect on their preferences and ensure that the different aspects of SDM are better appreciated by the clinician. However, subsequent consultations were only missed in 50 of 342 patients, so this

possible impact is fairly low.

In addition, the wide 95% CI show that the results might have benefitted from a larger sample size. A larger sample would probably have provided a more precise result. Nevertheless, significant factors influencing the level of SDM were found that should be considered in vascular surgical practice.

In conclusion, it was found that there remains ample room for more SDM with patients with AAA, IC, and VV, especially in supporting patients in understanding and deliberating the options. While the overall SDM level was found to be low, particularly in patients with IC and VV, nurse practitioners and residents in training need extra guidance to engage in SDM. Training in how to apply SDM in consultations may improve their skills. In addition, a longer consultation duration might be necessary to improve SDM.

Conflicts of interest statement and funding

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References

1. Stiggelbout AM, Pieterse AH, De Haes JC. Shared decision-making: concepts, evidence, and practice. Patient Educ Couns. 2015;98:1172-9.

2. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision-making: multistage consultation process. BMJ. 2017;359:j4891.

3. Ubbink DT, Koelemay MJ. Shared Decision-making in Vascular Surgery. Why Would You? Eur J Vasc Endovasc Surg. 2018;56:749-50.

4. Koelemay MJ, Ubbink DT. Can Health Literacy be Determined From the Nutritional Information on an Ice Cream Wrapping? Eur J Vasc Endovasc Surg. 2018;56:246.

5. Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision-making and patient outcomes. Med Decis Making. 2015;35:114-31.

6. Knops A, Goossens A, Ubbink D, Balm R, Koelemay M, Vahl A, et al. A decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm: a randomised clinical trial. Eur J Vasc Endovasc Surg. 2014;48:276-83.

7. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg. 2013;257:860-6.

8. Arterburn D, Wellman R, Westbrook E, Rutter C, Ross T, McCulloch D, et al. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. Health Aff (Millwood). 2012;31:2094-104.

9. Härter M, Moumjid N, Cornuz J, Elwyn G, van der Weijden T. Shared decision-making in 2017: International accomplishments in policy, research and implementation. Z fur Evidenz Fortbild Qual Gesundheitswes. 2017;123:1-5.

10. Santema T, Stubenrouch F, Koelemay M, Vahl A, Vermeulen C, Visser M, et al. Shared decision-making in vascular surgery: an exploratory study. Eur J Vasc Endovasc Surg. 2016;51:587-93.

11. Chang H-L, Li F-S, Lin C-F. Factors influencing implementation of shared medical decision-making in patients with cancer. Patient Prefer Adherence. 2019;13:1995.

12. Menear M, Garvelink MM, Adekpedjou R, Perez MMB, Robitaille H, Turcotte S, et al. Factors associated with shared decision-making among primary care physicians: Findings from a multicentre cross-sectional study. Health Expect. 2018;21:212-21.

13. Couët N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, et al. Assessments of the extent to which health-care providers involve patients in decision-making: a systematic review of studies using the OPTION instrument. Health Expect. 2015;18:542-61.

14. Mathijssen EG, Vriezekolk JE, Popa CD, van den Bemt BJ. Shared decision-making in routine clinical care of patients with rheumatoid arthritis: an assessment of audio-recorded consultations. Ann Rheum Dis. 2020;79:170-5.

15. Geessink NH, Ofstad EH, Rikkert MGO, van Goor H, Kasper J, Schoon Y. Shared decision-making in older patients with colorectal or pancreatic cancer: Determinants of patients' and observers' perceptions. Patient Educ Couns. 2018;101:1767-74.

16. Young HN, Bell RA, Epstein RM, Feldman MD, Kravitz RL. Physicians' shared decision-making behaviors in depression care. Arch Intern Med. 2008;168:1404-8.

17. de Mik S, Stubenrouch F, Legemate D, Balm R, Ubbink D. Improving shared decision-making in vascular surgery by implementing decision support tools: study protocol for the stepped-wedge cluster-randomised OVIDIUS trial. BMC Med Inform Decis Mak. 2020;20:1-10.

18. Gravel K, Légaré F, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. Implement Sci. 2006;1:16.

19. Stubenrouch FE, Peters LJ, de Mik SM, Klemm PL, Peppelenbosch AG, Schreurs SC, et al. Improving shared decision-making in vascular surgery: a stepped-wedge cluster-randomised trial. Eur J Vasc Endovasc Surg. 2022.

20. Coleman T. Using video-recorded consultations for research in primary care: advantages and limitations. Fam Pract. 2000;17:422-7.

21. Elwyn G, Grande SW, Barr P. Observer OPTION 5 Manual. Darthmouth: The Dartmouth Institute for Health Policy and Clinical Practice. 2016.

22. Stubenrouch FE, Pieterse AH, Falkenberg R, Santema TKB, Stiggelbout AM, van der Weijden T, et al. OPTION5 versus OPTION12 instruments to appreciate the extent to which healthcare providers involve patients in decision-making. Patient Educ Couns. 2016;99:1062-8.

23. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977:159-74.

24. Ubbink DT, Hageman M, Legemate DA. Shared Decision-Making in Surgery. Surg Technol Int. 2015;26:31.

25. Gionfriddo MR, Branda ME, Fernandez C, Leppin A, Yost KJ, Kimball B, et al. Comparison of audio vs. audio+ video for the rating of shared decision-making in oncology using the observer OPTION 5 instrument: an exploratory analysis. BMC Health Serv Res. 2018;18:522.

26. Stacey D, Hill S, McCaffery K, Boland L, Lewis KB, Horvat L. Shared decision-making interventions: theoretical and empirical evidence with implications for health literacy. Stud Health Technol Inform. 2017;240:263-83.

27. Stiggelbout AM, Van der Weijden T, De Wit MP, Frosch D, Légaré F, Montori VM, et al. Shared decision-making: really putting patients at the centre of healthcare. BMJ. 2012;344:e256.

28. Ubbink DT, Knops AM, Molenaar S, Goossens A. Design and development of a decision aid to enhance shared decision-making by patients with an asymptomatic abdominal aortic aneurysm. Patient Prefer Adherence. 2008;2:315.

29. Elwyn G, Pickles T, Edwards A, Kinsey K, Brain K, Newcombe RG, et al. Supporting shared decision-making using an Option Grid for osteoarthritis of the knee in an interface musculoskeletal clinic: A stepped wedge trial. Patient Educ Couns. 2016;99:571-7.

30. Wanhainen A, Verzini F, Van Herzeele I, Allaire E, Bown M, Cohnert T, et al. Editor's Choice–European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. Eur J Vasc Endovasc Surg. 2019;57:8-93.

31. Aboyans V, Ricco J-B, Bartelink M-LE, Björck M, Brodmann M, Cohnert T, et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS) Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries Endorsed by: the European Stroke Organization (ESO) The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). Eur Heart J. 2018;39:763-816.

32. Wittens C, Davies A, Bækgaard N, Broholm R, Cavezzi A, Chastanet S, et al. Editor's choice–management of chronic venous disease: clinical practice guidelines of the European Society for Vascular Surgery (ESVS). Eur J Vasc Endovasc Surg. 2015;49:678-737.

33. van der Weijden T, Pieterse AH, Koelewijn-van Loon MS, Knaapen L, Légaré F, Boivin A, et al. How can clinical practice guidelines be adapted to facilitate shared decision-making? A qualitative key-informant study. BMJ Qual Saf. 2013;22:855-63.

34. Driever EM, Stiggelbout AM, Brand PL. Shared decision-making: physicians' preferred role, usual role and their perception of its key components. Patient Educ Couns. 2020;103:77-82.

35. Garcia-Retamero R, Wicki B, Cokely ET, Hanson B. Factors predicting surgeons' preferred and actual roles in interactions with their patients. Health Psychol. 2014;33:920.

36. Bos-van den Hoek DW, Thodé M, Jongerden IP, Van Laarhoven HW, Smets EM, Tange D, et al. The role of hospital nurses in shared decision-making about life-prolonging treatment: A qualitative interview study. J Adv Nurs. 2021;77:296-307.

37. Lenzen SA, Daniëls R, van Bokhoven MA, van der Weijden T, Beurskens A. What makes it so difficult for nurses to coach patients in shared decision-making? A process evaluation. Int J Nurs Stud. 2018;80:1-11.

38. Deveugele M, Derese A, van den Brink-Muinen A, Bensing J, De Maeseneer J. Consultation length in general practice: cross sectional study in six European countries. BMJ. 2002;325:472.

39. Dobler CC, Sanchez M, Gionfriddo MR, Alvarez-Villalobos NA, Ospina NS, Spencer-Bonilla G, et al. Impact of decision aids used during clinical encounters on clinician outcomes and consultation length: a systematic review. BMJ Qual Saf. 2019;28:499-510.

40. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017;4:1-287.

Supplementary materials

Supplementary Table S1. Patient characteristics questionnaire.

We would like to receive your answers to the following questions:	
What is your date of birth?	___-___-_____
What is your gender?	□ Male
	□ Female
What vascular problem do you see the doctor for?	□ Dilated abdominal artery
	□ Narrowed carotid artery
	□ Window shopper's disease
	□ Varicose veins
What is the heighest level of education you have completed?	□ Primary education
	□ Secondary education
	□ Higher professional education
	□ Scientific education
What is your current employment status?	□ Working as:
	_____
	□ Job seeker
	□ Retired
What is your living situation?	□ Living together
	□ Single
	□ Nursing or healthcare facility
What is your ethnicity?	□ Dutch
	□ Surinamese
	□ Indonesian
	□ Dutch Antillean / Aruban
	□ Turkish
	□ Moroccan
	□ Otherwise, namely
	_____

Supplementary Table S2. Five item OPTION score list.

Item 1	**Option talk: alternate options** For the health issue being discussed, the clinician draws attention to or confirms that alternate treatment or management options exist or that the need for a decision exists. If the patient rather than the clinician draws attention to the availability of options, the clinician responds by agreeing that the options need deliberation.
Item 2	**Team Talk: support deliberation / forming a partnership** The clinician reassures the patient or re-affirms that the clinician will support the patient to become informed or deliberate about the options. If the patient states that they have sought or obtained information prior to the encounter, the clinician supports such a deliberation process.
Item 3	**Option Talk: information about options** The clinician gives information or checks understanding about the options that are considered reasonable (this can include taking no action), to support the patient in comparing alternatives. If the patient requests clarification, the clinician supports the process.
Item 4	**Decision Talk: eliciting preferences** The clinician makes an effort to elicit the patient's preferences in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive.
Item 5	**Decision Talk: integrating preferences** The clinician makes an effort to integrate the patient's elicited preferences as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician makes an effort to do so.

Items 1-5 of the OPTION[5] instrument representing the different steps of the Shared Decision-Making process.

Chapter 12

Thesis summary

The aim of this thesis was to explore the current level of shared decision-making (SDM) and risk communication in the out-patient clinic, and to improve this level by developing and implementing SDM and risk communication tools.

Part I: State of the art

To appreciate the current level of SDM during outpatient-clinic encounters between patients and surgeons, we conducted a systematic review, as presented in **Chapter 2**. This review indicated that the level of SDM still shows room for improvement. SDM levels as scored by independent observers, were low: ranging from 7% to 39%. In contrast, subjective SDM scores by patients and surgeons were high; 93% and 84%, respectively. This discrepancy seems due to ignorance or misunderstanding of the concept of SDM among both surgeons and patients. Hence, while unaware of the exact meaning of SDM, they may have scored other aspects of the consultation. For example their level of satisfaction or the informed consent procedure, rather than the level of SDM. Due to the wide range of tools and questionnaires available to study the level of SDM, it is hard to discern which metrics correlate best with the level of SDM.

To zoom in on the current levels of SDM in vascular surgery, an exploratory study was conducted and described in **Chapter 3**. Vascular surgeons of four different Dutch hospitals audio-recorded their outpatient-clinic consultations in which a treatment decision should be made. These audio-tapes were scored independently by two observers using the Observing Patient Involvement (OPTION) instrument, producing scores ranging from 0% (no SDM) to 100% (optimum SDM). The disorders presented in these consultations lend themselves to SDM. Vascular surgeon and patients filled out a SDM questionnaire immediately after the consultation. Three of the OPTION items were scored as 'not observed' in the majority of the audio-tape consultations: 'assessing the patient's preferred approach to receive information', 'checking if the patient understood the information', and 'eliciting the patient's preferred involvement'. The highest scoring items were 'the identification of a problem that needs a decision-making process', and 'exploring the patient's expectations'. Overall, we found a mean OPTION score of 31%, which demonstrates there is room for improving the objective SDM-levels, also among vascular surgeons.

To determine the current level of SDM in another, non-surgical but closely related specialism in the chain of care, a similar study was conducted in Anesthesiology. This is reported in **Chapter 4**. Consecutive preoperative patients visiting the pre-assessment outpatient-clinic of the department of Anesthesiology were invited. The SDM level of the consultation was scored in a way similar to the previous study: both objectively by two observers independently who judged audio-tapes of the consultation using the OPTION instrument, and subjectively by patients (using SDM-Q-9 and CollaboRATE questionnaires) and clinicians (SDM-Q-Doc questionnaire). Also in this study the OPTION score was low (30.5%). In contrast, the subjective scores of the SDM-Q-9 and CollaboRATE were high among patients: 91.7% and 96.3%, respectively. Among clinicians the SDM-Q-Doc score was 84.3%. Based on this discrepancy, we concluded that also in the preoperative screening clinic of Anesthesiology there is room for improving the awareness, understanding and level of SDM.

Correct and complete reporting of the outcomes of clinical trials is mandatory to appreciate available evidence and to inform patients properly about the possible different treatment

options. This may support clinical decision-making. Furthermore, to improve SDM and risk communication it is important that scientific publications report benefits and harms of interventions in an easily interpretable and applicable way for clinical practice. **Chapter 5** presents a systematic review of studies examining the manner they report benefits an harms of surgical interventions in randomized clinical trials (RCTs). For this review, we used RCTs published in 15 leading medical journals that compared a surgical treatment with any other treatment. The CONSORT statement and the CONSORT extension for harm check were used to assess the published RCTs on how well they reported their beneficial and harmful treatment outcomes, their definitions, and their precision measures. Of the in total 88 RCTs included, a total of 46 primary beneficial outcomes and 63 primary harmful outcomes were reported. In only 6 per cent of the studies adherence to the CONSORT statement was stated. Of the RCTs, 39% did not report the beneficial as well as the harmful outcomes of the intervention investigated in the study. Also, only five trials (6%) reported a number needed to treat, and none of the studies a number needed to harm. Thus, despite the fact that the CONSORT statement is supported widely, current trials fail to describe reported benefits and harms in surgical RCTs correctly, which is necessary to properly inform patients and facilitate shared decision-making.

Part II: New tools for shared decision-making

To promote SDM in vascular surgery, we developed various decision support tools (DSTs). **Chapter 6** described the development of these tools. The DSTs were developed for four vascular disorders, i.e., patients with an abdominal aortic aneurysm (AAA), carotid artery disease (CAD), intermittent claudication (IC) and varicose veins (VV). The various support tools included patient decision aids, consultation cards, and decision cards. Beside the usual content of DAs, the DAs we developed contain 3D-animations of each of the treatment options to better explain and illustrate what these treatments involve. The patients go through the decision aid prior to the decision-making consultation in order to enter this conversation as well prepared as possible. Consultation cards, also known as Option grids™, are one-page tools presenting the answers to the most frequently asked quetsions by patients. These cards can be used during the consultation so that clinicians find out what matters most to their patients, while patients get answers to the question(s) they find most relevant. The information on these consultation cards has been converted into a decision card. These cards presents the same information, but now visually in pictograms. These different tools were co-created with vascular surgeons, patient advocates and patients.

To measure the extent to which clinicians involve their patients in the decision-making process, various objective instruments have been developed. In **Chapter 7** we investigated the features of the more recently developed 5-item versus the 12-item versions of the Observing Patient Involvement instruments (OPTION). We compared the Dutch versions of both OPTION instruments in terms of inter-rater agreement and correlation in the outpatient-clinics of various specialisms (oncology and vascular surgery). Sixty audio-taped consultations were independently reviewed by two reviewers using both OPTION instruments. Inter-rater agreement between the two reviewers for each OPTION instrument was expressed as an unweighted Cohen's kappa (κ). The mean total scores for the 60 consultations were 23.7 (*SD* 7.8) and 39.3 (*SD* 12.7) for the OPTION^{12} and OPTION^{5} instruments, respectively. This showed that the OPTION^{5} instrument shows consistently higher total scores than

the OPTION[12] instrument. Besides, the OPTION[5] instruments seems more sensitive to differentiate between low and high scores for patient involvement. Therefore the OPTION[5] instrument is recommended for clinical application.

An essential step in the process of SDM, is the communication about the possible treatment options with their pros and cons. Because visual presentation of information may increase patient comprehension, a web-based, publicly available (www.mapping.nu) application that provides graphical representation of numerical benefits and risk of surgical treatment options was developed. In **Chapter 8** we described the pilot testing of this application, the Mapping All Patient Probabilities In Numerical Graphs (MAPPING app) application. In this application we predefined the percentages of the benefits and risks of surgical treatment options, based on best available evidence or guidelines. Thereby a clinician can change these percentages, for example: when he informs a patient with higher complication-risk due to comorbidity, or if the benefit or risk percentages from his surgeries do not correspond with the numbers from guidelines. The app shows the possible outcomes as bar charts, icon arrays, or natural frequency trees. Patients welcomed the app and were eager to understand the risks and benefits involved when presented as graphs. Surgeons judged the app as simple to use and valuable. So, overall surgeons' and patients' feedback revealed that the MAPPING app was useful to communicate the benefits and risks. Based on these preliminary data, this app appears to be a promising tool to facilitate surgical risk communication. Future research will need to focus on validation and promotion of SDM among different types of patients and disorders.

Part III: Promoting shared decision-making

Chapter 9 presents the protocol for the stepped-wedge cluster-randomised Operative Vascular Intervention Decision-making Improvement Using SDM tools (OVIDIUS) trial. In this study we examined the implementation and effect of DSTs on SDM in the vascular surgery outpatient-clinic. In this study, participating hospitals were randomised every two to four months (instead of patients) to start using the DSTs. This design has the advantage that at the end of the trial all participating hospitals have implemented at least some, or all of the DSTs offered. Patients receiving care in the control period did not receive any intervention apart from the regular information provided by their vascular surgeon. Patients who visited their vascular surgeon after implementing the DSTs received the decision aid for their disorder prior to their consultation. The level of SDM was measured by scoring the audio-tapes of the vascular out-patient clinic consultations. The results of this study are described in **Chapter 10**. In 13 different centers throughout the Netherlands, decision aids were sent prior to the consultation with the vascular surgeon. Consultation cards and decision cards were used during the consultation. Audio recordings were also made in this study and these were scored, so that they could be assessed objectively. This study showed that the introduction of decision support tools improves the degree of shared decision-making, the knowledge about treatment options and that patients opt less often for invasive treatments. In addition, it was seen that the online decision aid was most effective for patients and that the shared decision-making training was the most effective for clinicians.

A sub-cohort study of the OVIDIUS trial is described in **Chapter 11**. In this study we aimed to reveal predictors (patient and consultation characteristics) of a higher level of SDM in vascular surgery. Audio-recordings of patients with abdominal aortic aneurysm

(AAA), intermittent claudication (CI) or varicose veins (VV) were scored independently using the OPTION[5] instrument. Regression analysis showed that the mean SDM scores in consultations with patients with CI or with VV were lower than in patients with AAA. Consultations by a resident in training or nurse practitioner resulted in lower SDM scores than those conducted by a surgeon. A consultation longer than 30 minutes led to higher SDM scores than consultations lasting less than 10 minutes. In this study, it was found that SDM can still be improved, especially by helping patients understand and deliberate about their options. Spending time weighing their options, notably with patients with IC and VV, will also help improve the SDM process. Training to learn how to apply SDM in consultations is important, particularly for junior clinicians.

Chapter 13

Discussion and future perspectives

Discussion

Shared decision-making (SDM) has become one of the major movements in modern medicine to improve the quality of healthcare. Equality between doctor and patients is becoming increasingly important. In our modern society the ethical principle that patients have the right to be better involved in the decision-making process regarding their health issues gets more recognition, while at the same time an increasing number of treatment options has become available.

Barriers to overcome

To apply SDM in the current healthcare system, several initiatives have been launched and implemented but barriers and preoccupations remain to be overcome, as was found in our studies in various medical situations (**Chapters 3, 4, 6, and 8**). Implementation is a challenge and should be an integral effort, involving all healthcare professionals in the team, i.e., doctors, nurses as well as paramedics, especially while patients are increasingly treated by, and discussed in, multidisciplinary teams.

The first step in the implementation phase is to create awareness. Healthcare professionals must become aware that SDM is an inevitable process, and can no longer be ignored as patients want to be more involved in decision-making, and become more skilled and empowered to engage in this process. But even in patients awareness must be created, for example by using Decision Support Tools (DSTs), Decision Aids (DAs; e.g., keuzehulp.medify.eu), and the '3 good questions' (3 goede vragen). As such, patient organizations also have an important role to play. Besides awareness, healthcare professionals need intrinsic motivation, and acquire the attitude, habit, and essential skills to integrate SDM in their daily practice[1,2].

Despite the existing evidence on the benefits of SDM, the extent to which healthcare professionals apply this principle in their outpatient-clinic remains low[3]. Some barriers and preoccupations are frequently mentioned, but are gradually being disproved. An example is the frequently reported objection that applying SDM will take longer consultation time. To discuss all possible treatment options with their benefits and risks may take additional time[4,5]. This idea has burgeoned during the past years as more treatment options per disease have become available, while patients may absorb but little information, especially after having received bad news regarding their health situation. Discussing all these treatment options and eliciting patient preferences in a usually 10-minute outpatient consultation slot obviously is challenging, if not impossible. This implies that the decision-making consultation deserves more time and requires organizational changes. However, when more time is allocated to this first decision-making conversation, time will be gained eventually, because patients are less worried, have less questions, and are more adherent to the treatment choice when made co-responsible for this choice[3,6]. A Cochrane review showed that applying decision aids generally does not prolong, and may even reduce, the consultation time[7]. Furthermore, more structured consultations that direct toward SDM may shorten the duration of the consultation[8,9].

Another barrier of SDM as perceived by healthcare professionals is that many of their patients are not 'suitable' for SDM[10,11]: SDM may seem less feasible in some circumstances, i.e., in acute situations, dementia, elderly patients, those with low health literacy, or patients who otherwise cannot express their preferences (cognitively impaired or unconscious patients). Even in those circumstances SDM is possible, as treatment decisions can still be made with the partner or family. Even if only one intervention seems feasible, the pros

and cons of the alternative option of 'watchful waiting' or delaying a treatment should be considered and discussed to clarify why the intervention preferred by the clinician would outweigh any alternative. Thus, many perceived barriers and preoccupations are a result of misinterpretations caused by unawareness or a reluctance to change.

In general, policymakers in the Netherlands are in favor of the SDM concept and could play an important role in tackling these perceived barriers and preoccupations. Some of them, however, are concerned that SDM will increase the demand for more unnecessary or costly procedures. However, in a study of Walsh[12] none of the studies reported increased costs associated by using DSTs. Some studies showed the opposite: More involvement in the decision-making process might be associated with a reduction of costs[13-15]. In the surgical realm this notion is supported by the finding that patients tend to choose less or non-invasive procedures when informed about these options through decision aids[16].

Implementation initiatives

To overcome these barriers and preoccupations, and thereby to achieve a higher level of SDM, several laudable initiatives have been launched. For example in the Netherlands pre- and postgraduate education programs have been concerted by the national program 'Uitkomstgerichte Zorg', initiated by the Ministry of Health, in an attempt to provide and facilitate SDM education. This has led to the development of a set of competences for physicians and nurses to be used as a landmark in their education and practice. Second, practical SDM trainings were found to be an effective way to train and enhance the clinicians' communication skills and to apply SDM supporting instruments in the consultation room[6,17]. To make sure clinicians adopt and adhere to this way of clinical practice, these trainings are preferably provided in the medical curriculum. This is already common practice in an increasing number of institutes and has become part of the continuing medical education for healthcare professionals. Although this will surely demand extra time in already busy schedules, clinicians need accreditation points and their time investment is likely to be rewarded with more structured, focused, and time-saving consultations once trained[9].

Based on the results of the OVIDIUS trial (**Chapter 8**) and previous studies[7,16], Decision Support Tools (DSTs) have shown to be an effective means improving the level of SDM, not only for clinicians but also for patients. However, the mere development and availability of DSTs to be used prior to, or during the consultation[18] has proven to be insufficient to implement SDM as a routine in clinical practice[6,19]. Using a multilevel approach, by combining SDM-trainings, feedback on consultations, and available DSTs, is more promising to promote SDM[3,6,16], as is seen in oncology[20,21]. In addition, it is important to focus on the maintenance and incorporation of these tools in the ICT structures from the beginning of its design process. Besides, support from professional and patient organizations is needed to provide and embed disease-specific tools in clinical practice. Professional associations should keep the information evidence-based and up-to-date, while on the other hand patient advocacy organizations need to be involved in the design and promotion of the DSTs.

Comprehensive approach

Based on the possibilities to overcome current barriers and the experiences of previous implementation initiatives, a comprehensive approach appears essential to render SDM more successful and to sustain and promote the use of DSTs. This approach would comprise the

following: First, SDM education must be structurally incorporated in medical and nursing curricula, guided by the defined sets of competencies. Second, current healthcare professionals should be persuaded to participate in an SDM training. Subsequently, audio-recordings of their consultations in the outpatient clinic may be used to –preferably regularly– appreciate their SDM skills, followed by reflection and individual coaching on how to engage patients in the decision-making process and how to use DSTs. Next, interdisciplinary efforts must be made to promote SDM, for example during multidisciplinary team meetings, and again reflect on their course of action[21].

Patients, in turn, are often not aware of the possibility to participate in decision-making. To foster their involvement, patient awareness campaigns, such as the recent national public campaign (www.begineengoedgesprek.nl/campagne), or explanation and distribution of existing tools appear helpful (OVIDIUS). This will raise awareness of what SDM entails and could educate patients how to make their voice count in the decision-making process. Other countries have also started several initiatives to perform patient-centered care and SDM. In Germany several SDM tools have been developed. With the help of the government, public institutions and patient advisory boards, they aim to further implement SDM[22]. In Denmark a cultural change is pursued through national clinical guidelines recommending SDM, promoting SDM trainings, and implementing DAs. However, a lack of legilisation and a central push hampers its nationwide implementation[23]. In France SDM implementation remains scarce, although implementation initiatives supported by healthcare users' and patients' representatives have increased. Thus, implementation initiatives are needed to promote sustained adoption of SDM[24]. To achieve the greatest impact, this SDM principle should be promoted among clinicians, patients and healthcare organizations simultaneously.

Finally, other ways to promote SDM are to adjust legislation[25,WGBO], involve insurance companies[26], improve ICT support[27] (to integrate the existing tools in ICT structures) and out-patient-clinic logistics (for example longer time slots when a treatment decision has to be made).

Future perspectives

The introduction and implementation of SDM will require changes in the attitudes and practices of patients, clinicians, and policy makers. Besides encouraging clinicians' attitudes towards SDM, also patients should change their behavior in their encounters with clinicians and be encouraged to share what is important to them during the consultation[4]. For that purpose, they should be encouraged to change and be educated as to what to change[21,29]. For patients, in particular those with limited health literacy, several tools have been developed to engage them in SDM, for example YouTube animation videos and E-learnings[6,16,Opleidingsmateriaal - Kennisplatform Uitkomstgerichte Zorg].

Educating SDM is a time-consuming process. Therefore, alternatives must be investigated to see if there are other ways to educate the stakeholders. For example, appropriate e-learnings to educate clinicians and patients. Or even better, virtual reality e-learnings to simulate the clinical encounter setting and thereby experiencing real-life interactions and SDM. Similar VR e-learnings are already emerging in the skills training of surgical residents[31]. This could be taken into consideration when developing new training materials. There might even be a role for artificial intelligence (AI): There are studies ongoing to investigate how artificial intelligence can facilitate SDM[32]. The use of individualized and tailored information in AI

decision aids has been investigated, which might also be a promising tool. However, it is important to take into account a potential lack of emphasis on patients' values and preferences, as well as current poor reporting of AI interventions[33]. So overall, AI might be a promising tool in various ways to facilitate SDM, but is still in its infancy.

Apart from the efforts on a national level to increase the current clinicians' SDM skills, future doctors may more easily be molded to practice SDM as their standard attitude. Hence, efforts towards teaching new doctors appears most rewarding. Fortunately, this education is becoming an integral part of the curricula in an increasing number of medical faculties in the Netherlands. A study of available pre- and postgraduate education programs has been conducted by the national program "Uitkomstgerichte Zorg", in an attempt to provide and facilitate SDM education. This can make our country one of the leading countries (among several others) in the world regarding structural implementation of SDM in healthcare. In other countries the same challenges exist as to implementing SDM, so sharing best-practices and insights with each other might help integrate the SDM paradigm[22-24,34,35].

Also, other healthcare professionals, in particular nurses, should be trained to apply SDM. These care professionals could fulfill an important role in SDM as daily caregivers[36,37]; as they have more time to spend with their patients and may discuss specific nursing aspects of care. This could lead to better interprofessional SDM, for instance during multidisciplinary team meetings or clinical patient visits on the wards.

More and more tools are being developed to help clinicians and their patients to apply SDM structurally. In order to ensure that DSTs are easily and freely available to patients and clinicians (including doctors, nurses and paramedics), a national repository containing the majority, if not all, of the existing DSTs would be helpful. Several national healthcare institutions have joined forces to achieve this goal[38,39]. As SDM is an overarching principle in healthcare, we advocate policymakers to make this a salient item on their agenda. Currently, SDM already fits in nicely with other quality improvement initiatives like value-based and outcome-based healthcare. In the Netherlands, the 'Programma Uitkomstgerichte Zorg' will have a follow-up ('Integraal Zorgakkoord') in which these patient-centered themes, including SDM, will be implemented further in our healthcare system.

Overall, the history, relevance and general developments towards patient-centered care clearly demonstrate that SDM is not a passing fad: It is not a hype, it is here to stay![40]

The chapters in this thesis addressed the current level of SDM, a number of tools developed and tested to promote SDM, and some promising SDM implementation efforts. Overall, the findings in this thesis show the future perspectives of SDM are bright.

Are you willing to take SDM to the next level and what is your contribution to promote this paradigm?

References

1. Shinkunas, Laura A et al. "Shared decision making in surgery: a scoping review of patient and surgeon preferences." BMC medical informatics and decision making vol. 20,1 190. 12 Aug. 2020, doi:10.1186/s12911-020-01211-0

2. Javaid, Maham et al. "Use and Perceptions of Shared Decision-Making by General Surgery Faculty and Trainees." The Journal of surgical research vol. 276 (2022): 323-330. doi:10.1016/j.jss.2022.03.009

3. van Veenendaal, Haske et al. "Effects and Working Mechanisms of a Multilevel Implementation Program for Applying Shared Decision-Making while Discussing Systemic Treatment in Breast Cancer." Current oncology (Toronto, Ont.) vol. 30,1 236-249. 23 Dec. 2022, doi:10.3390/curroncol30010019

4. Driever, Ellen M et al. "Shared Decision-making in Different Types of Decisions in Medical Specialist Consultations." Journal of general internal medicine vol. 37,12 (2022): 2966-2972. doi:10.1007/s11606-021-07221-6

5. Søndergaard, Stine R et al. "The impact of shared decision making on time consumption and clinical decisions. A prospective cohort study." Patient education and counseling vol. 104,7 (2021): 1560-1567. doi:10.1016/j.pec.2020.12.014

6. Stubenrouch, Fabienne E et al. "Improving Shared Decision Making in Vascular Surgery: A Stepped Wedge Cluster Randomised Trial." European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery vol. 64,1 (2022): 73-81. doi:10.1016/j.ejvs.2022.04.016

7. Stacey, Dawn et al. "Decision aids for people facing health treatment or screening decisions." The Cochrane database of systematic reviews vol. 4,4 CD001431. 12 Apr. 2017, doi:10.1002/14651858.CD001431.pub5

8. van Veenendaal, Haske et al. "Accelerating implementation of shared decision-making in the Netherlands: An exploratory investigation." Patient education and counseling vol. 101,12 (2018): 2097-2104. doi:10.1016/j.pec.2018.06.021

9. Veenendaal, Haske van et al. "Shared decision-making and the duration of medical consultations: A systematic review and meta-analysis." Patient education and counseling vol. 107 (2023): 107561. doi:10.1016/j.pec.2022.11.003

10. Williams, Randi M et al. "Fostering informed decisions: a randomized controlled trial assessing the impact of a decision aid among men registered to undergo mass screening for prostate cancer." Patient education and counseling vol. 91,3 (2013): 329-36. doi:10.1016/j.pec.2012.12.013

11. Xu, Jun, and Anya E R Prince. "Shared decision-making in vascular surgery." Journal of vascular surgery vol. 70,5 (2019): 1711-1715. doi:10.1016/j.jvs.2019.03.002

12. Walsh, Thom et al. "Undetermined impact of patient decision support interventions on healthcare costs and savings: systematic review." BMJ (Clinical research ed.) vol. 348 g188. 23 Jan. 2014, doi:10.1136/bmj.g188

13. Stacey, Dawn et al. "Decision aids for people facing health treatment or screening decisions." The Cochrane database of systematic reviews ,1 CD001431. 28 Jan. 2014, doi:10.1002/14651858.CD001431.pub4

14. Oshima Lee, Emily, and Ezekiel J Emanuel. "Shared decision making to improve care and reduce costs." The New England journal of medicine vol. 368,1 (2013): 6-8. doi:10.1056/NEJMp1209500

15. Clapp, Justin T et al. "Surgical Overtreatment and Shared Decision-making-The Limits of Choice." JAMA surgery vol. 157,1 (2022): 5-6. doi:10.1001/jamasurg.2021.4425

16. Knops, Anouk M et al. "Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis." Annals of surgery vol. 257,5 (2013): 860-6. doi:10.1097/SLA.0b013e3182864fd6

17. van Veenendaal, Haske et al. "Accelerating implementation of shared decision-making in the Netherlands: An exploratory investigation." Patient education and counseling vol. 101,12 (2018): 2097-2104. doi:10.1016/j.pec.2018.06.021

18. Scalia, Peter et al. "The impact and utility of encounter patient decision aids: Systematic review, meta-analysis and narrative synthesis." Patient education and counseling vol. 102,5 (2019): 817-841. doi:10.1016/j.pec.2018.12.020

19. Elwyn, Glyn et al. "Why do clinicians not refer patients to online decision support tools? Interviews with front line clinics in the NHS." BMJ open vol. 2,6 e001530. 29 Nov. 2012, doi:10.1136/bmjopen-2012-001530

20. van Veenendaal, H et al. "Effect of a multilevel implementation programme on shared decision-making in breast cancer care." BJS open vol. 5,2 (2021): zraa002. doi:10.1093/bjsopen/zraa002

21. Scholl, Isabelle et al. "Evaluation of a program for routine implementation of shared decision-making in cancer care: results of a stepped wedge cluster randomized trial." Implementation science : IS vol. 16,1 106. 29 Dec. 2021, doi:10.1186/s13012-021-01174-4

22. Hahlweg, Pola et al. "Moving towards patient-centered care and shared decision-making in Germany." Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen vol. 171 (2022): 49-57. doi:10.1016/j.zefq.2022.04.001

23. Dahl Steffensen, Karina et al. "Implementation

of patient-centred care in Denmark: The way forward with shared decision-making." Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen vol. 171 (2022): 36-41. doi:10.1016/j.zefq.2022.04.005

24. Moumjid, Nora et al. "Implementation of shared decision-making and patient-centered care in France: Towards a wider uptake in 2022." Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen vol. 171 (2022): 42-48. doi:10.1016/j.zefq.2022.03.001

25. Ubbink, Dirk T et al. "Meer 'samen beslissen' nodig door aangescherpte Wgbo" [Updated Dutch law demands shared decision-making]. Nederlands tijdschrift voor geneeskunde vol. 165 D5775. 10 Jun. 2021

26. Alishahi Tabriz, Amir et al. "How Health-Care Organizations Implement Shared Decision-making When It Is Required for Reimbursement: The Case of Lung Cancer Screening." Chest vol. 159,1 (2021): 413-425. doi:10.1016/j.chest.2020.07.078

27. Scalia, Peter et al. "Integrating Option Grid Patient Decision Aids in the Epic Electronic Health Record: Case Study at 5 Health Systems." Journal of medical Internet research vol. 23,5 e22766. 3 May. 2021, doi:10.2196/22766

28. Driever, Ellen M et al. "Patients' preferred and perceived decision-making roles, and observed patient involvement in videotaped encounters with medical specialists." Patient education and counseling vol. 105,8 (2022): 2702-2707. doi:10.1016/j.pec.2022.03.025

29. Légaré, France, and Holly O Witteman. "Shared decision making: examining key elements and barriers to adoption into routine clinical practice." Health affairs (Project Hope) vol. 32,2 (2013): 276-84. doi:10.1377/hlthaff.2012.1078

30. Knops, A M et al. "A decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm: a randomised clinical trial." European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery vol. 48,3 (2014): 276-83. doi:10.1016/j.ejvs.2014.04.016

31. Batirel, Hasan F et al. "Auditorium of the future: e learning platform." Journal of thoracic disease vol. 13,3 (2021): 2038-2043. doi:10.21037/jtd.2019.12.69

32. Abbasgholizadeh Rahimi, Samira et al. "Application of Artificial Intelligence in Shared Decision Making: Scoping Review." JMIR medical informatics vol. 10,8 e36199. 9 Aug. 2022, doi:10.2196/36199

33. Hassan, Nehal et al. ''Clinicians' and patients' perceptions of the use of artificial intelligence decision aids to inform shared decision making: a systematic review'' The Lancet vol. 398. November 2021, doi:10.1016/S0140-6736(21)02623-4

34. Coulter, Angela et al. "Implementing shared decision-making in UK: Progress 2017-2022." Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen vol. 171 (2022): 139-143. doi:10.1016/j.zefq.2022.04.024

35. Légaré, France et al. "Shared decision-making in Canada: Update on integration of evidence in health decisions and patient-centred care government mandates." Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen vol. 171 (2022): 22-29. doi:10.1016/j.zefq.2022.04.006

36. Bos-van den Hoek, Danique W et al. "The role of hospital nurses in shared decision-making about life-prolonging treatment: A qualitative interview study." Journal of advanced nursing vol. 77,1 (2021): 296-307. Doi

37. Festen, Suzanne et al. "How to incorporate geriatric assessment in clinical decision-making for older patients with cancer. An implementation study." Journal of geriatric oncology vol. 10,6 (2019): 951-959. doi:10.1016/j.jgo.2019.04.006

38. Gerritse, Karl et al. "Decision-making approaches in transgender healthcare: conceptual analysis and ethical implications." Medicine, health care, and philosophy vol. 24,4 (2021): 687-699. doi:10.1007/s11019-021-10023-6

39. Colligan, Erica et al. "Shared decision-making in multiple sclerosis." Multiple sclerosis (Houndmills, Basingstoke, England) vol. 23,2 (2017): 185-190. doi:10.1177/1352458516671204

40. Légaré, France, and Philippe Thompson-Leduc. "Twelve myths about shared decision making." Patient education and counseling vol. 96,3 (2014): 281-6. doi:10.1016/j.pec.2014.06.014

Appendices

Nederlandse samenvatting

Het doel van dit proefschrift was om het huidige niveau van gedeelde besluitvorming en risicocommunicatie tijdens spreekkamer gesprekken te onderzoeken, en om het niveau hiervan te verbeteren door het ontwikkelen én implementeren van gedeelde besluitvorming- en risicocommunicatie-instrumenten.

Deel 1: Huidige stand van zaken

Om het huidige niveau van gedeelde besluitvorming tijdens spreekkamergesprekken tussen patiënten en chirurgen in kaart te brengen hebben we een systematische review uitgevoerd (**Hoofdstuk 2**). Hieruit blijkt dat er ruimte is voor verbetering. Gedeelde besluitvorming scores, gescoord door onafhankelijke beoordelaars, waren laag: variërend van 7% tot 39%. Daarentegen waren de subjectieve gedeelde besluitvorming scores van patiënten en chirurgen hoog; respectievelijk 93% en 84%. Deze discrepantie lijkt te wijten door onbegrip of onwetendheid over het concept gedeelde besluitvorming, bij zowel chirurgen als patiënten. Mogelijk waren beiden zich niet bewust wat de exacte betekenis van gedeelde besluitvorming was en hebben ze dus mogelijk andere aspecten van het spreekkamergesprek beoordeeld. Bijvoorbeeld, tevredenheid over het spreekkamergesprek of de informed consent procedure, in plaats van het niveau van gedeelde besluitvorming. Vanwege het brede scala aan instrumenten en vragenlijsten die beschikbaar zijn om het niveau van gedeelde besluitvorming te bestuderen, is het moeilijk te onderscheiden welke meetmethoden het beste correleren met het niveau van gedeelde besluitvorming.

In **Hoofdstuk 3** wordt de huidige stand op het gebied van gedeelde besluitvorming binnen de vaatchirurgie geëvalueerd. Patiënten uit vier verschillende ziekenhuizen werden geïncludeerd die een beslissing moesten maken voor een aandoening waarvoor er meerdere behandelopties mogelijk waren. Het gesprek tussen arts en patiënt werd middels audio-opnamen opgenomen om zo objectief de mate van gedeelde besluitvorming te kunnen meten. Deze audio-opnamen werden onafhankelijk van elkaar gescoord door twee beoordelaars met behulp van het Observing Patient Involvement (OPTION)-instrument. Dit leverde scores op variërend van 0% (geen gedeelde besluitvorming) tot 100% (optimale gedeelde besluitvorming). De aandoeningen die besproken werden tijdens deze spreekkamergesprekken leenden zich voor gedeelde besluitvorming. Vaatchirurgen en patiënten vulden direct na het consult een gedeelde besluitvorming vragenlijst in. Drie van de OPTION-items werden in het merendeel van de audio-opnamen gescoord als 'niet waargenomen': 'het vragen naar de voorkeur hoe de patiënt graag de nodige informatie wil ontvangen', 'controleren of de patiënt de informatie heeft begrepen', en 'het uitlokken van de gewenste betrokkenheid van de patiënt'. De hoogst scorende items waren 'aangeven dat er een probleem is waarover een beslissing genomen moet worden' en het 'verkennen van de verwachtingen van de patiënt'. We vonden een gemiddelde OPTION-score van 31%, wat aantoont dat er ook onder vaatchirurgen ruimte is voor verbetering van de mate van gedeelde besluitvorming.

Om het huidige niveau van gedeelde besluitvorming in een ander, niet-chirurgisch, maar nauw verwant specialisme te bepalen is bij de anesthesiologie een soortgelijk onderzoek uitgevoerd. Dit wordt beschreven in **Hoofdstuk 4**. Opeenvolgende preoperatieve patiënten, die de preassessment polikliniek van de afdeling Anesthesiologie bezochten, werden uitgenodigd. Het niveau van gedeelde besluitvorming van het consult werd op een vergelijkbare manier gescoord als in het vorige onderzoek: zowel objectief door twee beoordelaars, die

onafhankelijk van elkaar de audio-opnamen van de consulten beoordeelden met behulp van het OPTION-instrument, als subjectief door patiënten (met behulp van SDM-Q-9 en ColaboRATE vragenlijsten) en artsen (SDM-Q-Doc-vragenlijst). Ook in dit onderzoek was de OPTION-score laag (30,5%). Daarentegen waren de subjectieve scores van de SDM-Q-9 en CollaboRATE hoog onder de patiënten: respectievelijk 91,7% en 96,3%. Onder artsen bedroeg de SDM-Q-Doc-score 84,3%. Op basis van deze discrepantie concludeerden we dat er ook in de preoperatieve screening binnen de anesthesiologie ruimte is voor verbetering van het bewustzijn, begrip en niveau van gedeelde besluitvorming.

Correcte en volledige uitleg van de uitkomsten van klinische onderzoeken is verplicht om het beschikbare bewijsmateriaal te kunnen interpreteren en patiënten goed te kunnen informeren over de mogelijke verschillende behandelingsopties. Dit kan de klinische besluitvorming ondersteunen. Bovendien is het om gedeelde besluitvorming en risicocommunicatie te verbeteren belangrijk dat wetenschappelijke publicaties zowel de voordelen als nadelen van chirurgische interventies rapporteren op een gemakkelijk interpreteerbare wijze, opdat deze toegepast kunnen worden in de klinische praktijk.

In **Hoofdstuk 5** wordt een systematische review beschreven van onderzoeken naar de manier waarop de voor- en nadelen van chirurgische interventies gerapporteerd werden in gerandomiseerde klinische onderzoeken (RCT's). Voor deze review hebben we gebruik gemaakt van RCT's gepubliceerd in 15 toonaangevende medische tijdschriften waarin een chirurgische behandeling werd vergeleken met welke andere behandeling dan ook. De CONSORT-verklaring en de CONSORT-extensie voor nadelige uitkomsten werden gebruikt om de gepubliceerde RCT's te beoordelen op hoe goed zij hun voor- en nadelige behandelresultaten, hun definities en hun precisiemetingen rapporteerden. Van de in totaal 88 geïncludeerde RCT's werden in totaal 46 primaire voordelige behandelresultaten en 63 primaire nadelige behandelresultaten gerapporteerd. In slechts 6% van de onderzoeken werd aangegeven dat de CONSORT-verklaring werd gebruikt. Van de RCT's rapporteerde 39% niet zowel de voordelige als nadelige behandelresultaten van de in het onderzoek onderzochte interventie. Bovendien meldden slechts vijf onderzoeken (6%) een 'Number Needed to Treat' (NNT), en geen van de onderzoeken een 'Number Needed to Harm' (NNH). Ondanks het feit dat de CONSORT-verklaring breed wordt gesteund, slagen de huidige onderzoeken er dus niet in om de gerapporteerde voordelen en nadelen in chirurgische RCT's correct te beschrijven. Hetgeen nodig is om patiënten goed te informeren en gedeelde besluitvorming te vergemakkelijken.

Deel II: nieuwe hulpmiddelen voor gedeelde besluitvorming

Om gedeelde besluitvorming bij vaatchirurgie te bevorderen hebben we verschillende keuzeondersteunende hulpmiddelen ontwikkeld. **Hoofdstuk 6** beschrijft de ontwikkeling van deze hulpmiddelen. De keuzeondersteunende hulpmiddelen zijn ontwikkeld voor vier vaataandoeningen, namelijk patiënten met een verwijde buikslagader, vernauwde halsslagader, etalagebenen en spataderen. De verschillende keuzeondersteunende hulpmiddelen omvatten keuzehulpen, keuzetabellen en consultkaarten. Naast de gebruikelijke inhoud van keuzehulp bevatten de door ons ontwikkelde keuzehulpen 3D-animaties van elk van de behandelopties om beter uit te leggen en te illustreren wat deze behandelingen inhouden. De patiënten doorlopen, voorafgaand aan het spreekkamergesprek met de arts, de keuzehulp om zo goed mogelijk voorbereid dit gesprek in te gaan. Keuzetabellen, ook bekend als Option Grids™ , zijn hulpmiddelen van één pagina die de antwoorden op de meest gestelde vragen

van patiënten presenteren. Deze keuzetabellen kunnen tijdens het consult worden gebruikt, zodat artsen kunnen achterhalen wat het belangrijkst is voor hun patiënten, terwijl patiënten antwoorden krijgen op de vragen die zij het meest relevant vinden. De informatie op deze keuzetabellen is ook vertaald in consultkaarten. Deze kaarten presenteren dezelfde informatie, maar dan visueel met behulp van plaatjes. Deze verschillende hulpmiddelen zijn ontwikkeld in samenwerking met vaatchirurgen, patiëntorganisaties en patiënten.

Om te meten in hoeverre artsen hun patiënten bij het besluitvormingsproces betrekken, zijn verschillende objectieve instrumenten ontwikkeld. In **Hoofdstuk 7** onderzochten we of de 5-itemversie versus de 12-itemversies van de OPTION-instrumenten net zo efficiënt was om de mate van gedeelde besluitvorming te meten. We vergeleken de Nederlandse versies van beide OPTION-instrumenten op het gebied van de mate van overeenstemming tussen twee onafhankelijke beoordelaars en de correlatie in spreekkamergesprekken van verschillende specialismen (oncologie en vaatchirurgie). Zestig audio-opnamen van spreekkamergesprekken werden onafhankelijk beoordeeld door twee beoordelaars die beide OPTION-instrumenten gebruikten.

De mate van overeenstemming tussen twee onafhankelijke beoordelaars voor elk OPTION-instrument werd uitgedrukt als een ongewogen Cohen's kappa (κ). De gemiddelde totaalscores voor de 60 consultaties waren respectievelijk 23,7 (standaarddeviatie 7,8) en 39,3 (standaarddeviatie 12,7) voor de OPTION^{12}- en OPTION^{5}-instrumenten. Hieruit bleek dat het OPTION^{5}-instrument consistent hogere totaalscores laat zien dan het OPTION^{12}-instrument. Daarnaast lijkt het OPTION^{5}-instrument gevoeliger voor het maken van onderscheid tussen lage en hoge scores voor de mate van patiëntbetrokkenheid. Daarom wordt het OPTION^{5}-instrument aanbevolen voor klinische toepassing.

Een essentiële stap in het proces van gedeelde besluitvorming is de communicatie over de mogelijke behandelopties met hun voor- en nadelen. Omdat visuele presentatie van informatie het begrip van de patiënt kan vergroten, werd een internetapplicatie gemaakt (www.mapping.nu). Deze applicatie toont grafisch de voor- en nadelen van chirurgische behandelopties. In **Hoofdstuk 8** hebben we de pilottest van deze applicatie beschreven, de Mapping All Patient Probabilities In Numerical Graphs (MAPPING-app). In deze toepassing hebben we de percentages van de voordelen en risico's van chirurgische behandelopties vooraf gedefinieerd, op basis van de best beschikbare informatie of richtlijnen. Daarbij kan een arts deze percentages wijzigen, bijvoorbeeld wanneer hij een patiënt informeert met een hoger risico op complicaties als gevolg van comorbiditeit, of wanneer de risicopercentages van zijn operaties niet overeenkomen met de cijfers uit richtlijnen. De applicatie toont de mogelijke uitkomsten als staafdiagrammen, pictogrammenreeksen of natuurlijke frequentiebomen. Patiënten vonden deze applicatie fijn om zo de voor- en nadelen van behandelingen met behulp van grafieken te begrijpen. Chirurgen beoordeelden de applicatie als eenvoudig te gebruiken en waardevol. Uit de algemene feedback van chirurgen en patiënten bleek dus dat de MAPPING-app nuttig was om de voordelen en risico's te communiceren. Op basis van deze voorlopige gegevens lijkt deze applicatie een veelbelovend hulpmiddel om de communicatie over chirurgische risico's te vergemakkelijken. Toekomstig onderzoek zal zich moeten concentreren op de validatie en bevordering van gedeelde besluitvorming bij verschillende soorten patiënten en aandoeningen.

Deel III: Promoten van gedeelde besluitvorming

In **Hoofdstuk 9** wordt het protocol van de stapsgewijze cluster-gerandomiseerde Operative Vascular Intervention Decision-making Improvement Using Shared Decison-Making-tools (OVIDIUS) studie besproken. In deze studie onderzochten we de implementatie en het effect van keuzeondersteunende hulpmiddelen op gedeelde besluitvorming bij vaatchirurgische spreekkamergesprekken. In deze studie werden deelnemende ziekenhuizen elke twee tot vier maanden gerandomiseerd (in plaats van patiënten) om de keuzeondersteunende hulpmiddelen te gaan gebruiken. Dit heeft het voordeel dat aan het einde van de studie alle deelnemende ziekenhuizen tenminste een of alle keuzeondersteunende hulpmiddelen hadden geïmplementeerd. Patiënten in de controleperiode kregen geen andere zorg dan de gebruikelijke informatie van hun vaatchirurg. Patiënten die na de implementatie van de keuzeondersteunende hulpmiddelen hun vaatchirurg bezochten ontvingen voorafgaand aan hun consult de keuzehulp voor hun aandoening. Het niveau van gedeelde besluitvorming werd gemeten door het scoren van de audio-opnamen van de vaatchirurgische spreekkamergesprekken. De resultaten van dit onderzoek zijn beschreven in **Hoofdstuk 10**. In 13 verschillende centra door heel Nederland zijn voorafgaand aan het consult met de vaatchirurg keuzehulpen verzonden. Tijdens het spreekkamergesprek werd gebruik gemaakt van keuzetabellen en consultkaarten. Ook bij deze studie werden audio-opnamen gemaakt en deze zijn eveneens objectief gescoord. Uit dit onderzoek blijkt dat de introductie van keuzeondersteunende hulpmiddelen de mate van gedeelde besluitvorming verbetert, de kennis over behandelmogelijkheden verbetert en dat patiënten minder vaak kiezen voor invasieve behandelingen. Daarnaast bleek dat de online keuzehulp het meest effectief was voor patiënten en dat de training gedeelde besluitvorming het meest effectief was voor artsen.

Een substudie van de OVIDIUS-trial wordt beschreven in **Hoofdstuk 11**. In deze studie wilden wij voorspellers achterhalen (patiënt- en consultkenmerken) van een hoger niveau van gedeelde besluitvorming bij de vaatchirurgie. Audio-opnamen van patiënten met een verwijde buikslagader, etalagebenen of spataderen werden onafhankelijk gescoord met behulp van het OPTION^5-instrument. Regressieanalyse toonde dat de gemiddelde mate van gedeelde besluitvorming bij consulten met patiënten met etalagebenen en patiënten met spataderen lager was dan bij patiënten met een verwijde buikslagader. Consulten door een arts in opleiding of een verpleegkundig specialist resulteerden in minder gedeelde besluitvorming dan wanneer een arts het consult deed. Een consult langer dan 30 minuten resulteerde in meer gedeelde besluitvorming in vergelijking met consulten die korter dan 10 minuten duurden. Dit hoofdstuk laat opnieuw zien dat het niveau van gedeelde besluitvorming verbeterd kan worden, voornamelijk door te zorgen dat patiënten de informatie begrijpen en de opties beter kunnen afwegen. Ook door meer tijd te nemen om de opties af te wegen met patiënten met etalagebenen en spataderen zal het gedeelde besluitvormingsproces verbeteren. Training om te leren hoe gedeelde besluitvorming toe te passen is hierbij belangrijk, voornamelijk bij jonge artsen.

PhD portfolio

Name PhD student:	Fabienne E. Stubenrouch
PhD period:	January 2016 – December 2020
Promotor:	prof. dr. D.T. Ubbink
Copromotor:	prof. dr. D.A. Legemate

PhD training	**Year**	**Workload (ETCS)**
Courses		
AMC world of Science	2015	0.7
Clinical Epidemiology: Randomized Controlled Trials	2015	0.9
Basic course on Regulations and Organization of Clinical Trials (BROK)	2016	1.0
Scientific writing	2016	1.5
Clinical Epidemiology: Systematic Reviews	2016	0.9
Evidence Based Surgery, AMC, Amsterdam	2016	0.8
Practical training in shared decision-making, AMC, Amsterdam	2016	0.4
Seminars		
Journal club	2015-2018	3.0
Weekly surgical department seminars, AMC, Amsterdam	2015-2020	2.0
Vascular rounds, VUmc, Amsterdam	2016-2020	1.5
Attended (inter)national conferences		
Chirurgendagen, Veldhoven, the Netherlands	2016-2019	1.2
International Conference for Evidence Based Practice, Bandos, Maldives	2016	0.3
Minisymposium Gedeelde besluitvorming, Amsterdam, the Netherlands	2019	0.3
International Conference for Evidence Based Practice, Bandos, Maldives	2022	0.3
Presentations at (inter)national conferences		
The development of patient decision aids in vascular surgery International Conference for EBPC, Bandos, Maldives	2016	1.5
MAPPING app. International Conference for EBPC, Bandos, Maldives	2016	1.5
Webinar Samen Beslissen, online conference	2022	1.5
OVIDIUS study. International Conference for EBPC, Bandos, Maldives	2022	1.5
Workshop: Why and how to perform shared decision-making during a patient–caregiver encounter? International Conference for EBPC, Bandos, Maldives	2022	1.5
Teaching and supervising		
Tutoring and supervising 8 medical bachelor students	2016-2021	8.0
Tutoring and supervising 2 medical Master students	2016-2021	2.0
Teaching medical students about shared decision-making in surgery	2018	1.0
Teaching medical students about evidence-based decision aids	2018	1.0
Mentor medical bachelor students	2017-2018	6.0
Supervising student-assistants on OVIDIUS	2018-2022	2.0
Parameters of esteem (grants, awards and prizes)		
MD/PhD scholarship Academic Medical Center	2015	-
KNAW van Walree Beurs	2016	-

A

List of publications

In this thesis

Systematic review of shared decision-making in surgery.
De Mik, S.M.L., Stubenrouch, F.E., Balm, R., & Ubbink, D.T.
The British Journal of Surgery. 2018; 105(13): 1721–1730.

Shared Decision Making in Vascular Surgery: An Exploratory Study.
Santema, T.B., Stubenrouch, F.E., Koelemay, M.J., Vahl, A.C., Vermeulen, C.F., Visser, M.J., & Ubbink, D.T.
European Journal of Vascular and Endovascular Surgery. 2016; 51(4): 587–593.

The current level of shared decision-making in anesthesiology: an exploratory study.
Stubenrouch, F.E., Mus, E.M.K., Lut, J.W., Hesselink, E.M., & Ubbink, D.T.
BMC Anesthesiology. 2016; 17(1): 95.

Systematic review of reporting benefits and harms of surgical interventions in randomized clinical trials.
Stubenrouch, F.E., Cohen, E.S., Bossuyt, P.M.M., Koelemay, M.J.W., van der Vet, P.C.R., & Ubbink, D.T.
The British Journal of Surgery Open. 2020; 4(2): 171–181.

Development of three different decision support tools to support shared decision-making in vascular surgery.
De Mik, S.M.L., Stubenrouch, F.E., Balm, R., & Ubbink, D.T. (2021).
Patient Education and Counseling. 2021; 104(2): 282–289.

OPTION(5) versus OPTION(12) instruments to appreciate the extent to which healthcare providers involve patients in decision-making.
Stubenrouch, F.E., Pieterse, A.H., Falkenberg, R., Santema, T.K., Stiggelbout, A.M., van der Weijden, T., Aarts, J.A., & Ubbink, D.T.
Patient Education and Counseling. 2016; 99(6): 1062–1068.

A web-based application to communicate benefits and risks of surgical treatments.
Stubenrouch, F.E., Baumann, M., Legemate, D.A., & Ubbink, D.T.
Surgical Technology International. 2017; 30: 31–37.

Improving shared decision-making in vascular surgery by implementing decision support tools: study protocol for the stepped-wedge cluster-randomised OVIDIUS trial.
De Mik, Stubenrouch, F.E., S.M.L., Legemate, D.A., Balm, R., & Ubbink, D.T.
BMC Medical Informatics and Decision Making. 2020; 20(1): 172.

Improving shared decision making in vascular surgery: a stepped wedge cluster randomised trial.
Stubenrouch, F.E., Peters, L.J., de Mik, S.M.L., Klemm, P.L., Peppelenbosch, A.G., Schreurs, S.C.W.M., Scharn, D.M., Legemate, D.A., Balm, R., Ubbink, D.T., & OVIDIUS study group.
European Journal of Vascular and Endovascular surgery. 2022; 64(1): 73–81.

Predictors of the level of shared decision making in vascular surgery: a cross sectional study.
Peters, L.J., Stubenrouch, F.E., Thijs, J.B., Klemm, P.L., Balm, R., & Ubbink, D.T.
European Journal of Vascular and Endovascular Surgery. 2022; 64(1): 65–72.

Other publications

Treatment of varicose veins, international consensus on which major complications to discuss with the patient: a Delphi study.
De Mik, S.M., Stubenrouch, F.E., Legemate, D.A., Balm, R., & Ubbink, D.T.
Phlebology. 2019; 34(3): 201–207.

Delphi study to reach international consensus among vascular surgeons on major arterial vascular surgical complications.
De Mik, S.M.L., Stubenrouch, F.E., Legemate, D.A., Balm, R., Ubbink, D.T., & DISCOVAR study group.
World Journal of Surgery. 2019; 43(9): 2328–2336.

Correspondence.
De Mik, S. M. L., Stubenrouch, F. E., Balm, R., & Ubbink, D. T.
The British Journal of Surgery. 2019; 106(4): 508.

Shared decision-making in the management of congenital vascular malformations.
Horbach, S.E.R., Ubbink, D.T., Stubenrouch, F.E., Koelemay, M.J.W., van der Vleuten, C. J.M., Verhoeven, B.H., Reekers, J.A., Schultze Kool, L.J., & van der Horst, C.M.A.M.
Plastic and Reconstructive Surgery. 2017; 139(3): 725e–734e.

Comparison of the CollaboRATE and SDM-Q-9 questionnaires to appreciate the patient-reported level of shared decision-making.
Ubbink, D.T., van Asbeck, E.V., Aarts, J.W.M., Stubenrouch, F.E., Geerts, P.A.F., Atsma, F., & Meinders, M.J.
Patient Education and Counseling. 2022; 105(7): 2475–2479.

Effectiveness of individual feedback and coaching on shared decision-making consultations in oncology care: protocol for a randomized clinical trial.
Van Veenendaal, H., Peters, L.J., Ubbink, D.T., Stubenrouch, F.E., Stiggelbout, A.M., Brand, P.L., Vreugdenhil, G., & Hilders, C.G.
JMIR Research Protocols. 2022; 11(4): e35543.

Decision making for hematopoietic stem cell transplantation in pediatric, adolescent, and young adult patients with a hemoglobinopathy–shared or not?
Mekelenkamp, H., Smiers, F., Camp, N., Stubenrouch, F.E., Lankester, A., & de Vries, M.
Pediatric Blood & Cancer. 2021; 68(9): e29099.

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A

Curriculum Vitae

Fabienne Stubenrouch is geboren op 7 januari 1988 te Gouda. Zij groeide op in Rotterdam in een gezin met vier kinderen. Na het behalen van haar gymnasiumdiploma heeft zij voor een culturele uitwisseling in Salamanca te Spanje gewoond, alwaar Fabienne de Spaanse taal heeft geleerd. Aansluitend is zij in 2008 begonnen aan de studie biomedische wetenschappen aan de Universiteit van Amsterdam; welke werd afgerond met een verlengde wetenschappelijk stage naar de embryologische ontwikkeling van het reukorgaan bij professor Oostra, hoogleraar anatomie en embryologie. Na het behalen van haar eerste bachelor begon zij in 2012 aan de studie geneeskunde aan dezelfde universiteit. Gedurende beide bachelors heeft Fabienne tevens als docent gewerkt aan het Luzac Lyceum te Amsterdam; alwaar zij wiskunde, natuurkunde en scheikunde doceerde aan onder- en bovenbouwklassen van zowel de havo als het VWO.

Gedurende het tweedejaar van de geneeskundebachelor werd haar interesse voor wetenschappelijk onderzoek opnieuw gewekt door een project naar het syndroom van Pierre Robin bij professor Van der Horst, hoogleraar plastische chirurgie. Vervolgens heeft zij onder begeleiding van professor Ubbink, hoogleraar evidence-based medicine en shared decision-making, en professor Legemate, hoogleraar chirurgie, meegewerkt aan enkele, wetenschappelijke projecten. Hieruit heeft zij een promotievoorstel geschreven, welke door Graduate School en Raad van Bestuur van het Academisch Medisch Centrum werd beloond met een MD/PhD-scholarship voor de gehele duur van het promotietraject. In 2016 ontving zij tevens een KNAW Van Walree beurs. Hierop wisselde Fabienne vanaf januari 2016 volgens de structuur van het MD/PhD-scholarship periodes van promotieonderzoek af met coschappen. Hiernaast gaf zij onderwijs op het gebied van klinisch redeneren en shared decision-making aan zowel bachelor- als masterstudenten. Ook begeleidde ze meerdere studenten bij het schrijven van hun bachelor- en masterthesis.

Sinds januari 2021 is Fabienne in het Onze Lieve Vrouwe Gasthuis te Amsterdam in opleiding tot radioloog, van waaruit zij momenteel haar academische stage in het Amsterdam Universitair Medisch Centrum loopt. Zij woont met haar man in Abcoude, waar zij genieten met hun drie kinderen.

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PROMOTING **SHARED DECISION-MAKING** IN THE SURGICAL REALM

Fabienne E. Stubenrouch