FACULTY OF MEDICINE AND HEALTH SCIENCES

GHENT UNIVERSITY

Patient-specific virtual reality simulation: a patient-tailored approach of endovascular aneurysm repair

Liesbeth Desender

Ghent 2017

Doctoral thesis submitted in fulfilment of the requirements to obtain the degree of Doctor in the Medical Sciences

Cover:
‘Thoracic Aneurysm’, Kaitlin Walsh

Patient-specific virtual reality simulation: a patient-tailored approach of endovascular aneurysm repair.

Promotor

Prof. dr. Frank Vermassen

Ghent University Hospital, Ghent, Belgium

Co-promotor

Prof. dr. Isabelle Van Herzeele

Ghent University Hospital, Ghent, Belgium

Doctoral Advisory Committee

Prof. dr. M. Lachat

Zurich University Hospital, Zurich, Switzerland

Members of the Examination Board

Prof. dr. Luc De Baerdemaeker

Ghent University Hospital, Ghent, Belgium

Prof. dr. Johan Decruyenaere

Ghent University Hospital, Ghent, Belgium

Prof. dr. Inge Fourneau

University Hospital Gasthuisberg Leuven, Leuven, Belgium

Prof. dr. Katrien Francois

Ghent University Hospital, Ghent, Belgium

Prof. dr. Piet Pattyn

Ghent University Hospital, Ghent, Belgium

Prof. dr. ir. Patrick Segers

Ghent University, Ghent, Belgium

Prof. dr. Hence Verhagen

Erasmus MC University Medical Center, Rotterdam, The Netherlands

This thesis was financially supported by a part-time mandate from Ghent University and a Clinical Doctoral Grant from the Fund for Scientific Research – Flanders, Belgium.

Work hard, be kind, and amazing things will happen

Conan O’Brien

Voor Thomas, Clara en Annette

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Abbreviation list

3D	Three-dimensional
AAA	Infrarenal Abdominal Aortic Aneurysm
ASG scale	Anatomic Severity Grading scale
ATAI	Acute Traumatic Aortic Injury
CAS	Carotid Artery Stenting
CT(A)	Computed Tomography (Angiography)
DAP	Dose Area Product
DICOM	Digital Imaging and COmmunication in Medicine
EVAR	EndoVascular Aortic Repair
EVEREST	European Virtual reality Endovascular RESearch Team
GRS	Global Rating Scale
ICECAP	Imperial College Error CAPture record
IFU	Instructions For Use
IQR	InterQuartile Range
LSA	Left Subclavian Artery
MRI	Magnetic Resonance Imaging
OR	Operating Room
OSATS	Objective Structured Assessment of Technical Skills
OTAS	Observational Teamwork Assessment for Surgery
PACS	Picture Archiving and Communication System
PAU	Penetrating Aortic Ulcer
PAVLOV	PAtient-specific Virtual reality simuLation Of EVAR
PIP	Procedure Independent Pressure
PsR	Patient-specific virtual reality Rehearsal
RCT	Randomised Controlled Trial
TAA	Thoracic Aortic Aneurysm
TEVAR	Thoracic EndoVascular Aortic Repair
VR	Virtual Reality

1

General introduction and thesis outline

This chapter is based on the following article:

Training with simulation versus operative room attendance.

L. Desender[1]
I. Van Herzeele[1]
R. Aggarwal[2]
F. Vermassen[1]
N. Cheshire[3]
On behalf of EVEREST

J Cardiovasc Surg 2011;52:17-37.

Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium
[2]Department of Biosurgery and Surgical Technology, Imperial College Healthcare NHS Trust, London, UK
[3]Department of Surgery, Imperial College London, London, UK

General introduction

The endovascular approach of infrarenal aortic aneurysms (EVAR) and thoracic aortic disease such as aneurysms, dissections, and acute traumatic injury (TEVAR) has revolutionised the treatment of aortic pathology. Both EVAR and TEVAR procedures have become widely established treatments with excellent results.[1-3] Patient outcomes are related to individual anatomic patient considerations, operator and team experience, and hospital volume,[4-8] but current thinking emphasises the role of wider aspects of the surgical system in patient safety.[9]

Vascular procedures pose several complex safety risks, are associated with substantially higher adverse event rates than major nonvascular procedures and have one of the highest incidences of avoidable adverse events (8.1%).[10] Failure in aortic procedures is frequently caused by issues with team-working and equipment and is associated with patient harm. Additionally, there is evidence that endovascular procedures are consistently associated with more failures than open surgical operations.[11, 12] This may be explained by the rapidly evolving nature of the endovascular field and the different tool kit and skills required to perform endovascular procedures, resulting in an extensive and changing learning curve. Trainees as well as experienced physicians have to learn how to work in a three-dimensional (3D) environment while viewing a two-dimensional image, how to deal with reduced tactile feedback and how to handle the increased need for hand-eye-foot coordination. Furthermore, endovascular aortic procedures are often performed in a complex high-tech environment, staffed by teams of clinicians and technicians with various medical backgrounds, requiring precise communication and collaboration from all team members. To optimise patient outcomes in endovascular aortic procedures, we need to minimise avoidable errors. This may be achieved by enhancing non-technical skills (such as communication, team-working, leadership) and system factors (equipment planning, provision and maintenance, pressures on the operating team and their environment, provision of training), while continuing to improve the patient's preoperative condition and technical expertise among surgeons.

Patient safety may be addressed and enhanced by accurate preoperative planning

and preparation.[13] Preoperative planning not only includes technical components, but also extends to the preparation of the entire endovascular team to optimise team workflow, resource management and error prevention.[14] The Institute of Medicine 2000 report 'To Err is Human: Building a Safer Health System' highlighted the frequency of medical errors in modern healthcare and their subsequent impact on patient safety, and recommended medical simulation as an efficient tool to improve clinician training and shorten the learning curve without the risk of harming patients.[15]

Reduced training opportunities, a change in societal attitude to clinical training whereby learning and practicing new surgical techniques on real patients is considered unethical, increasing awareness of the importance of preventing errors and increasing complexity of endovascular intervention have led to advances in virtual reality (VR) simulation, and the emergence of patient-specific VR rehearsal (PsR).

VR simulation

VR simulation refers to the process of imitating a course of events using computer-generated images that allow sensory interaction, and may range from patient encounters and plastic modules to VR simulators. Contemporary, high-fidelity simulation is based on feedback systems that combine concepts of mechanical, electrical, computer, and control systems engineering to reproduce an interactive case.

VR simulation has the potential to enhance technical skills training outside the operating room without the ethical concerns associated with practice on animals or cadavers.[16-18] Most of the current VR systems offer a wide range of clinical scenarios at varying levels of difficulty and allow for repeated practice using the same simulator, simulated tools and devices, without any risk to patients. Finally, the VR simulated modules can be used for formative and summative assessment since automatic assessment measures are being registered.[19] These objective metrics may monitor progress while learning and practicing technical skills, and can be used to define the proficiency criteria that need to be reached prior to train on real patients.

One of the first computerised surgical simulators was described in 1993 for laparoscopic surgery with a 3D reconstruction of the human abdomen.[20] VR simulation training has been shown to improve technical proficiency and shorten learning curves in other minimal invasive fields requiring fine dexterity and hand-eye coordination, such as laparoscopic surgery and endoscopy.[21, 22] By transferring these skills to the operating room (OR) or bedside, simulation-based education has been shown to improve patient outcomes.[21, 23-27]

Endovascular VR simulation

Since Dawson described the initial developments leading to an endovascular VR device in 2000, VR simulation for endovascular surgery has evolved considerably.[28] VR simulation software is now available for almost every vascular bed: cerebral, carotid, coronary, renal, aortic, iliofemoral, and below the knee procedures. Endovascular simulators usually consist of one or two haptic devices ("legs") connected to LED monitors, displaying tools and a simulated fluoroscopy screen, and a laptop computer, from which a facilitator may select tools as instructed and manipulate physiological parameters, according to the scenario. Guide wires, catheters, balloons, stents, and stent grafts may be inserted and deployed as in real-life endovascular procedures, and both static and dynamic fluoroscopic imaging may be undertaken, while physicians can use a foot pedal, a virtual C-arm, and zoom toggles to control simulated radiological exposure and table movement. Currently, a number of systems are available on the commercial market, including the VIST (Vascular Intervention Simulation Trainer; Mentice, Gothenburg, Sweden), ANGIOMentor (3D Systems formerly Simbionix, Cleveland, Ohio, USA), SimSuite (Medical Simulation Corporation, Denver, Colorado, USA), and CathLab VR Surgical Simulator (CAE Healthcare, Montreal, Quebec, Canada) (Figure 1).[29]

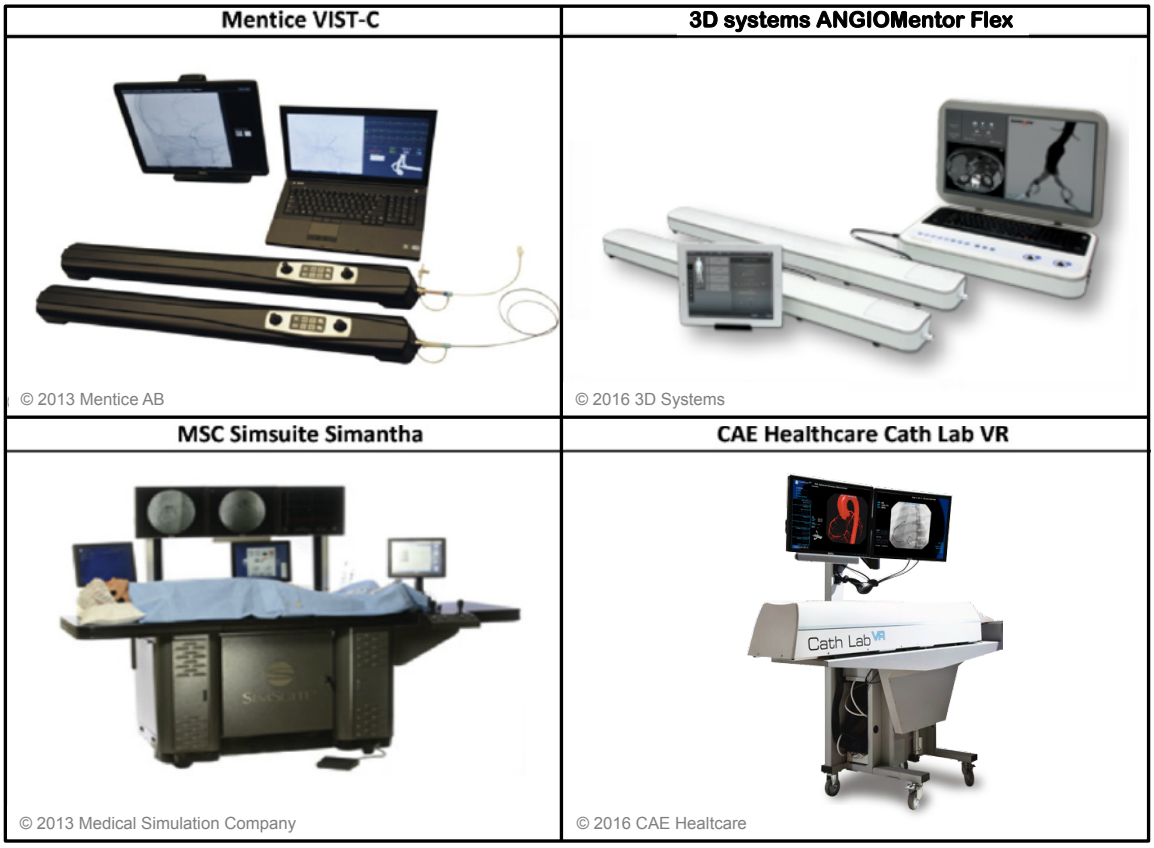

Figure 1. *Commercially available endovascular simulators: VIST-C; ANGIOMentor Flex; SimSuite Simantha; and CathLab VR.*

Several training studies have demonstrated improved performances of novices following repetitive practice using endovascular VR simulators in femoral, iliac, renal and carotid interventions.[30-39] Additionally, endovascular VR simulation has shown to improve experienced interventionalists' performances in carotid artery stenting (CAS) on a VR simulator.[18] Several studies have reported transferability of endovascular skills post-VR simulation training, with improvement of real-world performances during endovascular treatment of lower extremity occlusive disease.[40-42]

Assessment of endovascular procedures

Evaluation of the simulation

Simulation models are approximate imitations of real-world systems that are built for a specific purpose or set of objectives, but never exactly imitate the real-world system. Therefore, a model should be validated to check the accuracy of the model's representation of the real system and its validity should be determined for the

intended application of the model. The validity of simulations may be assessed against a range of parameters (Table 1).[43]

Face validity	Extent to which the examination resembles real life situations
Content validity	Extent to which the domain that is being measured is measured by the assessment tool
Construct validity	Extent to which a test measures the trait that it purports to measure; the extent to which a test discriminates between various levels of expertise
Concurrent validity	Extent to which the results of the assessment tool correlate with the gold standard for that domain
Predictive validity	Ability of the examination to predict future performance

Table 1. *Simulation validity.*

Assessment of technical skills

The lack of agreed definitions of technical endovascular skills and valid tools for objective measurement of these skills remains a challenge to assess technical performances in real life. Surrogate measures of technical skill, such as time to complete tasks, contrast use, fluoroscopy exposure time, and number of errors (e.g. advancement of catheters without guidewires, number of contacts of stiff wire with vessel wall), may not adequately reflect the quality of endovascular skill, and certainly, there is little evidence that improved performance in these metrics correlates with procedural experience or results in superior procedural outcomes.[33, 44, 45] The gold standard to observe surgical performance is the validated Objective Structured Assessment of Technical Skills (OSATS), consisting of a Global Rating Scale (GRS) and a procedure-specific checklist.[46] This OSATS is often modified to ensure that it can be used to evaluate a specific surgical procedure, e.g. for assessment of endovascular skills.[47] Procedure-specific rating scales for various endovascular procedures have also been developed, enabling evaluation of procedure-specific technical endovascular skills using post hoc video-based analysis of fluoroscopy screen images.

Assessment of non-technical skills

It has long been recognised that differentiation between novice and expert

performance of surgical procedures is based not solely on degrees of technical skill but also, and perhaps more importantly, on non-technical or human factor skills (Figure 2).

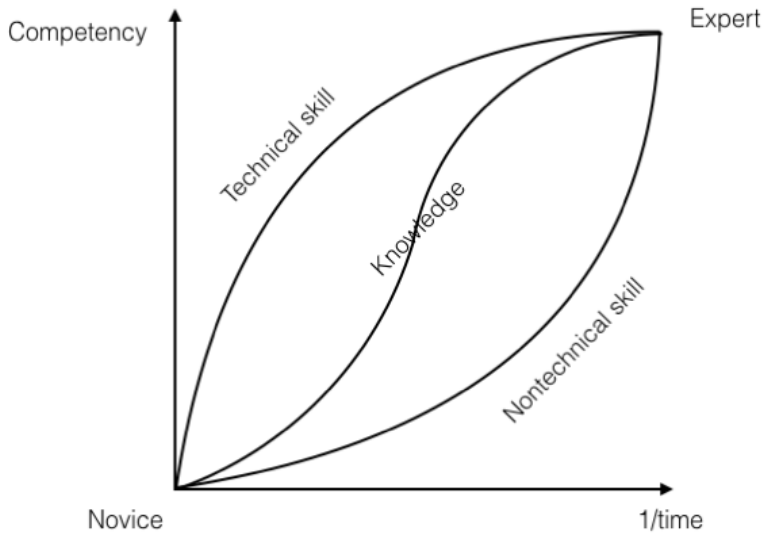

Figure 2. *The contributions of knowledge and technical and non-technical skills in the development from novice to expert performance.*[48]

Generic non-technical skills relate to how individuals interact within their team members and comprise both interpersonal (e.g. communication, teamwork, and leadership) and cognitive skills (e.g. decision-making, situational awareness, and mental readiness). Most intraoperative errors during endovascular procedures arise from failures in situation awareness, teamwork, and communication skills.[11, 49] Non-technical rating scales, such as the Oxford Non-Technical Skills Scale,[50] the Mayo High Performance Teamwork Scale,[51] and the Observational Teamwork Assessment for Surgery (OTAS),[52] may be used to evaluate non-technical skills and whole team performance. Recently, a novel teamwork assessment tool specifically designed to evaluate the quality of teamwork during endovascular procedures (Endo-OTAS) was developed, but further validation is required before it can be implemented in clinical practice.[53]

Assessment of error

A valid, reliable and clinically applicable error assessment tool is a prerequisite for error identification and analysis. Mason et al. described a structured error assessment tool for use in vascular and endovascular surgery, the Imperial College Error CAPture (ICECAP) record.[54] This tool has been developed from observational data and expert opinion and validated for capturing and categorising errors occurring in (endo)vascular procedures.[54] Primary failure categories are: equipment, communication, procedure-independent pressures (distractions, team member absence, external pressures), technical, safety awareness and patient-related. Each of the primary categories has a number of secondary fields. A failure was defined as any event that prevented the procedure from progressing in an ideal manner. The term failure encompasses different types: failures in the surgical system (system factors), human errors and sources of inefficiency. Major and minor failures were defined by their immediate consequences during surgery. Failures that caused intraoperative delay of more than 15 minutes, caused harm, or placed the patient at significant risk of harm were referred to as major failures. Harm was defined as injury to the patient evidenced by a physiological response to the injury (such as cardiovascular instability), or by the need for further invasive intervention.

The assessment tools used in this thesis are discussed in the respective chapters, and included in Chapter 8.

Patient-specific simulation in surgery

The next step in the evolution of endovascular simulation was the ability to incorporate real patient-specific data in the VR simulations. The principles and utility of the so-called procedure rehearsal, or mission rehearsal, are already well recognised in the fields of sports and music and other high-stakes industries.[55] Briefly, computed tomography angiography (CTA) or magnetic resonance images (MRI) are used to generate patient-specific 3D reconstructions using proprietary software. These 3D volume rendered images have various applications. The imagery can facilitate the comprehensive review of two-dimensional data that can otherwise be difficult to interpret.[56] The 3D reconstructions can also be used to provide ‘augmented reality’, by superposition of the 3D rendered imagery on the real

intraoperative view to provide 'a transparent view' and facilitate navigation.[57] The 3D information can also be incorporated into different VR simulator platforms for the purpose of simulated rehearsal and enable the practitioner and team to practice and treat 'real' cases on a virtual patient prior to performing the procedure on the actual patient (Figure 3). As such, patient-specific VR rehearsal (PsR) not only facilitates procedure planning (cognitive rehearsal) and technical hands-on practice (psychomotor rehearsal), but also enables team rehearsal.

Figure 3. *Stepwise process of the set-up of a patient-specific procedure rehearsal.*

Several reports only including small numbers have described the use of patient-specific simulation in the field of laparoscopy, orthopaedics, neurosurgery, and plastic surgery.[58-61] Face validity was most commonly investigated, but several authors also acknowledged the potential of patient-specific simulation as a preprocedural planning and rehearsal tool.[62]

PsR has mostly been used and evaluated in the endovascular field. The first mission rehearsal was conducted using a Procedicus Vascular Interventional System Trainer (Mentice AB, Gothenburg, Sweden) at EuroPCR prior to a live CAS procedure in 2005.[63] A high degree of similarity and a good correlation of endovascular device movement were noted between the simulated and actual patient case. However, the pre-processing of patient imagery required technological support from the company, and made it time-consuming, expensive and unpractical in the clinical setting.
In 2006 the commercially available PROcedure rehearsal studio software for the ANGIOMentor endovascular simulators (3D systems formerly Simbionix USA Corp., Cleveland, Ohio, USA) was launched, allowing a straightforward generation of simulations by physicians. This software enables an automated and manual

segmentation of MRI or CTA DICOM data of the vascular tree using a friendly user interface. The resulting simulated case contains a model of the patient's anatomy and replicates the visual and tactile aspects of the planned procedure for that particular patient. The simulator also records various objective assessment parameters (e.g. total procedure time, fluoroscopy time, contrast use) and tool selection, and enables the user to save procedural steps to create a preoperative strategic plan.

Scientific research performed by EVEREST (European Virtual reality Endovascular RESearch Team) initially focussed on the use of PsR prior to CAS using distal embolic protection systems, a complex and high-risk endovascular procedure. It was demonstrated that it is feasible to create patient-specific simulations using standard patient CTA or MRI imagery in different hospital settings.[64] This case-specific rehearsal prior to CAS influenced tool selection and fluoroscopy preferences of both experienced and inexperienced interventionalists,[65] and improved performances of novice interventionalists during a virtual CAS procedure compared to any generic simulation-based warm-up. [66] Part-task rehearsal (e.g. repeated cannulation of the common carotid artery) was shown to be equally effective as full-task rehearsal to enhance endovascular performance in a simulated CAS intervention as long as the most challenging part was identified, making the rehearsal less time-consuming and easier to implement in daily practice.[67] Finally, procedure rehearsal may also optimise patient selection, providing information on procedure complexity, specific hazards, and risk stratification.[68] In the actual operating room, a strong similarity between the simulated and real CAS procedures was noted.[63, 69, 70] Willaert et al. demonstrated that preoperative PsR performed by the endovascular team less then 24 hours before the real CAS procedure was rated highly because it provided valuable information about access strategy, selection of endovascular tools and choice of optimal C-arm angulation, although certain biomechanical vessel properties do need further improvement. The authors concluded that patient-specific CAS rehearsal has the potential to optimise preoperative preparation of the endovascular therapist and his team.[71]

In 2011, software became available to create patient-specific simulations of TEVAR and EVAR procedures, enabling the endovascular therapist to deploy different types

and sizes of stent grafts in patient-specific anatomy, to identify the optimal C-arm angulation – perpendicular to the aorta - to visualise the target landing zones and obtain maximal stent coverage (Figure 4), to identify potential hazards (e.g. errors in stent graft sizing, endoleaks) prior to implantation of the device in the real patient, and to optimise the team readiness.

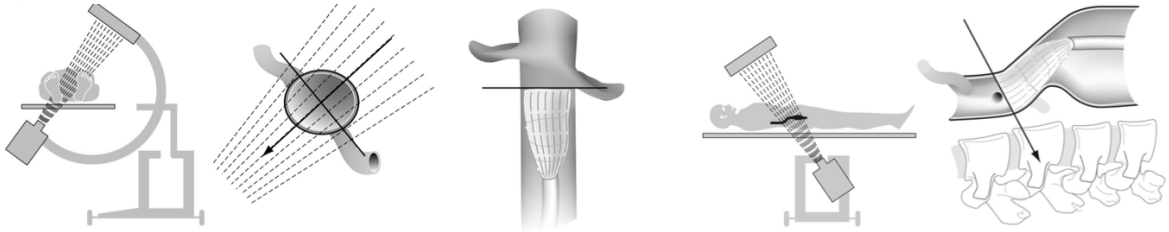

Figure 4. *Optimal C-arm angulation to visualise the proximal landing zone and obtain maximal stent coverage.*

Kendrick et al. demonstrated that patient-specific TEVAR rehearsal can improve performances of trainees during a virtual TEVAR case, with less experienced practitioners showing the greatest reduction in procedure and fluoroscopy time.[72] Kim et al. showed that PsR of an EVAR procedure can be used as a training tool for novice and experienced operators, as an instrument for evaluation by assessing performance measures such as procedure time, fluoroscopy time, and proximal stent coverage, and has potential as a planning tool.[73] However, these studies did not investigate whether the skills learned on the simulator transfer to real-world TEVAR and EVAR procedures.

Thesis outline

To allow a comprehensive evaluation of PsR for aortic disease, the following research questions were explored in consecutive studies that form the basis of this thesis.

1. Is it feasible to create realistic patient-specific TEVAR simulations and to conduct PsR prior to TEVAR in clinical daily practice? **(Chapter 2)**
2. Is it feasible to create realistic patient-specific EVAR simulations and to perform PsR prior to EVAR in clinical daily practice? **(Chapter 3)**
3. What are the potential benefits of conducting PsR prior to EVAR? **(Chapter 3)**
4. Does the use of PsR prior to EVAR increase patient safety? **(Chapter 4)**
5. Which practitioners and what type of infrarenal abdominal aneurysm may benefit from PsR prior to EVAR? **(Chapter 4)**
6. Is PsR prior to EVAR useful as a preoperative planning and briefing tool? **(Chapter 5)**
7. Does the use of PsR prior to EVAR lead to an increase in technical and non-technical performance? **(Chapter 5)**

Chapter 2 seeks to explore the feasibility of implementing patient-specific TEVAR rehearsal by evaluating the ease of generating a 3D reconstruction of the patient's relevant anatomy based on CTA data and performing subsequent patient-specific simulations on the VR simulator in two hospitals. The utility and practicality of conducting PsR with the endovascular team prior to performing the actual TEVAR procedure was evaluated by applying this technology in clinical practice. A secondary aim was to evaluate the face validity (realism) of the obtained patient-specific simulations.

Similarly, **Chapter 3** describes the prospective, multicentre pilot study conducted to evaluate the feasibility of creating realistic patient-specific EVAR simulations and performing the rehearsals with an experienced endovascular team prior to the real EVAR procedure. To evaluate if the process is consistent and reproducible, the set-up was replicated at three independent hospital institutions. The study evaluated the correlation between the virtual and real case with respect to realism, endovascular

materials used and fluoroscopy preferences, and enabled us to gain insight into the potential benefits of PsR prior to the actual procedure and the subjective advantages as rated by the team members involved.

Based on the promising results of the pilot study, a randomised controlled trial (RCT) was initiated in 6 centres across Europe to study the effect of PsR prior to elective EVAR on patient safety and procedural efficiency.
Hundred patients were randomised to preoperative patient-specific EVAR rehearsal or to the control group. Preoperative rehearsals were routinely performed by the endovascular team, consisting of the lead implanter, the assisting implanter and the scrub nurse.

The impact of PsR prior to EVAR on patient safety was studied by registering the number of errors that occurred during the real EVAR procedure and by assessment of technical performances, measured by operative metrics such as endovascular procedure time, fluoroscopy time, contrast volume, number of angiograms, and radiation dose. Additionally, we studied if the influence of PsR prior to EVAR is dependent on the complexity of the aneurysm repair or on the experience of the endovascular team. This research is described in **Chapter 4**.

The secondary outcomes of the RCT focussing on the utility of PsR prior to EVAR as a preoperative planning and briefing tool are described in **Chapter 5**. The influence of PsR on the treatment plan and the non-technical skills has been evaluated. The RCT also provided insight into the subjective sense of usefulness of this technology as rated by the team members involved.

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2

Patient-specific simulation of endovascular thoracic aortic repair: initial experience.

L. Desender[1]
I. Van Herzeele[1]
Z. Rancic[2]
C. Bicknell[3]
I. Zairis[4]
F. Vermassen[1]
J. Rundback[5]

Ann Thorac Surg 2017. In press.

[1]*Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium*
[2]*Department of Vascular Surgery, Zurich University Hospital, Zurich, Switzerland*
[3]*Department of Surgery and Cancer, St. Mary's Hospital, Imperial College, London, UK*
[4]*Department of Cardiothoracic Surgery, Holy Name Medical Center, Teaneck, NJ, USA*
[5]*Interventional Institute, Holy Name Medical Center, Teaneck, NJ, USA*

Abstract

Purpose

Endovascular thoracic aortic repair (TEVAR) has become the treatment modality of diverse aortic pathology. We report the use of patient-specific simulation using a dedicated PROcedure^{TM} Rehearsal Studio platform (Simbionix USA Corp., Cleveland, Ohio, USA) prior to TEVAR and evaluate the feasibility and realism of this technology.

Description

Virtual three-dimensional models of the patient's relevant anatomy were reconstructed from computed tomography data. In two patients PRS was used prior to TEVAR. In a multicentre retrospective observational study, we evaluated how PRS compares to real TEVAR.

Evaluation

PRS prior to TEVAR was feasible and demonstrated good correlation with the actual procedure. In the retrospective study, 16 cases were reconstructed (median duration 26 mins; IQR 21-36). The realism of the simulated angiographies was rated highly (median 4; IQR 3-4). Final angiography revealed type 1 endoleak in two simulated cases and one real case.

Conclusions

Patient-specific rehearsal prior to TEVAR is feasible and permits the creation of realistic case studies, but software updates are required to improve face validity and to foster implementation in clinical practice.

Introduction

Endovascular thoracic aortic repair (TEVAR) has revolutionised the treatment of aneurysms, dissections, and penetrating atherosclerotic ulcers with reduced procedural morbidity and mortality compared to open surgery.[1-3] Due to the anatomic complexity of the aortic arch and supra-aortic branches, optimal preparation using cross-sectional images and dedicated three-dimensional (3D) planning software is essential to choose the appropriate access site, endograft, and landing zones. Preoperative planning may also enhance team workflow, resource management and prevent errors.[4]

Planning has become routine but chances to “practice” endovascular thoracic procedures prior to treat the real case are limited. Recent advancements in medical simulation, i.e. patient-specific VR rehearsal (PsR), enable the endovascular team to practice and treat the aortic pathology on a virtual platform prior to treat the actual patient. These rehearsals may increase the procedural comfort, influence the selection of landing zones and devices, and optimise device deployment, resulting in improved technical success.

We describe two cases in which PsR was performed prior to TEVAR, and the results of a multicentre retrospective observational study evaluating the feasibility and realism of patient-specific TEVAR simulations.

Technology and technique

The PROcedure^{TM} Rehearsal Studio software (Simbionix USA Corp., Cleveland, Ohio, USA) was used to generate 3D reconstructions of the patient’s relevant anatomy (aorta, supra-aortic branches, celiac trunk, superior mesenteric artery, renal and iliac arteries) from patient-specific uploaded Computed Tomography Angiography (CTA) data. The 3D reconstruction of this data is achieved by the level set method of segmentation and is a partially automated step. Manual enhancement of aortic side branches, e.g. carotid artery may be required. Next, bony landmarks are assigned to the arterial reconstruction as fiducial references to indicate the correct location of the vasculature with respect to the virtual fluoroscopy imagery of the spine and pelvis. Calculation of the vessel centreline is done automatically for the aorta and iliac arteries, but for the supra-aortic branches it has to be performed

manually. The end result is a 3D reconstruction with a centreline that can be uploaded to form the scaffold for the VR simulation (Figure 1). The ANGIO Mentor™ Express Dual Access Simulation System (Simbionix USA Corp., Cleveland, Ohio, USA) was used to conduct the patient-specific simulations. Technical details have previously been described.[5]

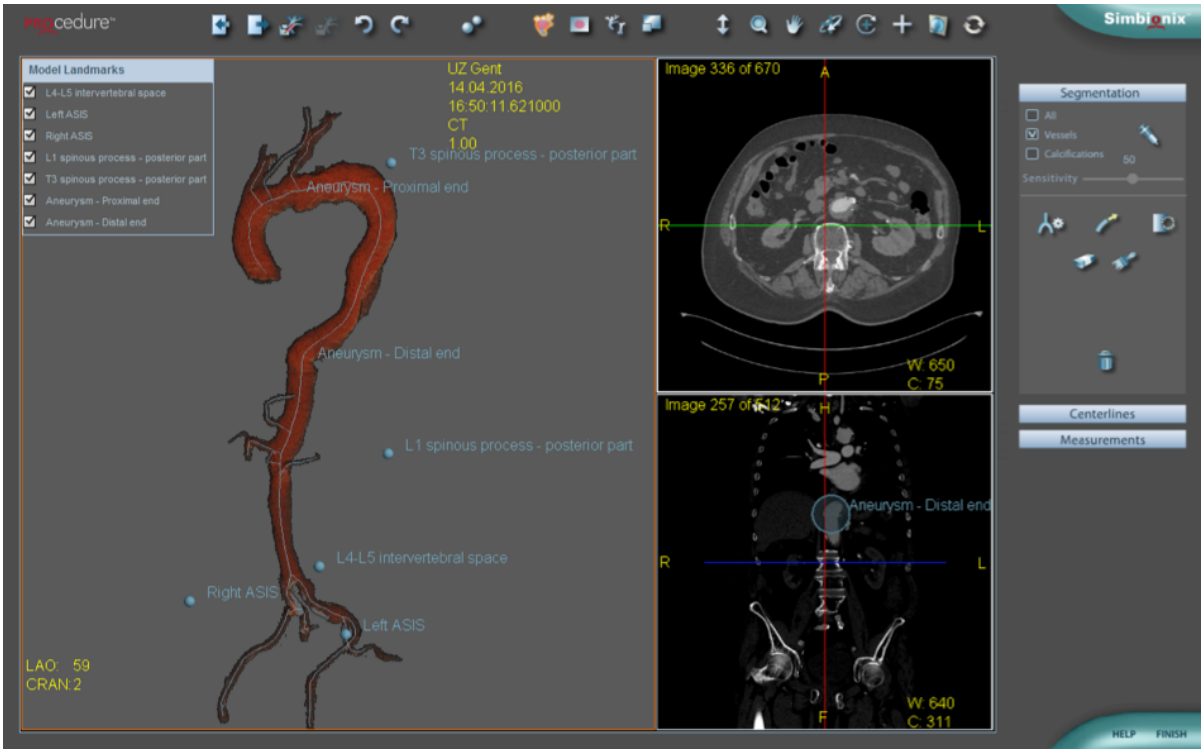

Figure 1. *Construction of a virtual three-dimensional model with the Simbionix PROcedure™ rehearsal software.*

Clinical experience

Case 1 (Figure 2)

A 71-year-old gentleman with a chronic type B aortic dissection extending from the left subclavian artery (LSA) to the celiac trunk, initially managed medically, presented with aneurysmal dilatation of the distal aortic arch and proximal descending thoracic aorta to a maximal diameter of 60 mm. The treatment plan was to cover the origin of the LSA with a stent graft to obtain a good proximal landing zone and to successfully exclude the aneurysm. Pre-emptive revascularization of the LSA was performed by a transposition to the left common carotid artery. Based on the CTA data, a 3D reconstruction of the patient's relevant anatomy was created. Immediately before the

TEVAR, the endovascular team (lead implanter, assistant and scrub nurse) performed the PsR. The simulation was completed in 16 minutes. Based upon the rehearsal, a 55° left anterior oblique was identified as the optimal C-arm angulation for visualization of the proximal and distal landing zone, which was confirmed by angiographic images in real life. In the simulated and actual TEVAR, the thoracic aneurysm was successfully excluded using two Valiant® Thoracic stent grafts (Medtronic Vascular, Santa Rosa, CA, USA) introduced via a left femoral access. No complications occurred and the patient was discharged after four days. Follow-up CTA at two months showed complete thrombosis of the false lumen in the treated segment.

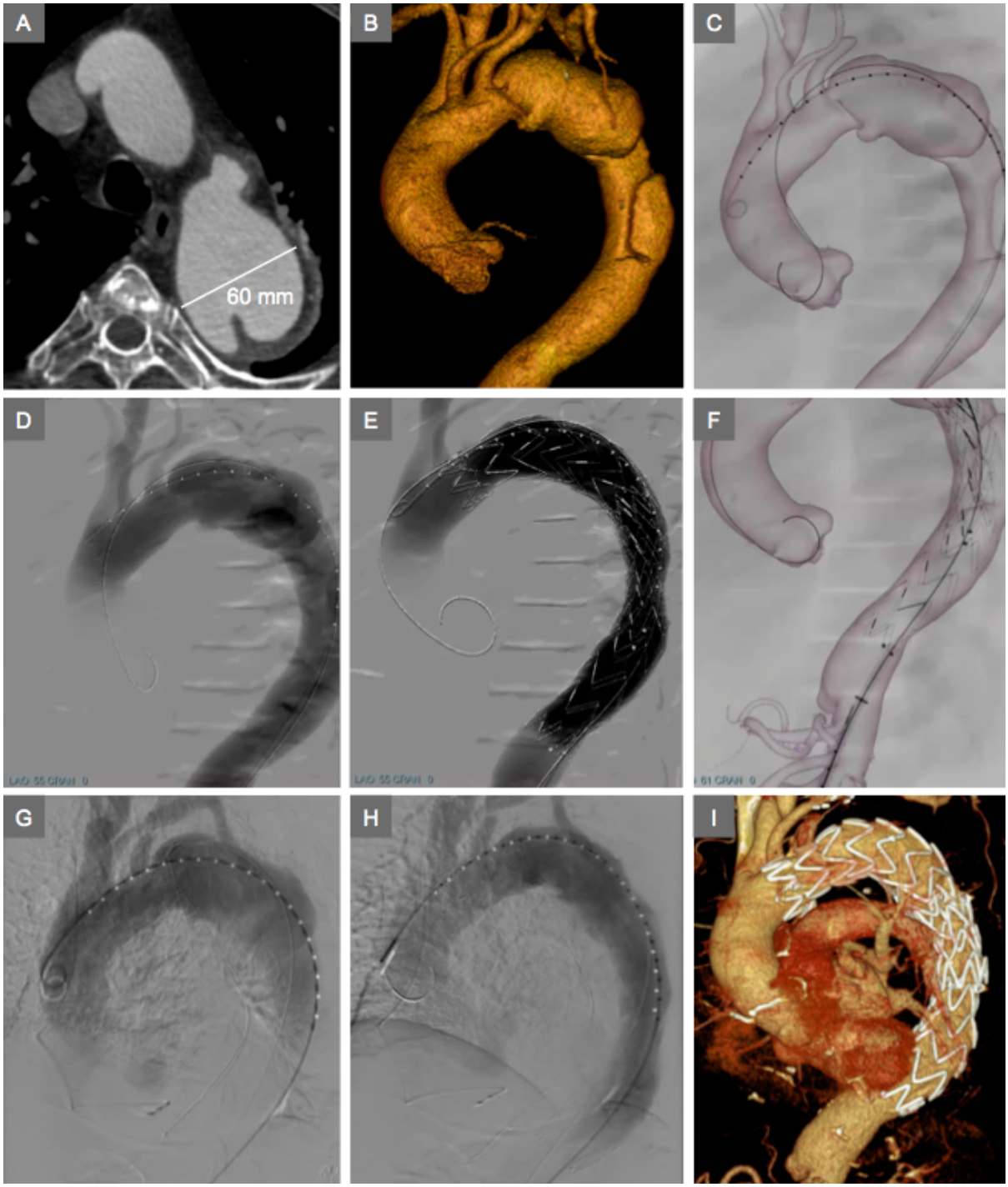

Figure 2. *Patient with chronic type B dissection and aneurysmal dilatation of the distal aortic arch and proximal descending thoracic aorta. (A) Computed Tomography Angiography shows an aneurysm with maximal diameter of 60 mm. (B) Surface rendered three-dimensional (3D) reconstruction. (C) Virtual 3D model reconstructed with the Simbionix PROcedure™ rehearsal studio software. Based upon simulation, a 55° left anterior oblique was identified as the optimal C-arm angulation to visualise proximal (D) and distal (E-F) landing zone. Angiographic images of the real TEVAR with identical projections for the proximal (G) and distal (H) landing zone show excellent correlation. (I) Surface rendered 3D reconstruction at 2 months follow-up.*

Case 2 (Figure 3)

A 79-year-old male with a past medical history of chronic obstructive pulmonary disease, hypertension and dyslipidaemia presented with an enlarging thoracic arch aneurysm (maximum diameter of 74 mm), extending to the LSA (< 5 mm) and less than two centimetres from the left common carotid origin. Due to the short proximal neck endograft implantation between the left carotid and LSA (zone 2) with subsequent open carotid subclavian bypass was planned. Procedural simulation was performed by the endovascular team the day before the actual procedure, and was critical in identifying the optimal oblique fluoroscopic projection (75° left anterior oblique) for graft deployment within zone 2 to preserve the ostium of the left carotid artery. Endograft selection using a single 42 mm diameter x 15 cm Gore cTAG® (W.L. Gore & Associates, Inc., Sunnyvale, California, USA) was verified during PsR. During rehearsal, the graft was initially deployed distal to the LSA but subsequently repositioned on the virtual platform so that the proximal end abutted the left carotid artery. The actual procedure was performed via percutaneous right femoral approach. There was excellent correlation with the PsR anatomy, graft selection, and C-arm angulations resulting in exclusion of the thoracic aneurysm. Subsequently, the planned left carotid subclavian bypass was carried out and the LSA was ligated. The patient recovered uneventfully and was discharged home four days post TEVAR.

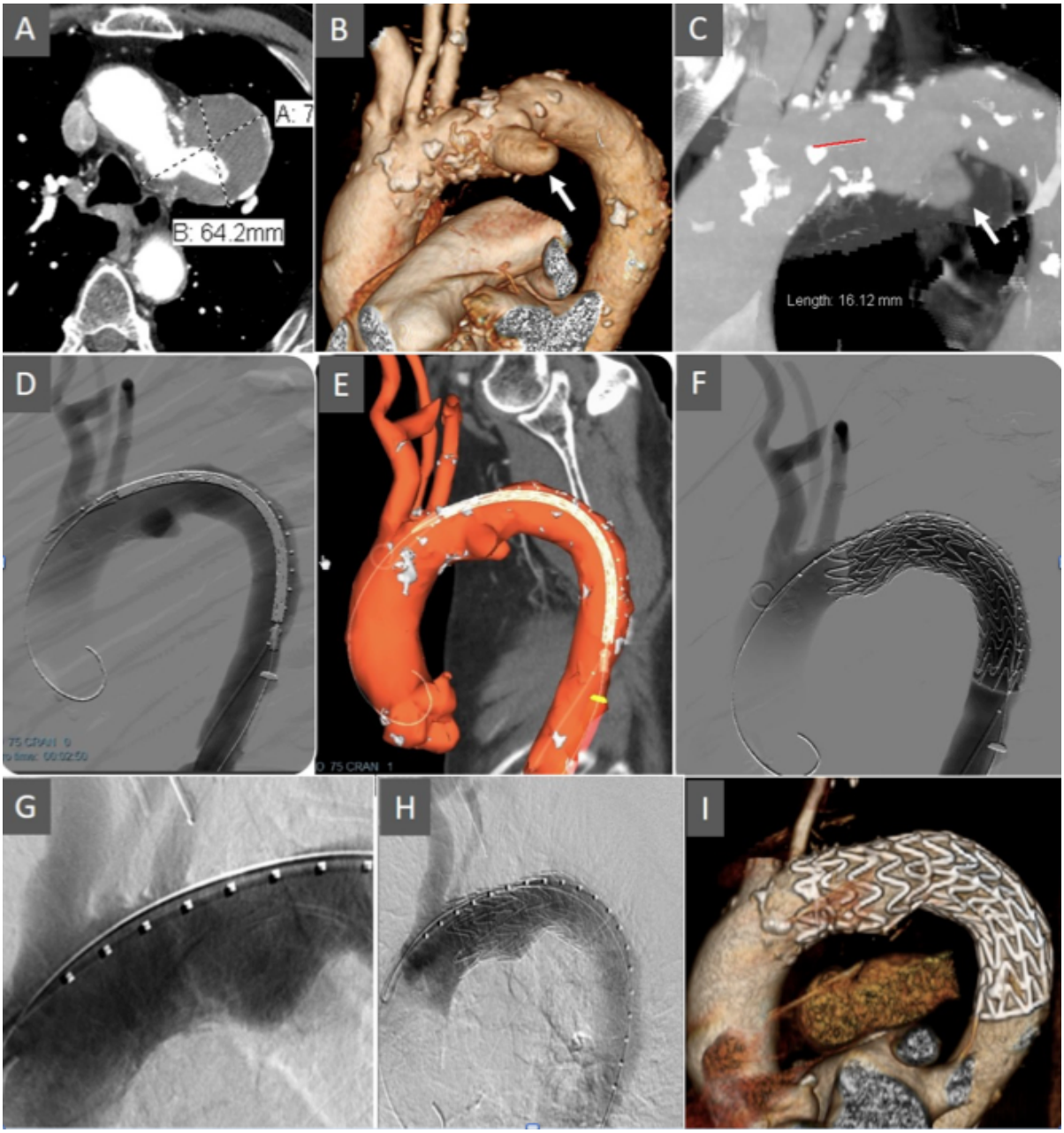

Figure 3. *79-year-old patient with thoracic arch aneurysm in close proximity to the left subclavian artery. The aneurysm is well seen on the axial CT images (A) as well as on surface rendered (B) and maximum intensity pixel (C) reconstructions. Simbionix PROcedure™ rehearsal studio software images during simulation show graft positioning in subtracted and contrast overlay modes (D-E) and after deployment (F). Based upon the simulation, a 75° left anterior oblique was identified as the optimal projection for identifying the aortic branch origins for graft deployment. Angiographic images from the actual TEVAR procedure (G-I) show excellent correlation with the simulation images and successful implantation preserving the left carotid artery.*

Retrospective study

We conducted a multicentre retrospective study to evaluate how patient-specific simulated TEVAR compares to real TEVAR. Patients with a thoracic aortic aneurysm (TAA), a traumatic aortic injury (ATAI), or a penetrating aortic ulcer (PAU) suitable for endovascular repair using the Gore cTAG® or Medtronic Valiant® thoracic stent grafts were included in three vascular centres. The 3D model of the patient's anatomy was generated. Pre-, intra- and postoperative imaging were evaluated. Two independent vascular surgeons completed a questionnaire addressing the realism of the angiographic images and stent graft deployment. Responses were rated on a Likert scale from 1 (not at all) to 5 (very much).
28 patients (12 TAA, 13 ATAI, 3 PAU) were screened but only 16 patients (8 TAA, 5 ATAI, 3 PAU) were included. Nine patients were excluded because of incomplete imaging (e.g. images of iliac arteries unavailable), making 3D case creation impossible. An additional three cases were excluded because the device selection in the real procedure could not be reproduced during simulation (the stent graft used in real life was considered undersized by the simulator software and disappeared after deployment; the selected stent graft could not be deployed at the level of the aortic arch because the simulated introducer sheath was too short; and the order of deployment of different stent grafts (large to small diameter) could not be replicated) (Figure 4).

3D reconstruction of the cases took a median of 26 (interquartile range (IQR) 21 to 36) mins, and largely depended on the quality of the CTA scan and the underlying aortic pathology. The simulations were performed by the lead researcher and focused on the most important steps of the procedure (e.g. angiographies to visualise the landing zones, device deployment). The median time needed to complete the simulations was 5 mins (IQR 4 to 6 mins). Additional data are provided in Table 1.

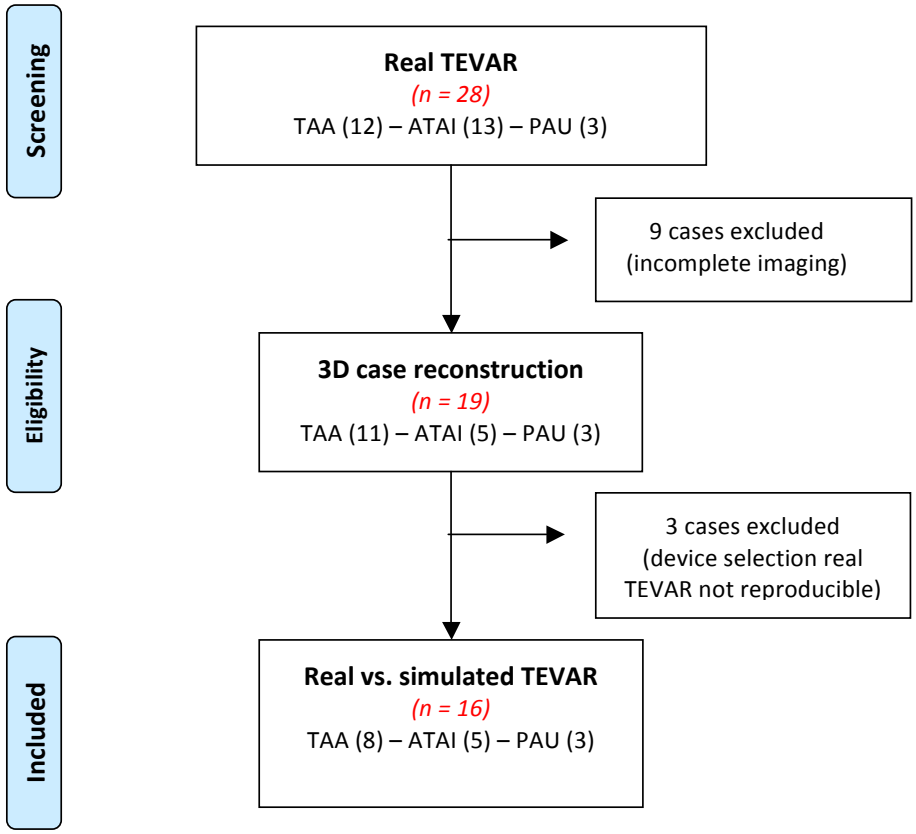

Figure 4. *Flow diagram of the retrospective multicentre trial evaluating the realism of patient-specific rehearsal of thoracic endovascular aortic repairs (TEVAR).*
TAA: thoracic aortic aneurysm; ATAI: acute traumatic aortic injury; PAU: penetrating aortic ulcer.

	Total time 3D reconstruction (mins)	Segmentation (mins)	Landmarks (mins)	Centreline (mins)	Time to complete simulation (mins:secs)
All cases (n=16)	26 (21-36)	17 (12-25)	2 (2-3)	7 (6-8)	5:13 (4:06-5:57)
TAA (n=8)	28 (20-32)	19 (12-25)	2 (2-3)	7 (5-8)	5:24 (4:19-7:23)
ATAI (n=5)	38 (24-38)	21 (16-29)	2 (2-2)	7 (6-8)	5:20 (4:10-5:52)
PAU (n=3)	23 (21-24)	11 (10-12)	2 (2-3)	10 (8-10)	4:08 (3:31-5:34)

Table 1. *Time needed for 3D reconstruction of the CTA data and for performing the simulation.*
Values are median (interquartile range). TAA: thoracic aortic aneurysm; ATAI: acute traumatic aortic injury; PAU: penetrating aortic ulcer.

The realism of the simulated angiographic images of the proximal (median 4; IQR 3-4) and distal (median 4; IQR 4-5) landing zone, and the deployment of the stent graft (median 4; IQR 3-4) was rated highly.

Endoleaks occurred in ten simulated and five real cases. Final angiography revealed an endoleak in two simulated cases and in one real case. However, there was a poor correlation between the simulated and real cases: the same type of endoleak was observed in only one case, while none of the final angiographies revealed the same type of endoleak in the simulated and real procedure (Table 2).

Endoleak	**Patient-specific simulation**		**Real TEVAR**		**Similar endoleak simulated & real TEVAR**	
	During case	**Final angiography**	**During case**	**Final angiography**	**During case**	**Final angiography**
TAA (n=8)	5/8 *(4x1a, 3x1b)*	1/8 *(1a)*	4/8 *(3x1a, 4x1b)*	1/8 *(1b)*	1/8	0/8
ATAI (n=5)	2/5 *(1x1a, 1x1b)*	1/5 (1a)	0/5	0/5	0/5	0/5
PAU (n=3)	3/3 *(2x1a, 1x1b)*	0/3	1/3 *(1b)*	0/3	0/3	0/3

Table 2. *Endoleaks occurring during the patient-specific simulation and during the real thoracic endovascular aortic repair (TEVAR).*
TAA: thoracic aortic aneurysm; ATAI: acute traumatic aortic injury; PAU: penetrating aortic ulcer; 1a: endoleak type 1a; 1b: endoleak type 1b.

Comment

To our knowledge, this is the first report on the use of PsR prior to TEVAR. Similar to previous research on case-specific rehearsal of endovascular infrarenal aneurysm repair,[5] this report demonstrates that patient-specific TEVAR rehearsal can be created and implemented in the clinical setting, with realistic imaging of the proximal and distal landing zone. PsR may help to identify optimal imaging projections for

device deployment, reconfirm device selection and implantation, detect potential endoleaks or vascular compromise, and optimise team preparation and confidence.
However, the software has its limitations. The time required to reconstruct the 3D model largely depends on the quality of the CT scan. The ideal scan ranges from lower neck till pubis with 1 mm slices in the arterial phase. In hemodynamically unstable patients (e.g. patients with ATAI) the reconstruction may be more challenging and time consuming. Importation of segmentations created with dedicated 3D sizing software or predefined templates may offer a solution in the near future. Secondly, the biomechanical properties are not accurately replicated in the simulated cases, e.g. crossing stenotic or heavily calcified lesions and deployment of the stent graft. Thirdly, the occurrence of type 1 and 3 endoleaks in the simulated setting is based upon instructions for use provided by the manufacturer, and does not always reflect real life. The use of finite element analysis to evaluate the mechanical interaction between endovascular equipment and the vasculature, could lead to a significant improvement.[6] Finally, the time, expertise, and equipment (software and hardware) needed to generate 3D reconstructions and to practice the simulated cases add considerable costs. On the other hand, simulator costs (acquisition and maintenance) can be diminished, since these can be used for training various endovascular procedures at different training levels, while staffing costs can be addressed by performing rehearsals with the endovascular team in between cases or during the preoperative preparation of the actual patient.
In conclusion, setting up PsR prior to TEVAR is feasible in clinical practice. It permits creation of realistic case studies, which may be useful to evaluate and optimally prepare the case prior to treat the actual patient. However, software updates are crucial to improve face validity and enable implementation of this technology in clinical practice.

Funding

The ANGIO Mentor™ Express Dual Access Simulation System and Simbionix PROcedure™ rehearsal studio software are in clinical use at Ghent University Hospital and Holy Name Medical Center. No additional funds were needed for this study. The authors had full control of the design of the study, methods used, outcomes, data analysis, and production of the written report.

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3

Patient-Specific Rehearsal prior to EVAR: a Pilot Study.

L. Desender[1]
Z. Rancic[2]
R. Aggarwal[3]
J. Duchateau[4]
M. Glenck[2]
M. Lachat[2]
F. Vermassen[1]
I. Van Herzeele[1]

Eur J Vasc Endovasc Surg 2013;45:639-647.

[1]Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium
[2]Department of Cardiovascular Surgery, Zurich University Hospital, Zurich, Switzerland
[3]Department of Biosurgery and Surgical Technology, St. Mary's Hospital, Imperial College, London, UK
[4]Department of Vascular Surgery, Sint-Maarten Hospital, Duffel, Belgium

Abstract

Objectives

To evaluate feasibility, face validity, influence on technical factors and subjective sense of utility of patient-specific rehearsal (PsR) prior to endovascular aortic aneurysm repair (EVAR).

Design

A prospective multicentre observational pilot study.

Methods

Patients suitable for EVAR were enrolled and a three-dimensional (3D) model of the patient's anatomy was generated. Less than 24 hours prior to the real case, rehearsals were conducted in the laboratory or clinical angiosuite. Technical metrics were recorded during both procedures. A subjective questionnaire was used to evaluate realism, technical and human factors aspects (scale 1 to 5).

Results

Ten patients were enrolled. In one case, the treatment plan was altered based on PsR. In 7/9 patients, the rehearsal significantly altered the optimal C-arm position for the proximal landing zone and an identical fluoroscopy angle was chosen in the real procedure. All team members found the rehearsal useful for selecting the optimal fluoroscopy angle (median 4, IQR 4-5). The realism of the EVAR procedure simulation was rated highly (median 4, IQR 3-4). All team members found the PsR useful to prepare the individual team members and the entire team (median 4, IQR 4-5).

Conclusions

PsR for EVAR permits creation of realistic case studies. Subjective evaluation indicates that it may influence optimal C-arm angles and be valuable to prepare the entire team. A RCT is planned to evaluate how this technology may influence technical and team performance, ultimately leading to improved patient safety.

Introduction

Various drivers are currently pushing the use of VR simulation in healthcare, e.g. growth in medical knowledge, changes in medical education, the European Working Time Directive, patient availability and patient safety. Much of the stimulus behind the focus on the patient safety dates to the Institute of Medicine 2000 report 'To Err is Human: Building a Safer Health System'.[1] This report increased the level of public and institutional awareness of the high prevalence of medical errors in modern healthcare and proposed medical simulation as an efficient tool to enhance physician training, by allowing skills acquisition and training of procedures in a safe and controlled environment where patients cannot be harmed.

Subsequently, extensive research by EVEREST (European Virtual reality Endovascular RESearch Team) and others was conducted to establish the role of VR simulation as a training and assessment tool for teaching and practicing endovascular techniques to physicians at various levels of experience.[2-7]

In accordance with the developments in other high-stake industries, such as military,[8] aerospace and in the domains of music and sports the next step in medical simulation science was the development of patient-specific VR rehearsal (PsR). This technology allows a patient-tailored approach in various domains of surgery, enabling the practitioner and his/her team to perform and practice 'real' cases on a virtual patient prior to performing the procedure on the actual patient. It has also been referred to as 'mission' or 'procedure' rehearsal.

In the endovascular field, PsR prior to carotid artery stenting (CAS) procedures is feasible in various hospital settings.[9] The rehearsals, including endovascular tool selection and angiographies, are regarded as realistic.[10-13] Furthermore, it is suggested that case-specific rehearsal for CAS may have the potential to tailor endovascular tool choice, enhance non-technical skills, and improve patient safety.[14, 15] Recently, this novel technology has been developed to practice endovascular infrarenal aortic aneurysm repairs (EVAR).

The objectives of this research project are firstly to evaluate if creating PsR for EVAR is feasible, secondly how it may influence technical factors, thirdly to evaluate face validity and finally the subjective sense of utility rated by endovascular teams.

Materials and Methods

Patient inclusion

All patients with an infrarenal abdominal aortic (AAA) or iliac aneurysm suitable for endovascular exclusion with the Gore® Excluder® AAA endoprosthesis using the Gore® C3 Delivery System (W.L. Gore & Associates, Inc., Sunnyvale, California, USA) were eligible for inclusion in the study. Prior to inclusion, patients at two academic and one district hospital provided informed consent to use their computed tomography (CT) imagery and to record (anonymous) video's of the EVAR procedure.

Relevant items of the anatomic severity grading (ASG) scale (Table 1), developed by the ad hoc Committee for Standardized Reporting Practices in Vascular Surgery/American Association for Vascular Surgery, were used to describe the anatomic diversity and complexity of the aneurysm.[16] The ASG score can be calculated from CT images with the aid of three-dimensional (3D) image-rendering software and correlates with the technical difficulty of EVAR.[17]

Three-dimensional model reconstruction

The Simbionix PROcedure™ rehearsal studio software (Simbionix USA Corp., Cleveland, Ohio, USA) was used to generate 3D reconstructions of the patient's relevant anatomy. They were created by the lead researcher (L.D.). CT data in DICOM (Digital Imaging and Communications in Medicine) format were uploaded by means of a CD-ROM, on which the imaging from a local Picture Archiving and Communication System (PACS) client was saved.

The 3D data reconstruction of the anatomy of interest (e.g. aorta and iliac arteries) is achieved by the level set method of segmentation. It is a partially automated step although manual enhancement of the 3D model is usually required. Calcification of the vessel wall is also automatically reconstructed. The celiac trunk, superior mesenteric artery and renal arteries need manual augmentation.

The next step consists of assigning three bony landmarks to the arterial reconstruction, which serve as anchors that indicate the correct location of the vasculature with respect to the rest of the anatomy in the simulator (virtual fluoroscopy imagery of the thoracic and lumbar spine, and the pelvis).

Calculation of the vessel centreline is done automatically for the aorta and iliac arteries, but for the celiac trunk, superior mesenteric artery and both renal arteries it should be performed manually. The end result is a 3D reconstruction with a centreline that can be uploaded into the VR simulations to form the scaffold for the VR simulation (Figure 1).

During the creation phase of the 3D model reconstructions, findings (e.g. time to create an adequate 3D model, difficulties with vessel segmentation, centreline calculation or simulation software) were recorded in field notes by the lead researcher (L.D.) and document analysis was performed.[18]

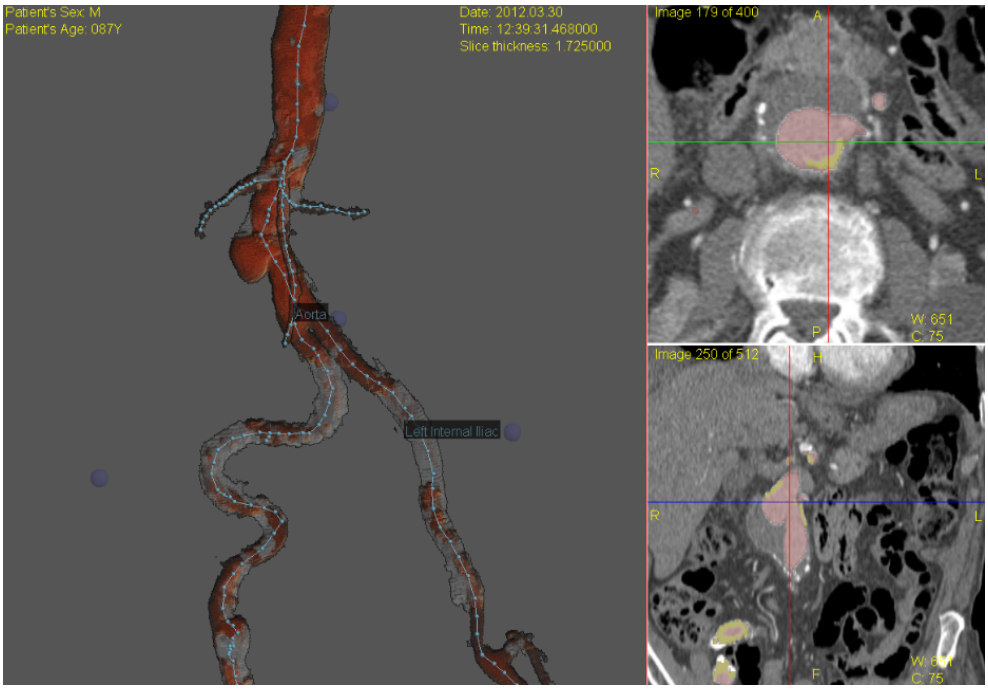

Figure 1. *3D segmentation with the Simbionix PROcedure™ Rehearsal software.*

Simulator device

The ANGIO Mentor™ Express Dual Access Simulation System (Simbionix USA Corp., Cleveland, Ohio, USA) was used to conduct the patient-specific simulations. The simulator is a part-task VR device and consists of two haptic devices, a laptop and two LCD screens. The two haptic hardware devices allow the user to perform endovascular procedures that require simultaneous access from two sites, insert and manipulate guidewires, deploy balloons, stents and stent grafts. Table movement, C-arm positioning and use of an aortic pump are available.

Interventional team and simulation environment

In two hospitals the interventional team consisted of a lead interventionalist, an assistant, a scrub nurse, a circulating nurse and an anaesthetist. In the other unit, the latter was not included since all EVAR procedures were performed under local anaesthesia. The circulating nurse was only included in three rehearsals. Subsequently, the anaesthetist and circulating nurse were both excluded from further analysis. The remaining team members completed a questionnaire to assess their endovascular and EVAR experience and exposure to VR simulators.

Preoperative rehearsals were carried out in the laboratory, the operating room (OR) or the real angiosuite ('in-situ' simulation) and were chosen upon availability.[15] The operating table, fluoroscopy screens and the simulator were placed identically to the real life setting (Figure 2).

Figure 2. *Patient-specific rehearsal with the interventional team: 'in-situ simulation (top) and corresponding real intervention in the angiosuite (bottom).*

Study design

A 3D reconstruction and VR simulation was created for every case. Rehearsals were carried out within 24 hours of the actual EVAR intervention. The same team performed the real EVAR intervention at Ghent and Zurich University Hospital in the angiosuite (hybrid operating room), at St. Maarten Hospital the patient was treated in the OR.

Technical factors

Before and after the rehearsal, the lead interventionalist completed a questionnaire with his selection of C-arm angulation to adequately visualise the target landing zones based on dedicated 3D workstations and case-specific rehearsal. C-arm positioning was recorded during both the simulated and real EVAR procedure. A change of at least ten degrees in either cranio-caudal or oblique fluoroscopy angle was considered to be clinically significant. Similarly, an 'identical' C-arm positioning was defined as a change of less than ten degrees of fluoroscopy angulation for both cranio-caudal and oblique views between the simulated and real procedure.

Automatically recorded simulator metrics and the corresponding values in real life were used to evaluate technical performances. These included total procedure time, fluoroscopy time, contrast volume and number of angiographies taken, starting from the introduction of the first guidewire to removal of the last guidewire.

Subjective questionnaire

A questionnaire was put forward to each team member after the real EVAR procedure. This questionnaire was created by three vascular surgeons with experience in EVAR and endovascular VR simulation. Questions addressed simulation realism (e.g. images, endovascular tool manipulation), effectiveness on technical issues, communication and teamwork. Responses were rated on a Likert scale from 1 (not at all) to 5 (very much). Participants also had the possibility to write down any suggestions or comments (Appendix 1, Chapter 8).

Data analysis

Data were entered in the Statistical Package for the Social Sciences version 20.0 (SPSS, Chicago, Illinois, USA). Non-parametric tests were applied for data analysis. The Mann-Whitney U test was used to compare groups (simulation versus real

operation) for continuous variables; the Chi-Square test was used for categorical variables. A level of $p<0.05$ was considered to be statistically significant. All data are presented as median values unless otherwise indicated. Interquartile ranges are noted in parentheses.

Results

Patient demographics

Between March and June 2012, ten consecutive patients were enrolled. Nine had an infrarenal aortic aneurysm with a maximum outer diameter of at least 55 mm; one patient had a small aortic aneurysm (42 mm) and a left common iliac aneurysm of 50 mm.

One patient presented with a pseudoaneurysm at the level of the proximal anastomosis after previous open abdominal aortic aneurysm repair with an aortobifurcated graft. During the preoperative rehearsal of this case a type 1a endoleak occurred (Figure 3). Based on a case review instigated by this practice run, the physician altered his treatment plan. The intervention was postponed and the aneurysm was successfully excluded using a stent graft with suprarenal fixation. This case was excluded from further analysis.

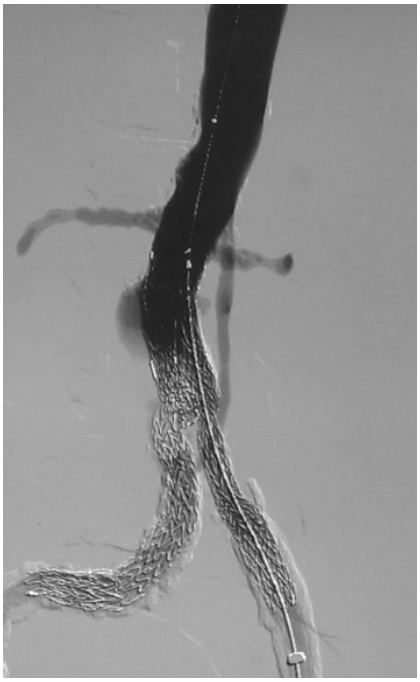

Figure 3. *Type 1a endoleak observed during patient-specific EVAR rehearsal.*

Patient demographics and anatomical aneurysm characteristics are summarised in Table 1.

The nine patient-specific rehearsals and nine real EVARs were carried out successfully. No major adverse events occurred.

Age (y)	74 (64-89)			
Gender M/F	9/0			
Maximal outer diameter AAA (mm)	58 (42-65)			
Aortic neck: length (mm)	21 (12-49)			
Aortic neck: diameter (mm)	21 (19-24)			
	Absent	**Mild**	**Moderate**	**Severe**
Aortic neck: calcification/thrombus	8/9	1/9	0/9	0/9
Suprarenal angle	6/9	2/9	0/9	1/9
Infrarenal angle	2/9	1/9	4/9	2/9
Iliac artery: calcification	0/9	7/9	1/9	1/9
Iliac artery: angle	0/9	1/9	6/9	2/9
Iliac artery: tortuosity index	0/9	3/9	4/9	2/9

Table 1. *Patient demographics (medians (range)).*
M/F: male/female. Categorical Scores (Absent, Mild, Moderate and Severe) according to the anatomic severity grading (ASG) scale.[16]

3D model reconstruction

The degree of automated segmentation is heavily dependent on the quality of the initial DICOM dataset. Multiple factors such as patient motion and streaking artefacts, overriding bone, adjacent vascular structures, insufficient contrast enhancement or inappropriate slice thickness may lead to an inadequate automated segmentation, requiring manual enhancement of the 3D model. Furthermore, both common iliac arteries should be accessible. Otherwise, centreline calculation is defective and a simulation cannot be started. Ideally, the entire aorta should be scanned to increase the realism of the rehearsal. Centreline calculation of the aorta and its side branches was uncomplicated. This process only failed if touching vessels were present in the original segmentation. It occurred predominately between the common iliac and hypogastric arteries, and was easily manually

corrected by returning to the initial segmentation. Assignment of bony landmarks to the arterial reconstruction was uncomplicated and not time-consuming.
Of the initial 10 CT angiographies, all could be reconstructed. Overall, a reconstruction took between 60 and 180 minutes, mainly influenced by the quality of the CT scan images.

Interventional team and simulation environment

One rehearsal was performed in the angiosuite, two in the OR and six in the laboratory environment. Seven different teams, consisting in total of 24 team members, performed the simulated and real EVAR procedures. Each team differed from another by at least one team member. A preceding training session accustomed all team members to the simulator setup. The lead interventionalists were consultants and experienced practitioners who had performed more than 500 endovascular procedures and the majority (7/9) had performed at least 50 EVAR procedures as the primary operator. Five of them were vascular surgeons, four were interventional radiologists. However, in three rehearsals the assistant (N=3) and/or scrub nurse (N=2) was inexperienced in EVAR (<10 EVAR). In three cases, the scrub nurse was not present during the case rehearsal.

Technical factors

Patient specific VR rehearsals were performed more rapidly than the corresponding life EVAR cases (total procedure time, median 32 (IQR 24-41) vs. 43 (IQR 39-60) mins, p=0.015) (Figure 4). Fluoroscopy time (13 mins (IQR 11-16) vs. 10 mins (IQR 8-18), p=0.35), the amount of contrast used (80 mls (IQR 75-97) vs. 80 mls (IQR 61-92), p=0.42) and the number of angiographies taken to complete the endovascular exclusion of the aneurysm (5 (IQR 4-8.5) vs. 6 (IQR 4.5-7), p=0.79) were similar between simulated and real cases.

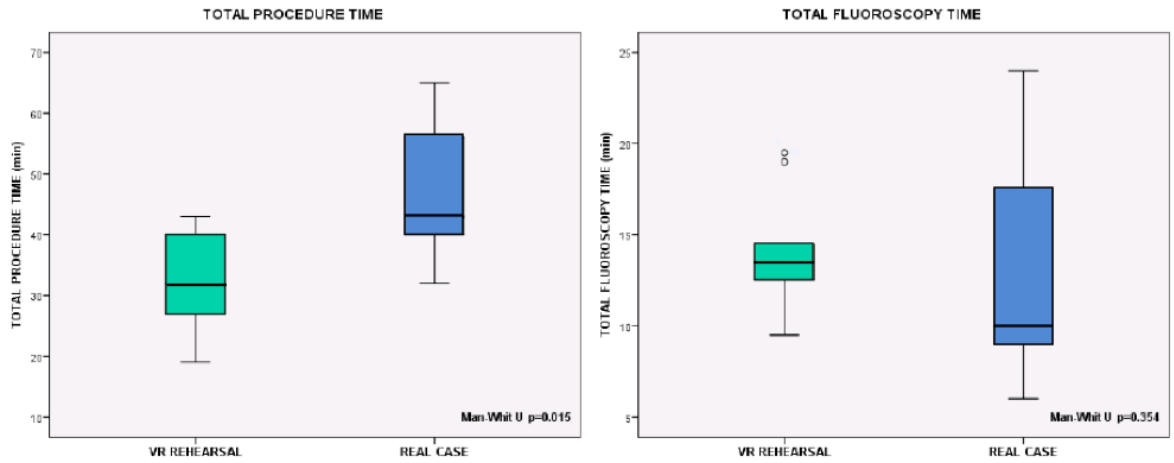

Figure 4. *Total time and fluoroscopy time for the virtual and real cases.*

In 7/9 patients, the C-arm angulation to visualise the infrarenal aneurysm neck and the optimal proximal landing zone was modified significantly after the rehearsal. In six patients, the cranio-caudal or oblique fluoroscopy preferences changed and in one patient, both angles were altered following the rehearsal. In real life, identical fluoroscopy angles were chosen in 6/9 patients. In the remaining three cases, identical oblique or cranio-caudal angulations were selected.

To visualise the distal contralateral landing zone C-arm angulations were altered significantly in 6/9 patients, and identical angulation was used in 4/9 of the real cases. In another two cases, identical cranio-caudal or oblique view was chosen.

In one case, a type 1b endoleak was observed during the simulation. An additional angiography of the contralateral limb could identify this endoleak in the real case, and supplementary moulding of the endoprosthesis was required (Figure 5).

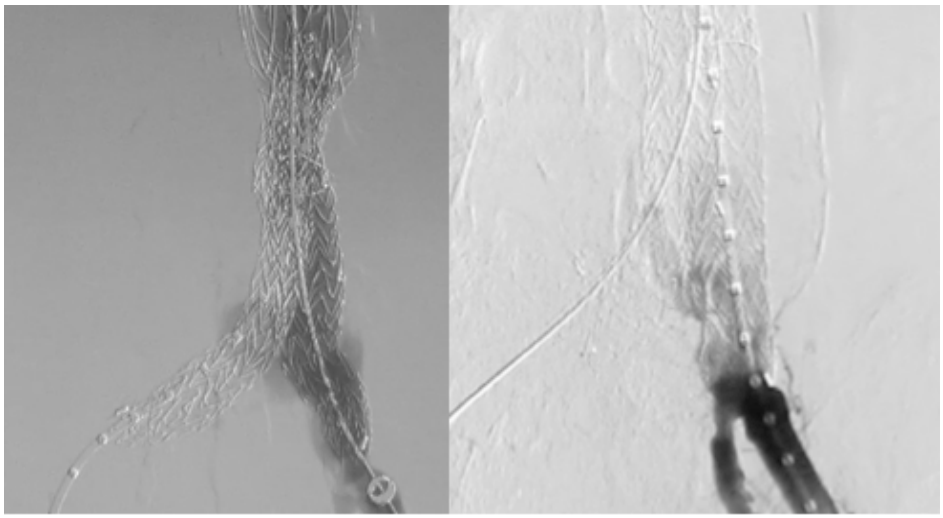

Figure 5. *Type 1b endoleak observed during simulation (left) and real procedure (right).*

Subjective questionnaire

Subjective questionnaires were completed by all team members (N=24). Table 2 summarises the overall scores for the rating of the face validity and subjective evaluation of the procedure rehearsal potential. The realism of the simulated EVAR procedure, including the simulated angiographies of the aorta and iliac vessels were rated highly by each team member. However, experienced team members rated the realism of the simulated angiographies significantly higher than the inexperienced team members (median 4 vs. 3, p=0.032). All team members found the rehearsal especially useful for selecting the optimal C-arm angulation to adequately visualise the target landing zones. Furthermore, it was considered to be valuable to optimally prepare the entire team and to improve communication and teamwork. All team members thought case-specific rehearsal may lead to increased patient safety. Compared to the lead interventionalist, both the assistant and the scrub nurse thought the rehearsal to be significantly more effective at increasing overall efficiency of tool use (median 4 (assistant) and 4.5 (scrub nurse) vs. 3, p=0.001) and communication with the circulating nurse (median 4 vs. 3, p=0.006). The scrub nurse found the rehearsal significantly more effective than the lead interventionalist and assistant for understanding their role during the intervention (median 4.5 vs. 4, p=0.004). Furthermore, scrub nurses indicated that their preconceived thought of how the procedure would be performed was altered more frequently (median 4 vs. 3, p=0.007).

No notable differences were seen between the experienced and inexperienced team members for the various items described above.

Free text comments by all physicians (N=9) indicated that the biomechanical properties of the simulation (e.g. catheterization contralateral limb, stent deployment, stretching of the vessel by wire insertion) were not accurately replicated in the preoperative simulation. This became more apparent in non-calcified, tortuous iliac vessels.

	Median	**IQR**
Realism of		
• Procedure simulation	4	3-4
• Angiography aorta	4	3-5
• Angiography iliac vessels	4	4-4
PsR is useful		
• For selecting the optimal C-arm angulation	4	4-5
• To practice the 'real' case prior to treat the actual patient		
- For the individual team members	4	4-5
- For the entire team	4	4-5
• To review the case preoperatively	4	4-4
• To identify potential difficulties	4	4-4
• To increase		
- Coordination	4	4-4
- Communication	4	3-4
- Confidence	4	3-4
PsR may lead to increased patient safety	4	3-4
PsR influenced the choice of		
• Guidewire	2	2-3
• Selective catheter	3	2-3
• Diameter of the stent graft	2.5	2-3.75

Table 2. *Face validity and subjective evaluation of patient-specific procedure rehearsal potential. Scores are for all team members combined. Ratings are on a Likert scale from 1 (not at all) to 5 (very much). PsR: Patient-specific rehearsal.*

Discussion

This study presents the first scientific report on PsR prior to EVAR. Similar to previous research on case-specific rehearsals for CAS interventions,[9-13, 19] this pilot study has shown that it is feasible to set up and use PsR for EVAR in the clinical setting, with an excellent level of face validity. The most important finding is the potential of this novel technique to influence decision-making of the interventionalist and his/her team during the real procedure.

In the majority of cases, PsR was able to predict and alter fluoroscopy preferences for optimal visualisation of the proximal and distal landing zones during the real intervention. PsR not only facilitates procedure planning (cognitive rehearsal, comparable to dedicated 3D planning workstations) but also permits a hands-on rehearsal of the actual procedure (psychomotor rehearsal). Consequently, it may enable the physician and team to familiarise with the behaviour of a chosen device in a particular anatomy, identify potential hazards (e.g. endoleaks) and alter the treatment plan (e.g. select a device with suprarenal instead of infrarenal fixation). This is particularly valuable for complex procedures such as EVAR, as it is well established that the technical difficulty and 30-day mortality of EVAR is dependent on factors related to individual anatomic patient considerations, operator experience and hospital volume.[17, 20, 21] These findings were supported by the subjective ratings from the experts and team members regarding the usefulness of PsR prior to EVAR for preoperative planning, practicing and preparation of the entire team.

The choice of tool kit, size of the device, and the number of iliac extensions were not altered in this study, probably due to meticulous preoperative sizing on dedicated workstations by experienced teams.

Besides its important role as a technical adjunct to the interventionalist, PsR may also be applied to enhance non-technical skills.[14, 15] This finding is supported by the results from this study, as team members regarded PsR as a valuable tool to increase coordination, communication and confidence during the real procedure.

Several limitations of the current generation of simulation rehearsal capabilities have been described.[9] Similar to this report, the 3D reconstruction of the relevant vasculature was identified as the most variable and time-consuming step in the

whole process. Subsequently the quality of the CT DICOM data is of major influence for both the set-up time and the quality of the simulated rehearsal.

Furthermore, biomechanical properties were often not accurately replicated in the preoperative simulation, e.g. cannulation of the contralateral limb, absence of vessel straightening by insertion of guidewires and deployment of the stent graft. Several authors have noted this phenomenon for CAS rehearsals as well.[11, 15] The integration of additional biomechanical characteristics, using finite element analysis to evaluate the mechanical interaction between endovascular equipment and the vasculature, could lead to a significant improvement.[22] However, increasing levels of simulator fidelity do not automatically translate into higher quality performances and improved transfer of skills.[23-25]

Additionally, VR rehearsals depend on simulator availability and add a considerable cost, potentially affecting the cost-effectiveness of the rehearsed procedures. However, staffing costs can be addressed by performing rehearsals during the preoperative preparation of the patient. Furthermore, simulator costs (acquisition and maintenance) can be distributed, as they have a wide range of use, e.g. training, familiarisation of OR personnel and assessment.

Potential limitations introduced in this study include a relatively small number of cases.

Furthermore, the median length of the proximal aortic neck is quite long. It reflects that the use of PROcedure™ rehearsal studio software is currently limited to the rehearsal of cases with an anatomy suitable for endovascular exclusion using a device with infrarenal fixation. Although this study demonstrated that PsR may be useful to determine which cases are not suitable for exclusion using this device with infrarenal fixation, this may have an impact on decision-making and subjective evaluation of the interventionalist and his/her team. Additionally, the software only allows the rehearsal of an entire EVAR procedure. Ideally, the physician should be able to go back and forth, return to a particular step, deploy various devices, and practice merely challenging parts of the intervention (part-task rehearsal).[12]

Additionally, only experienced interventionalists and team members were evaluated using this new technology. Although this allowed for an accurate comparison of the virtual and corresponding real operation, it presumably underestimated the inherent value of PsR. Less experienced operators and team members may benefit more

from this technology as their tool choices, fluoroscopy preferences and team interactions are less automated, especially for complex procedures.[26]

In conclusion, the results from this pilot study indicate that setting up a PsR prior to EVAR is feasible for various anatomies in different hospital settings. It permits creation of realistic simulated case studies, rated highly by endovascular experts. Although the impact on selecting endovascular tools seems limited, EVAR rehearsals may influence fluoroscopy preferences and alter the treatment plan. Furthermore, it may be useful to evaluate the real case, identify potential pitfalls and increase confidence within the team.
Further research will evaluate the potential of PsR prior to EVAR to increase patient safety by optimising patient and device selection, improving preoperative planning, preventing complications and reducing radiation dose and identifying for which patients (anatomy) and physicians (experience) preoperative rehearsal may be useful. A randomised controlled trial has been initiated to investigate if this new technology may enhance technical and non-technical performance, clinical safety and efficiency, i.e. if patients actually benefit from physicians and team members conducting PsR of EVAR interventions.

Funding

Rajesh Aggarwal is funded by a Clinician Scientist Award from the National Institute for Health Research, Department of Health, U.K.
This study was technically supported by Simbionix, Cleveland, USA. However, they did not interfere in the study design, data collection, analysis or interpretation of the data nor in the decision to submit the manuscript for publication.

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4

Patient-specific Rehearsal Before EVAR: Influence on Technical and Non-technical Operative Performance. A Randomised Controlled Trial.

L. Desender[1]
I. Van Herzeele[1]
M. Lachat[2]
Z. Rancic[2]
J. Duchateau[3]
N. Rudarakanchana[4]
C. Bicknell[4]
J. Heyligers[5]
J. Teijink[6]
F. Vermassen[1]
On behalf of the PAVLOV Study Group

Ann Surg 2016;264:703-709.

[1]Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium
[2]Department of Vascular Surgery, Zurich University Hospital, Zurich, Switzerland
[3]Department of Vascular and Thoracic Surgery, St. Maarten Hospital, Duffel, Belgium
[4]Department of Surgery and Cancer, St. Mary's Hospital, Imperial College, London, UK
[5]Department of Vascular Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands
[6]Department of Vascular Surgery, Catharina Hospital, Eindhoven, The Netherlands

Abstract

Objective

To assess the effect of patient-specific virtual reality rehearsal (PsR) prior to endovascular infrarenal aneurysm repair (EVAR) on technical performance and procedural errors.

Background data

Endovascular procedures, including EVAR, are executed in a complex multidisciplinary environment, often treating high-risk patients. Consequently, this may lead to patient harm and procedural inefficiency. PsR enables the endovascular team to evaluate and practice the case in a virtual environment prior to treating the real patient.

Methods

A multicentre, prospective randomised controlled trial recruited 100 patients with a non-ruptured infrarenal aortic or iliac aneurysm between September 2012 and June 2014.

Cases were randomised to preoperative PsR or postoperative PsR. Primary outcome measures were errors during the real procedure and technical operative metrics (total and endovascular procedure time, fluoroscopy time, contrast volume, number of angiograms, and radiation dose).

Results

There was a 26% (95% confidence interval (CI): 9-40%; p=0.004) reduction in minor errors, a 76% (95% CI: 30-92%; p=0.009) reduction in major errors and a 27% (95% CI: 8.2-42%, p=0.007) reduction in errors causing procedural delay in the PsR group.

The number of angiograms performed to visualise proximal and distal landing zones was respectively 23% (95% CI: 8-36%; p=0.005) and 21% (95% CI: 7-32%; p=0.004) lower in the PsR group.

Conclusions

PsR prior to EVAR can be used in different hospital settings by teams with various EVAR experience. It reduces perioperative errors and the number of angiograms required to deploy the stent graft. Ultimately, it may improve patient safety and procedural efficiency.

Introduction

Endovascular aneurysm repair (EVAR) is an established treatment for infrarenal aortic aneurysms (AAA) with excellent results in patients with a suitable aorto-iliac anatomy. It is increasingly used to exclude aneurysms with less favourable anatomy and even ruptured aneurysms.[1-3] Patient outcomes are related to individual patient anatomy, operator and team experience, and hospital volume.[4, 5]

Vascular procedures, and AAA repair in particular, pose several complex safety risks and have substantially higher adverse event rates than major nonvascular procedures. Moreover, the incidence of preventable adverse events is high (8.1%), and these events mostly related to technique errors.[6] Additionally, Albayati et al. found that the incidence of intraoperative events is amplified within the endovascular environment.[7]

The 2000 Institute of Medicine report, “To Err is Human”, highlighted the incidence of medical errors in modern healthcare and their impact on patient safety, and recommended the use of medical simulation to enhance physician training.[8] It has inspired a continuous evolution of medical simulation, resulting in the development of patient-specific virtual reality rehearsal (PsR).[9] This technology enables the practitioner and team to practice ‘real’ cases on a virtual patient prior to performing the procedure on the actual patient. Previous research by our group has established that PsR prior to carotid artery stenting (CAS) and EVAR is feasible and that it may improve preoperative planning and preparation of the endovascular team.[10, 11]

This randomised controlled trial (RCT) aims to evaluate the effect of PsR prior to EVAR on patient safety and procedural efficiency.

Methods

Trial Design and Participants

This study is a prospective, multicentre, parallel-group trial that randomised patients with an AAA or iliac aneurysm suitable for EVAR to either preoperative PsR (intervention group) or postoperative PsR (control group). The trial was conducted in six vascular centres, each of which perform at least 30 elective EVAR procedures per year: two centres in Belgium (one academic, one district hospital), two in The Netherlands (district hospitals), one in Switzerland (academic) and one in the United

Kingdom (academic). EVAR was carried out in a hybrid angiosuite with a fixed fluoroscopy unit or in an operating theatre with a mobile system.

Eligible participants were adults aged 18 or over with an AAA or iliac aneurysm suitable for endovascular exclusion with the Gore® Excluder® AAA endoprosthesis using the Gore® C3 Delivery System (W.L. Gore & Assoc., Sunnyvale, California, USA) or with the Endurant® (Medtronic Vascular, Santa Rosa, California, USA) stent graft. Both AAA within and outside instructions for use (IFU) were included. The suitability for EVAR was based upon the physician's evaluation. Participants with a previous stent graft implanted in the abdominal aorta were excluded.

Based on preoperatively acquired Computed Tomography Angiography (CTA) data, the lead researcher (LD) created a three dimensional (3D) reconstruction of the patient's relevant anatomy, using the Simbionix PROcedure™ rehearsal studio software (Simbionix USA Corp., Cleveland, OH, USA). This 3D model forms the scaffold for the patient-specific simulations. A virtual reality simulator (ANGIO Mentor™ Express Dual Access Simulation System, Simbionix USA Corp., Cleveland, OH, USA) was used to conduct the PsR. Technical details have previously been described in the pilot study.[11] Three members of the endovascular team (lead implanter, assistant, and scrub nurse) were familiarised to the simulator set-up and subsequently performed the preoperative rehearsal less than 24 hours before the actual EVAR procedure.

The trial protocol was approved by the institutional review boards or ethics committees at each trial site and registered at ClinicalTrials.gov (NCT01632631). All patients gave written informed consent before enrolment. All theatre staff were informed about the research and provided verbal consent.

Randomisation, blinding and sample size

Patients were randomised to either the intervention or the control group in a 1:1 ratio using a computer-generated list. Randomisation was by block permutations, with a block size of four. The allocation sequence was concealed from the researcher (LD) enrolling and assessing patients by using sequentially numbered, opaque sealed envelopes. Randomisation took place after obtaining informed consent and creating the 3D model. Outcome assessors and data analysts were blinded to the allocation. Since recent literature does not provide any data regarding the primary outcomes of

this trial, a power analysis could not be performed. A number of 50 patients per group was chosen as a sufficient and achievable target.

Outcomes

The primary outcomes of this study were the number of errors occurring during the actual EVAR procedure and the technical performance measured by operative metrics. Additionally, in-hospital and 30-day mortality were reported.

Errors

For every EVAR procedure, the lead researcher (vascular surgeon) noted in real-time from incision to skin closure any event that prevented the procedure progressing in an ideal manner. These events were recorded and categorised using the Imperial College Error CAPture (ICECAP) tool (Appendix 2, Chapter 8).[12] Six primary failure categories have been defined: equipment, communication, procedure-independent pressures (distractions, team member absence, external pressures), technical, safety awareness and patient-related. Additional information about persons or items involved, circumstances, timing of the event (whether or not during the rehearsed part of the procedure) and estimated delay were also recorded. The determination of a 'true error' and assessment of the severity (minor or major) and estimated delay of the error were independently performed by two investigators who were unaware whether the incident occurred in the intervention or the control group. Events classified as non-errors were excluded from further analysis. The definitions used to classify incidents are provided in Table 1.

Term	Definition
Error	Any event that prevented the operation progressing in an ideal manner (from knife-to-skin to final suture). Events occurring before knife to skin should be excluded. Anticipated patient related problems (e.g. tortuosity of vessels, obesity) should be excluded.
Minor error	Error that causes minimal or no disruption to the operation (less than 15 mins delay), does not cause harm directly, and does no have the potential to harm in the majority of circumstances. Seemingly inconsequential
Major error	Error that causes major disruption to the operation (more than 15 mins delay), causes harm directly, or has the potential to cause harm in the majority of circumstances. Potentially dangerous or harm-producing
Harm	Injury to a patient as evidenced by physiological response to the injury (e.g. patient has cardiovascular consequences from blood loss), or necessitated further intervention (i.e. additional invasive procedure, does not include additional angiograms). Intraoperative harm may have occurred with or without further sequels (lasting disability).

Table 1. *Definitions of errors used in the study.*

Technical operative metrics

Total and endovascular (starting from the introduction of the first guide wire to removal of the last guide wire) procedure time, fluoroscopy time, contrast medium use, number of angiograms, and patient radiation dose in dose area product (DAP) were recorded. Angiograms were divided into 3 groups: number of angiograms performed until deployment of the main body of the stent graft, reflecting the angiograms needed to visualise the optimal proximal landing zone; number of angiograms performed until deployment of all stent grafts (including main body, contralateral limb, and iliac extensions), reflecting the angiograms needed to visualise proximal and distal landing zones, and total number of angiograms, including those to evaluate and treat potential endoleaks.

In a separate analysis, the primary outcomes were corrected for difficulty of the aneurysm repair and experience of the endovascular team. The complexity of the aneurysm repair was evaluated using the Anatomic Severity Grading (ASG) score. This score was developed by the ad hoc Committee for Standardized Reporting Practices in Vascular Surgery/American Association for Vascular Surgery and has been validated.[13, 14] An experienced endovascular team was defined as a team consisting of at least two (out of three) team members who had performed (lead interventionalist) or assisted (assistant, scrub nurse) at least 50 EVAR cases.

Statistical analysis

All analyses were performed using SAS® 9.4 (SAS Institute Inc., NC, USA) and using an intention-to-treat basis. The Kappa statistic was used to investigate inter-rater reliability of error assessment. The number of errors was compared between the intervention and the control group using unadjusted and adjusted (covariates aneurysm difficulty and team experience) Poisson regression. Multiple Poisson regression was used to test the interaction between randomisation group and team experience. A two-sample t-test and adjusted (covariates aneurysm difficulty and team experience) linear regression were applied to the log transformed technical operative metrics. The interaction between randomisation group and team experience was also tested using linear regression. All analyses were considered significant at the 5% level.

Results

Study population

Between September 2012 and June 2014, 100 patients (90% male) were enrolled at the six trial centres and randomised to the two study groups. Figure 1 shows the flow of patients through the trial.

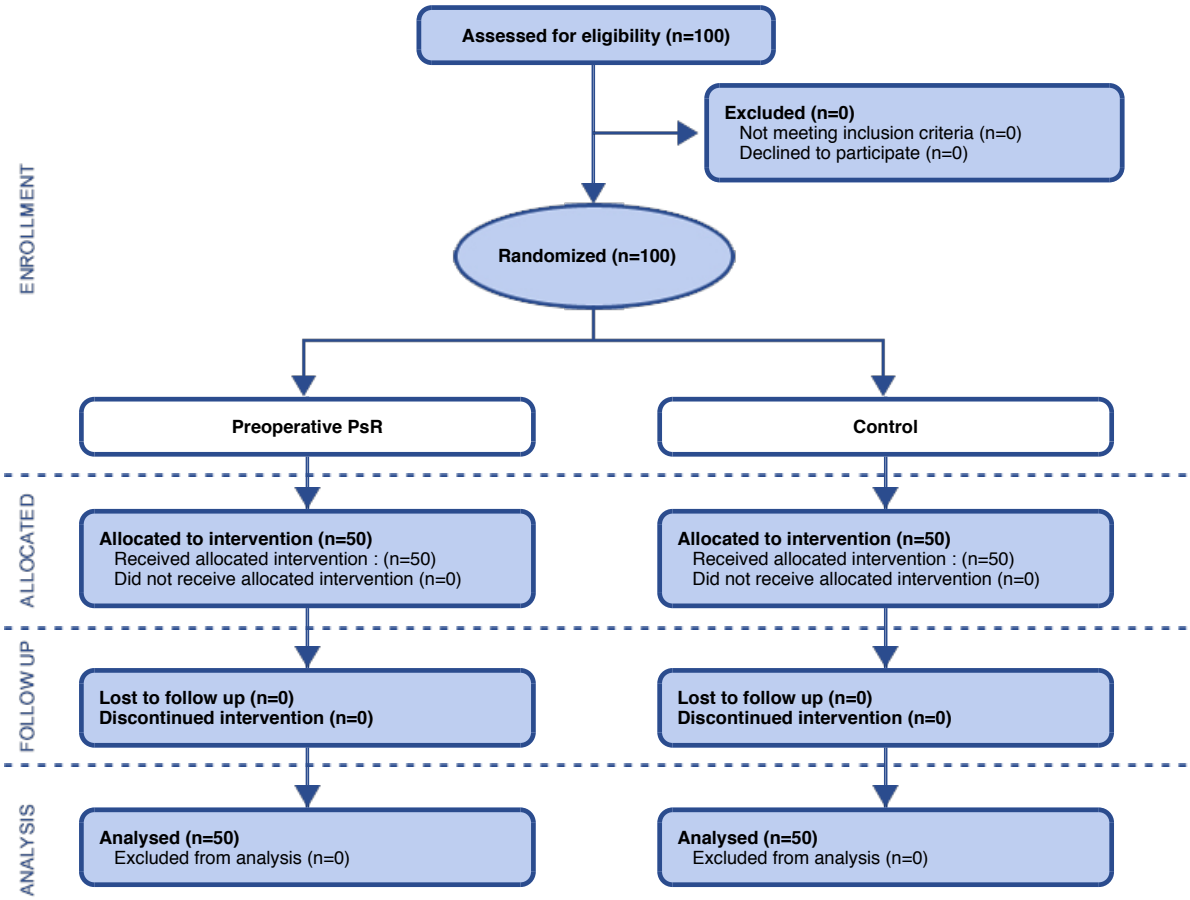

Figure 1. *CONSORT 2010 diagram showing flow of patients through the trial.*

Baseline variables including age, sex, maximal aneurysm diameter, ASG score and treatment within or outside IFU, were balanced between the groups (Table 2).
No patient was excluded from the analysis.

Variable	Intervention group (n=50)	Control group (n=50)
Age (years)	72 (11)	68 (20)
Male sex	43 (86%)	47 (94%)
ASA classification		
ASA II	22 (44%)	22 (44%)
ASA III	28 (56%)	26 (52%)
ASA IV	0	2 (4%)
Maximum aortic diameter (mm)	59 (14)	57 (9)
ASG score	27 (7)	27 (7)
Within IFU	35 (70%)	28 (56%)
Brand device		
Gore® Excluder®	32 (64%)	29 (58%)
Medtronic Endurant®	18 (36%)	21 (40%)
Academic Centre	29 (58%)	32 (64%)
Hybrid angiosuite	30 (60%)	28 (56%)
Experienced team	32 (64%)	36 (72%)

Table 2. *Baseline characteristics randomised by group.*
Values are means (SD) or numbers (%). ASA: American Society of Anaesthesiologists; IFU: instructions for use; ASG score: Anatomic Severity Grading score[13]

Outcomes

Errors

A total of 410 potential errors were identified and two independent assessors rated 390/410 (95%) of these events as 'true errors'. Both raters assessed the severity (i.e. minor or major error) similarly in 370/390 (95%) errors, with a good to excellent inter-rater reliability (Kappa=0.61, 95% CI 0.46 to 0.76). The majority of errors (122/390) was related to technical issues (e.g. unfamiliarity with the procedure, equipment or techniques). The number of minor errors occurring during the entire procedure and the endovascular (rehearsed) part of the procedure was significantly lower (-26 %; 95% CI -40 to -9%, p=0.004 and -21%; 95%CI -36 to -2%, p=0.03 respectively) in the intervention group compared to the control group. Similarly, the number of major

errors arising during the complete procedure and the endovascular part was significantly lower (-76 %; 95% CI -92 to -30%, p=0.009 and -82%; 95%CI -96 to -18%, p=0.03 respectively) in the intervention group. Additionally, the number of errors causing delay was significantly lower in the intervention group (-27%; 95% CI -42 to -8.2%, p=0.007), as was the number of errors occurring during the non-endovascular part of the procedure (-70%; 95% CI -86 to -35%, p=0.003). After multiple Poisson regression with correction for complexity of the aneurysm repair and team experience, the positive effect of PsR on the reduction of minor and major errors remained significant. Additional data are provided in Table 3 and 4.

Variable	Number of errors per EVAR		Difference intervention vs. control group	95% confidence interval	p-value*	p-value multivariate analysis‡
	Intervention group	Control group				
	Mean (95% CI)					
Minor errors Complete procedure	3.14 (2.67 to 3.67)	4.24 (3.71 to 4.85)	-25.9%	-39.8 to -9.0%	0.004	0.002
Minor errors Endovascular part	3.02 (2.58 to 3.54)	3.82 (3.32 to 4.40)	-20.9%	-36.1 to -2.1%	0.03	0.02
Major errors Complete procedure	0.08 (0.03 to 0.21)	0.34 (0.21 to 0.55)	-76.5%	-92.1 to -30.1%	0.009	0.009
Major errors Endovascular part	0.04 (0.01 to 0.16)	0.22 (0.12 to 0.40)	-81.8%	-96.0 to -18.0%	0.03	0.03
Total errors Endovascular part	3.06 (2.61 to 3.59)	4.04 (3.52 to 4.64)	-24.3%	-38.6 to -6.6%	0.01	0.006
Total errors Non-endovascular part	0.16 (0.08 to 0.32)	0.54 (0.37 to 0.79)	-70.4%	-86.5 to -34.8%	0.003	0.002
Errors without delay	0.78 (0.57 to 1.07)	1.20 (0.93 to 1.55)	-35.0%	-56.6 to -2.7%	0.04	0.04
Errors causing delay	2.46 (2.06 to 2.94)	3.38 (2.91 to 3.93)	-27.2%	-42.3 to -8.2%	0.007	0.003

Table 3. *Errors occurring during procedure by randomised group.*

** Univariate Poisson regression*

‡ multiple Poisson regression with correction for aneurysm difficulty and team experience

Variable	Total number of errors (%)	Number of errors per EVAR Intervention group Mean (95% CI)	Control group Mean (95% CI)	Difference intervention vs. control group	95% confidence interval	p-value*
Technical issues	122/390 (31%)	0.78 (0.57 to 1.07)	1.64 (1.32 to 2.04)	-52.4%	-67.5 to -30.4%	< 0.001
• Minor errors	108/368 (29%)	0.70 (0.50 to 0.97)	1.46 (1.16 to 1.84)	-52.1%	-68.0% to -28.3%	< 0.001
• Major errors	14/22 (64%)	0.08 (0.03 to 0.21)	0.18 (0.10 to 0.35)	-55,6%	-86,4% to 44,3%	0,18
PIP	92/390 (23%)	0.86 (0.64 to 1.16)	0.98 (0.74 to 1.30)	-12.2%	-41.7 to 32.2%	0.53
Equipment	83/390 (21%)	0.84 (0.62 to 1.14)	0.84 (0.62 to 1.14)	0.0%	-34.8 to 53.4%	1.0
Communication	76/390 (19%)	0.60 (0.42 to 0.86)	0.92 (0.69 to 1.23)	-34.8%	-58.8 to 3.3%	0.07

Table 4. *Main categories of errors occurring during procedure by randomised group*
PIP: Procedure-independent Pressure
** Univariate Poisson regression*

Technical operative metrics

The number of angiograms performed until deployment of the main body of the stent graft and until deployment of all implanted stent grafts was significantly lower (-23 %; 95% CI -8 to -36%; p=0.005 and -21%; 95%CI -7% to -32%; p=0.004 respectively) in the preoperative PsR group compared to the control group. After multiple linear regression with correction for complexity of the aneurysm repair and team experience, the effect of PsR on both outcomes remained significant (p= 0.007 and p=0.005 respectively). No statistically significant differences were noted between groups for other technical operative metrics (Table 5).

The effect of simulation on the primary outcomes was similar for experienced and inexperienced teams, except for major errors occurring during the complete procedure (p=0.03). For the experienced team there was a more pronounced effect of PsR on the total number of major errors.

In-hospital mortality was 1/50 (2%) in the control group and 0/50 (0%) in the intervention group (p=1.00). 30-day mortality was 1/50 (2%) in the control group and 2/50 (4%) in the intervention group (p=1.00), of which one was aneurysm related.

Variable	Intervention group (n=50)	Control group (n=50)	Difference in geometric mean intervention vs. control group	95% confidence interval	p-value*	p-value multivariate analysis‡
	Geometric mean (95% CI)					
Total procedure time (min)	91.4 (82.6-101.2)	98.6 (89.1-109.1)	7.3%	-19.7% to 7.0%	0.30	0.19
Endovascular procedure time (min)	52.1 (46.2-58.8)	54.6 (48.4-61.6)	-4.6%	-19.6 to 13.2%	0.59	0.48
Fluoroscopy time (sec)	916 (763-1099)	864 (720-1037)	6.0%	-18.1 to 37.3%	0.66	0.66
Contrast medium use (ml)	81 (73-91)	93 (84-104)	-12.8%	-25.3 to 1.7%	0.08	0.10
N of angiograms until deployment of main body	2.2 (1.9-2.4)	2.8 (2.5-3.2)	-23.1%	-35.8 to -7.8%	0.005	0.007
N of angiograms until deployment of all stent grafts	4.3 (3.8-4.8)	5.4 (4.8-6.0)	-20.5%	-32.0 to -7.1%	0.004	0.005
Total N of angiograms	6.5 (5.9-7.2)	7.5 (6.7-8.2)	-12.6%	-24.1 to 0.7%	0.06	0.07
Radiation dose (DAP) (mGycm²)	103951 (79657-135653)	112943 (86548-147387)	-8.0%	-36.8 to 34.1%	0.66	0.57

Table 5. *Technical operative metrics by randomised group.*

N: number; DAP: Dose Area Product

* Two-sample t-test

‡ multiple linear regression with correction for aneurysm difficulty and team experience

Discussion

In this multicentre, prospective RCT, PsR by the endovascular team prior to EVAR significantly reduced the number of minor and major errors (by 26% and 76% respectively) and the numbers of errors causing delay (by 27%) during the real life procedure. The number of minor and major errors during the endovascular (rehearsed) part of the actual EVAR was significantly lower (21% and 82% respectively), as well as the total number of errors during the non-endovascular part (70%). This may be explained by the fact that PsR acts as a preoperative briefing tool, improving communication between team members and enabling the team to get acquainted with the procedural flow, familiarise themselves with the behaviour of a chosen device in a particular anatomy, and identify potential hazards (e.g. endoleaks). In line with current literature that shows preoperative briefings to be effective, our results suggest that PsR prior to EVAR reduces potential errors, thereby reducing delays caused by error and improving procedural efficiency, and may increase patient safety.[15-17] In our study, most errors were of low severity (minor errors). The clinical effect of minor failures is difficult to quantify. Many will remain latent, but a small failure at a critical point in a procedure or an accumulation of small failures may lead to a substantial event.[18]

Similar to dedicated 3D software, PsR allows the interventionalist to evaluate patient anatomy and define the optimal angles for visualization of the landing zones prior to performing the actual procedure. Although all participating centres used dedicated sizing software, the number of angiograms performed to visualise the proximal and distal landing zone was significantly lower in the group with preoperative PsR (23% and 21% respectively). These findings did not differ significantly between experienced and inexperienced teams. Apparently interventionalists had more confidence in the results and observations made during PsR, as suggested by the subjective ratings of realism and usefulness of PsR prior to EVAR reported in a pilot study.[11] However, the total number of angiograms, the total endovascular procedure time, fluoroscopy time, contrast medium use, and radiation dose were not significantly lower in the intervention group. This is plausible because some events that resulted in additional angiograms, such as type 2 endoleaks, are not replicated in the simulation. Furthermore, radiation dose also depends on thickness of the part of the body that is imaged, field of view, pulse frequency and dose level of

fluoroscopy employed. Specifically, PsR appears to lead to the use of more oblique angles for optimal visualization of the landing zones, thereby increasing radiation dose.

Several studies have reported that PsR may influence endovascular tool choice and improve non-technical skills and patient safety, highlighting the utility of PsR for preoperative case evaluation.[11, 19-22] A retrospective study showed that the Simbionix PROcedure™ rehearsal studio software adequately replicates EVAR procedures and that sizing using this software was similar to operative cases.[23] Consistent with this research, our study demonstrates that patient-specific simulation has great potential as a preprocedural planning and rehearsal tool.

The prospective, randomised nature of this study was designed to rigorously evaluate the effect of PsR prior to EVAR on patient safety. Although a formal power analysis to detect a difference in errors occurring during the procedure was not possible, the incidence of errors was significantly higher in the control group. Another limitation of this study was the inability to blind the observer of intraoperative events to the randomisation group, which implies a possible bias. However, the construction of an event log was performed without judgment. The decision whether an intraoperative event constituted an error was taken by two blinded assessors, who had significant experience in EVAR procedures and error definition. Notwithstanding the limitations noted above, this study reflects real life practice, performed in academic and district hospitals by experienced and inexperienced teams, cases were treated within and outside IFU, and patient demographics were in line with those previously reported in large randomised EVAR trials.[1, 24] The results of this study indicate that PsR prior to EVAR can be used reliably and effectively in different hospital settings by teams with various experience for patients with diverse aneurysm characteristics. These conclusions may not be applicable to other stent grafts as only Gore® Excluder® or Endurant® stent grafts could be simulated during the rehearsal.

The current generation of commercially available endovascular PsR software has several limitations, including time, expertise and costs to generate the 3D reconstructions, reliance on the quality of the preoperative imaging, and inadequate modelling of vessel biomechanical properties, e.g. straightening of the iliac arteries by stiff wires and stent grafts.[11, 23] Ongoing collaboration between clinicians and industry is paramount to address these concerns, by facilitating integration of the 3D

models produced with dedicated sizing software, and by enabling part-task rehearsals to practice the more challenging steps of the procedure. Simulator costs (acquisition and maintenance) can be distributed, since these can be used not only for rehearsal but also to train individuals or whole endovascular teams, across a range of experience levels, in almost any endovascular procedure. Staffing costs may be addressed by performing rehearsals with the endovascular team during anaesthetic preparation time. This technology may be used as a preoperative planning tool to adjust treatment plans and reconfirm stent graft measurements, a potentially cost-saving measure given the high costs of current stent graft devices. Further research is needed to evaluate how PsR prior to EVAR may be implemented in daily clinical practice and if such rehearsals are cost-effective.

Conclusions

PsR prior to EVAR can be used in different hospital settings by teams with various EVAR experience. It can reduce errors occurring during the procedure, delay caused by error, and the number of angiograms needed to deploy the stent graft, thereby improving procedure efficiency. Ultimately, this technology may improve patient safety.

Funding

This trial was supported by Simbionix USA Corp, Cleveland, Ohio, USA (technical support), W.L. Gore & Associates Inc, Flagstaff, Arizona, USA (research grant), and Medtronic Inc, Santa Rosa, California, USA (research grant). For Imperial College Staff, the research was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London.

The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the sponsors. Neither the funder nor the sponsor had any role in study design, data collection and analysis, interpretation of results, or the decision to submit the manuscript for publication.

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5

A multicentre randomised controlled trial of patient-specific rehearsal prior to EVAR: impact on procedural planning and team performance.

L. Desender[1]
I. Van Herzeele[1]
M. Lachat[2]
J. Duchateau[3]
C. Bicknell[4]
J. Teijink[5]
J. Heyligers[6]
F. Vermassen[1]
On behalf of the PAVLOV Study Group

Eur J Vasc Endovasc Surg 2017;53:354-361.

[1]Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium
[2]Department of Vascular Surgery, Zurich University Hospital, Zurich, Switzerland
[3]Department of Vascular and Thoracic Surgery, St. Maarten Hospital, Duffel, Belgium
[4]Department of Surgery and Cancer, St. Mary's Hospital, Imperial College, London, United Kingdom
[5]Department of Vascular Surgery, Catharina Hospital, Eindhoven, The Netherlands
[6] Department of Vascular Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands

Abstract

Objectives

Patient-specific rehearsal (PsR) prior to endovascular aneurysm repair (EVAR) enables the endovascular team to practice and evaluate the procedure prior to treating the real patient. This multicentre randomised controlled trial aims to evaluate the utility of PsR prior to EVAR as a preoperative planning and briefing tool.

Material and methods

Patients with an aneurysm suitable for EVAR were randomised to preoperative or postoperative PsR. Before and after the PsR, the lead implanter completed a questionnaire to identify a deviation from the initial treatment plan. Additionally, all team members completed a questionnaire evaluating realism, technical issues, and human factor aspects pertinent to PsR, on a Likert scale from 1 (not al all) to 5 (very much). Technical and non-technical skills, and technical and clinical success rates were compared between both randomisation groups.

Results

100 patients were enrolled between September 2012 and June 2014. The plan to visualise proximal and distal landing zones was adapted in 27/50 (54%) and 38/50 (76%) cases respectively. The choice of the main body, contralateral limb, or iliac extensions was adjusted in 8/50 (16%), 17/50 (34%), and 14/50 (28%) cases, respectively. At least one of the above-mentioned parameters was changed in 44/50 (88%) cases.

199 subjective questionnaires post-PsR were completed for 100 EVAR cases. The realism of PsR was rated highly (median 4, IQR 3-4) and the rehearsal was considered as useful for selecting the optimal C-arm angulation (median 4, IQR 4-5). PsR was recognised as a helpful tool for team preparation (median 4, IQR 4-4), to improve communication (median 4, IQR 3-4) and encourage confidence (median 4, IQR 3-4). Technical and human factor skills, and technical and initial clinical success rates were similar between the randomisation groups.

Conclusion

PsR prior to EVAR has a significant impact on the treatment plan and may be useful as a preoperative planning and briefing tool. Subjective ratings indicate that this technology may facilitate planning of optimal C-arm angulation and improve non-technical skills.

Introduction

Endovascular aneurysm repair (EVAR) is an established treatment for infrarenal aortic aneurysms, often performed in a complex high-tech environment staffed by teams of clinicians and technicians with various medical backgrounds. Patient outcomes are influenced by individual anatomic patient considerations, operator experience and skill, necessitating accurate preoperative planning and preparation.[1-4] Preoperative planning of EVAR procedures not only includes technical components, but also extends to the preparation of the entire interventional team to optimise team workflow, resource management and error prevention.[5] Increasing awareness of the importance of preventing errors, in combination with increasing complexity of endovascular intervention, have led to advances in VR simulation, and the emergence of patient-specific rehearsal (PsR). This technology enables the practitioner and team to practice 'real' cases on a virtual patient prior to performing the procedure on the actual patient. Several reports only including small numbers have described patient-specific simulation of medical procedures in the field of laparoscopy, orthopaedics, neurosurgery, and plastic surgery. Face validity was most commonly reported, but several authors also acknowledged the potential of patient-specific simulation as a preprocedural planning and rehearsal tool.[6]

Our group conducted a multicentre, randomised controlled trial (PAVLOV study: **Pa**tient-specific **V**irtual reality simu**l**ation **o**f E**V**AR), to evaluate the effect of PsR prior to EVAR on patient safety and procedural efficiency. The results of the PAVLOV study showed that PsR prior to EVAR reduces perioperative errors as well as the number of angiograms to deploy the stent graft, thereby reducing delays.[7]

The present publication from the PAVLOV trial aimed to evaluate the utility of PsR as a preoperative planning and briefing tool, and to evaluate the influence on technical and non-technical skills and on technical and clinical success rates.

Methods

The PAVLOV study is a prospective, multicentre, parallel-group trial that randomised patients with a non-ruptured infrarenal aortic aneurysm suitable for endovascular repair (EVAR) to either preoperative PsR (intervention group) or postoperative PsR

(control group). The study was conducted in six vascular centres across Europe (three academic and three district hospitals).

Study methodology has been reported in detail.[7] In brief, patients with an infrarenal or iliac aneurysm were screened according to defined selection criteria (Table 1).

Inclusion criteria	**Exclusion criteria**
Age 18 years or over	Adult patients who do not have capacity to consent
Non-ruptured infrarenal aortic aneurysm OR Non-ruptured iliac aneurysm	Previous stent-graft implanted in the abdominal aorta
Aneurysm suitable for endovascular exclusion with the - Gore® Excluder® AAA endoprosthesis (W.L. Gore & Assoc., Sunnyvale, California, USA) OR - Endurant® stent graft (Medtronic Vascular, Santa Rosa, California, USA)	
AAA within AND outside instructions for use (as described by the manufacturer)	

Table 1. *Eligibility criteria.*

Based on preoperatively acquired Computed Tomography Angiography (CTA) data, a virtual three dimensional (3D) model of the patient's relevant anatomy was created, using the Simbionix PROcedure™ rehearsal studio software (Simbionix USA Corp., Cleveland, OH, USA). A virtual reality simulator (ANGIO Mentor™ Express Dual Access Simulation System, Simbionix USA Corp., Cleveland, OH, USA) was used to conduct the PsR. Three members of the endovascular team (lead implanter, assistant, and scrub nurse) performed the preoperative rehearsal less than 24 hours before the actual EVAR procedure. In the control group, only the lead interventionalist carried out the postoperative rehearsal.

An experienced endovascular team was defined as a team consisting of at least two (out of three) team members who have performed (lead interventionalist) or assisted (assistant, scrub nurse) at least 50 EVAR cases.

Randomisation took place after obtaining informed consent and creating the 3D model. The random allocation sequence (two arms: A = PsR, B = control; 1:1 ratio;

block size of 4) was generated using a computer-generated list. The allocation sequence was concealed from the researcher enrolling and assessing patients by using sequentially numbered, opaque, sealed envelopes. Outcome assessors and data analysts were blinded to the allocation.

The trial protocol was approved by the institutional review boards or ethics committees at each trial site and registered at ClinicalTrials.gov (NCT01632631). All patients gave written informed consent before enrolment. All theatre staff were informed about the research and provided verbal consent.

The primary study outcomes were the number of errors occurring during the actual EVAR procedure and the technical performance measured by operative metrics, such as endovascular procedure time, fluoroscopy time, contrast medium use, number of angiograms, and patient radiation dose.

The secondary outcomes include deviation from the initial treatment plan, the subjective sense of realism and usefulness of the rehearsal reported by the team members, and technical and non-technical skill assessment. Primary, assisted primary, and secondary technical and initial clinical success rates as previously defined by Chaikof et al. (Appendix 3, Chapter 8),[8] in-hospital and 30-day mortality were reported. Evaluation of the radiographic criteria was based on the report of the postoperative CTA, performed by an independent radiologist.

Deviation from initial treatment plan

All teams used dedicated 3D workstations for sizing and evaluation of the case. Before and after rehearsal of the cases randomised to the intervention group, the lead implanter completed a questionnaire focussing on his choice of brand, diameter, length and number of stent grafts, the C-arm angulation to visualise the target landing zones, the introduction site for the main body, and the positioning of the contralateral limb with respect to the ipsilateral limb (anterior, anterolateral, posterior, or ballerina). To assess the deviation from the initial treatment plan, data of both questionnaires were compared. The subsequent implementation of these changes in the clinical setting was evaluated by comparing the data of the post-rehearsal questionnaire with the C-arm angles, characteristics and positioning of the stent grafts used during the real EVAR procedure. Changes of at least 10° in either cranio-caudal or oblique fluoroscopy angle were considered to be clinically significant. For

the implanted devices (main body, contralateral limb, iliac extensions), a change of brand, diameter, or length was considered as a deviation from the initial treatment plan.

Subjective questionnaire

All team members participating in the PsR completed a questionnaire that addressed realism (e.g. images and endovascular tool manipulation), technical issues (e.g. choice of optimal fluoroscopy angle to visualise the target landing zones, influence on procedure time, etc.) and human factor aspects (coordination, confidence, communication skills, patient safety) pertinent to the PsR. Responses were rated on a Likert scale from 1 (not at all) to 5 (very much) (Appendix 1, Chapter 8).

Technical and non-technical skills

Hand movements and fluoroscopy screens were videotaped and post-hoc evaluated by an independent experienced vascular surgeon who was blinded for the randomisation group. The previously validated OSATS-derived Global Rating Scale (GRS) for generic endovascular skills (Appendix 4, Chapter 8),[9] and a procedure-specific rating scale including a pass rating (Appendix 5, Chapter 8) were used to assess the technical performance.

An overview camera videotaped the endovascular team, including the nurses. Two independent physicians blinded to the randomisation group and previously trained in using the Observational Teamwork and Assessment for Surgery (OTAS) tool scored post-hoc the non-technical skills of the endovascular and nursing teams. This previously validated tool assesses five facets of teamwork: communication, leadership, cooperation, coordination, and team monitoring/situation awareness on a Likert scale from 0 to 6, with clearly defined anchors and demonstrative scenarios to guide ratings (Appendix 6, Chapter 8).[10, 11]

Statistical analysis

All analyses were performed using SAS® 9.4 (SAS Institute Inc., NC, USA). Technical skills were compared using Mann-Whitney U tests or Fisher's exact tests (depending on the variable type) and non-technical skills were compared using *t* tests. Fisher's exact tests were used to compare technical success, clinical success

and change of treatment plan between intervention and control group. All analyses were considered significant at the 5% level.

Results

Between September 2012 and June 2014, 100 patients were enrolled across the six trial centres and randomly assigned to the two study groups. 61 patients (61%) were treated in an academic hospital, and 68 of the EVAR procedures (68%) were performed by an experienced team. In 63 cases (63%), the aneurysm repair was within instructions for use, as described by the manufacturer of the stent graft. Baseline characteristics have been described previously and were not different between the treatment groups.[7] The median time needed by the lead researcher to create the simulations was 33 minutes (IQR 21-44 min). The median time to perform the PsR was 25 minutes (IQR 20–30 min).

Analysis of the outcomes was on an intention-to-treat basis. Two patients in the intervention group and five patients in the control group were excluded from analysis of technical skill assessment due to incomplete recording of the fluoroscopy screen. Similarly, one patient in the control group was excluded from analysis of the non-technical skills. Figure 1 shows the flow of patients through the trial.

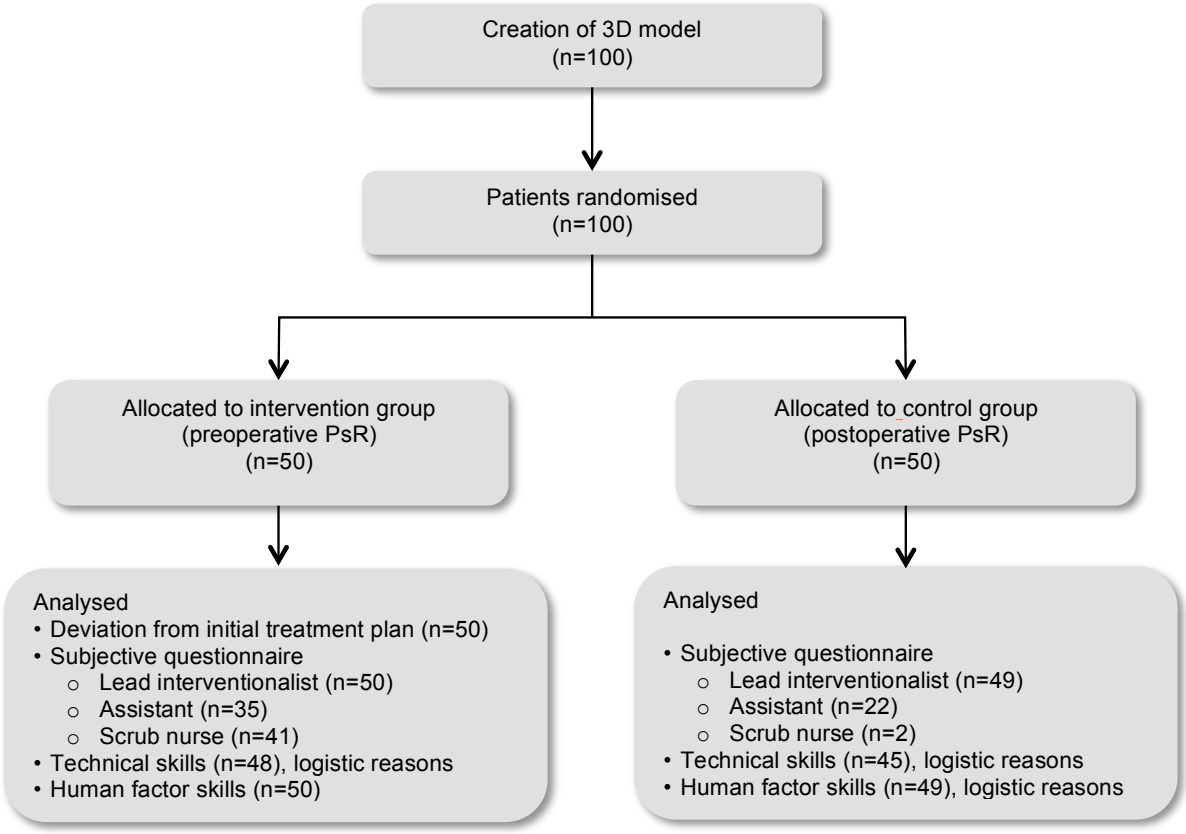

Figure 1. Diagram showing flow of patients through the trial.
PsR: patient-specific rehearsal

Deviation from initial treatment plan

After the preoperative PsR, the interventionalist changed his plan to visualise the proximal and distal landing zones in 27/50 (54%) and 38/50 (76%) of the cases respectively. The diameter or length of the main body of the stent graft, the contralateral limb, or the iliac extensions was adjusted in 8/50 (16%), 17/50 (34%), and 14/50 (28%) respectively. The orientation of the contralateral limb was altered in 8/50 (16%) and the introduction site of the main body in 1/50 (2%) cases. In 44/50 (88%), at least one of the above-mentioned parameters was changed. Of the 191 observed changes, 176 (92%) were implemented in the real EVAR procedure. Additional data are provided in Table 2.There was no statistically significant difference in change of treatment plan between experienced (> 50 EVAR cases) and inexperienced lead interventionalists (27/29 (93%) vs. 17/21 (81%); p = 0.19).

Parameter	Change of treatment plan	Changes implemented in clinical setting	Rehearsal followed in clinical setting
C-arm angulation			
- Proximal landing zone (CC+OB)	27/50 (54%)	32/34 (94%)	97/100 (97%)
- Distal landing zones (Left CC + OB; Right CC + OB)	38/50 (76%)	77/95 (81%)	171/200 (86%)
Main body			
- Proximal diameter	3/50 (6%)	2/3 (67%)	46/50 (92%)
- limb diameter	1/50 (2%)	1/1 (100%)	48/50 (96%)
- length	6/50 (12%)	6/6 (100%)	50/50 (100%)
Contralateral limb			
- diameter	3/50 (6%)	2/3 (67%)	47/50 (94%)
- length	16/50 (32%)	13/16 (81%)	44/50 (88%)
Iliac extension			
- diameter	10/50 (20%)	5/10 (50%)	39/50 (78%)
- length	14/50 (28%)	11/14 (79%)	44/50 (88%)
Orientation contralateral limb	8/50 (16%)	8/8 (100%)	47/50 (94%)
Introduction site main body	1/50 (2%)	1/1 (100%)	50/50 (100%)
Any of the above	44/50 (88%)	176/191 (92%)	683/750 (91%)

Table 2. *Change of initial treatment plan and implementation in real life*
CC = cranio-caudal C-arm angulation; OB = oblique C-arm angulation

Subjective questionnaire

For the 100 performed EVAR procedures, a total of 199 subjective questionnaires post-PsR were completed by 99 lead interventionalists, 57 assistants, and 43 scrub nurses. The majority of the team members (63%) were highly experienced in EVAR, having performed over 50 EVAR procedures. The realism of PsR was rated highly (median 4, IQR 3-4), especially that of the simulated angiographies of the aorta (median 4, IQR 4-5) and iliac vessels (median 4, IQR 4-5). The lead interventionalist found the rehearsal useful for selecting the optimal C-arm angulation (median 4, IQR 4-5). PsR was recognised as a helpful tool to prepare individual team members (median 4, IQR 3-5) and the entire team (median 4, IQR 4-4), improve communication (median 4, IQR 3-4) and encourage confidence (median 4, IQR 3-4) prior to the actual intervention. There were no significant differences in ratings

between inexperienced and experienced team members. Additional data are provided in Table 3.

	Lead Implanter (n=99)		**Assistant** (n=57)		**Scrub nurse** (n=43)	
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
N of completed questionnaires	50	49	35	22	41	2
N of different operators	21		24		18	
Realism of the						
- procedure	4 (3-4)		4 (3-4)		4 (4-4)	
- angiographic images of the aorta	4 (4-5)		4 (4-5)		4 (4-4)	
- angiographic images of the iliac vessels	4 (4-5)		4 (4-5)		4 (4-5)	
Overall usefulness of rehearsal	4 (4-5)		4 (4-5)		4 (3-4)	
Useful for C-arm angulation	4 (4-5)		4 (4-5)		4 (3-4)	
- proximal landing zone	4 (3-5)		4 (4-5)		4 (4-4)	
- distal landing zone	4 (3-5)		4 (3-5)		4 (4-4)	
Helpful to						
- prepare individual team members	4 (4-5)		4 (4-5)		4 (3-4)	
- prepare entire team	4 (4-5)		4 (3-4)		4 (4-4)	
- improve communication	4 (3-4)		3 (3-4)		4 (3-4)	
- encourage confidence	4 (3-4)		4 (3-4)		4 (3-4)	

Table 3. *Subjective sense of realism and usefulness of the rehearsal reported by the team members.*
Values are median (IQR)

Technical and non-technical skills

The post-hoc assessment of technical and non-technical skills were similar between the randomised groups (Table 4).

Primary, assisted primary, and secondary technical and initial clinical success rates were similar between both groups (Table 5). In-hospital mortality was 1/50 (2%) in the control group and 0/50 (0%) in the intervention group (p=1.00). 30-day mortality

was 1/50 (2%) in the control group and 2/50 (4%) in the intervention group (p=1.00), of which one was aneurysm related.

Variable	Intervention group	Control group	p-value
Technical skills	**(n=48)**	**(n=45)**	
GRS (total score, maximum 35)	29 (26-31)	28 (25-31)	0.79*
PRS (pass rating): yes	37 (77%)	35 (78%)	1.00‡
PRS (total score, maximum 35)	27 (24-30)	26 (23-29)	0.40*
Non-technical skills	**(n=50)**	**(n=49)**	
OTAS surgical team (total score, maximum 30)	19 (16-24)	17 (12-22)	0.20*
OTAS nursing team (total score, maximum 30)	18 (14-22)	18 (15-22)	0.85*

Table 4. *Secondary outcomes - post-hoc video-based assessment of technical and non-technical skills randomised by group.*
Values are median (IQR) unless stated otherwise. GRS: global rating scale; PRS: procedure-specific rating scale; OTAS: Observational Teamwork Assessment for Surgery tool.
** Mann-Whitney U test*
‡ Fisher's exact test

Variable	Intervention group (n=50)	Control group (n=50)	p-value*
Technical success			
Primary	41 (82%)	39 (78%)	0.80
Assisted primary	47 (94%)	43 (86%)	0.32
Secondary	47 (94%)	46 (92%)	1.00
Initial clinical success			
Primary	45 (90%)	49 (98%)	0.20
Assisted primary	47 (94%)	49 (98%)	0.62
Secondary	48 (96%)	49 (98%)	1.00

Table 5. *Primary, assisted primary, and secondary technical and initial clinical success rates*
Values are number (%)
** Fisher's exact test*

Discussion

The results of this multicentre, randomised controlled trial showed that PsR with the endovascular team prior to EVAR influences the preoperative treatment plan and is regarded as a useful tool for preoperative planning and preparation by all team members, experienced as well as inexperienced.

Preoperative planning of EVAR procedures using dedicated 3D planning and sizing software has become common practice.[5] Clinical evidence suggests that accurate planning directly influences EVAR-related outcomes. A recent study involving 295 patients demonstrated that the routine use of dedicated 3D sizing software for EVAR is associated with a significant reduction in the incidence of type 1 endoleaks and their related secondary interventions.[4] According to Velazquez et al., the employment of modern sizing software significantly reduces the use of unplanned iliac extensions in EVAR procedures.[12]

Similar to dedicated 3D software, PsR allows the interventionalist to evaluate the anatomy of the patient, determine the required number and sizes of stent grafts, define the optimal angles for visualisation of the landing zones, and assess the suitability for endovascular repair before performing the actual procedure.[13] A retrospective study showed that the Simbionix PROcedure™ rehearsal studio software adequately replicates EVAR procedures and sizing using this software was similar to peroperative findings.[14] Additionally, previously published results of this randomised controlled trial showed that PsR prior to EVAR significantly reduces the number of angiograms performed to visualise the target landing zones.[7] Although all participating centres in this trial used dedicated sizing software, considerable alterations to the initial treatment plan were made in the majority of cases (88%) post-rehearsal. 92% of these alterations were subsequently implemented in real life. A possible explanation is that the interventionalists had more confidence in the results and observations made during PsR, as suggested by the subjective ratings of realism and usefulness of PsR prior to EVAR. The implementation of changes of the diameter of the stent grafts may be improved by performing the rehearsal more in advance, enabling the lead implanter to order the required stent graft in time for the scheduled procedure.

It is evident that the scope of preoperative preparation of EVAR procedures does not only involve the technicalities of endograft planning and implantation, but can be extended to the preparation of the whole interventional team.[5] Although operator experience and skill have been shown to have a direct influence on outcome following EVAR,[3, 15] increasing awareness of preventable technical and non-technical errors has highlighted the importance of team planning and training in order to target and reduce errors whilst improving efficiency overall.[13, 16, 17] Our group has demonstrated that for EVAR procedures, the majority of errors (31%) are related to technical issues, e.g. unfamiliarity with the procedure, the equipment or techniques used during the procedure. According to Albayati et al., the most common intraoperative errors in endovascular procedures arise from failures in situation awareness, teamwork and communication skills.[16] Evidence exists that improving teamwork in the operating theatre is associated with a reduction in morbidity and mortality.[18, 19] Several authors have demonstrated that preprocedural team rehearsal can significantly reduce errors made during vascular procedures. [20, 21] In addition, our group has confirmed that preoperative PsR significantly reduces the number of major and minor errors occurring during EVAR procedures.[7]

Although there was a change in the treatment plan in the majority of cases and subjective ratings indicate that PsR prior to EVAR is helpful to improve the technique and non-technical skills, no effect was observed on technical and non-technical performances, nor on technical and clinical success rates. This may be expected as these outcome measures are a reflection of the experience and composition of the team, which were similar in both groups. Additionally, technical skills in both groups were scored highly using the GRS which may, although proven construct-valid, not be able to discriminate increasing levels of clinical experience.[22, 23]

Furthermore, this study describes the secondary outcome parameters of the PAVLOV randomised controlled trial and the number of patients may have been too small to detect a difference in these outcome measures.

Another limitation is that only the interventionalist, assistant and scrub nurse were involved during rehearsals. Accordingly, only the non-technical skills between the interventional and nursing team were evaluated and not the interaction with e.g. anaesthesiologists. Additionally, the non-technical skills were rated post-hoc based on video recordings, and subtle interactions between team members may have been missed.

Finally, patient outcome parameters were only recorded until one month postoperatively. Long-term follow-up is required to evaluate if PsR with subsequent alterations of the treatment plan may decrease the number of secondary interventions or improve long-term outcomes.
Further research is needed to explore the role of PsR as an advanced training and debriefing tool, to evaluate how PsR prior to EVAR may be implemented in daily clinical practice and if these rehearsals may be cost-effective.

In conclusion, PsR prior to EVAR can be useful as a preoperative planning and briefing tool, even for experienced interventionalists. It has a significant influence on the treatment plan. Subjective ratings indicate that this technology may facilitate planning of optimal C-arm angulation and improve non-technical skills, particularly team preparedness.

Funding

This trial was supported by Simbionix USA Corp, Cleveland, Ohio, USA (technical support),
W.L. Gore & Associates Inc, Flagstaff, Arizona, USA (research grant), and Medtronic Inc, Santa Rosa, California, USA (research grant). For Imperial College Staff, the research was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London.
The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the sponsors. Neither the funder nor the sponsor had any role in study design, data collection and analysis, interpretation of results, or the decision to submit the manuscript for publication.

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6

General discussion and future perspectives

General discussion

Although modern medicine is technically advanced and can effectively improve health and cure illnesses, a significant number of patients may be harmed while being in the hospital.[1] The highest rate of adverse events occurs in surgical patients, particularly in those undergoing a major vascular procedure.[2] This has generated a wide interest in patient safety issues and a demand to reduce the risks for patients undergoing procedures or treatments. For a long time, the focus was primarily on optimising patient outcomes by focusing on the patient's preoperative condition and by improving the technical skills of the individual surgeon or interventionalist. Currently, errors are no longer regarded as an individual failure but as the result of a chain of events within the 'system', emphasising the role of a wider range of factors of the surgical system on patient safety, such as non-technical skills and team performance.[3-6] System failures, failures of communication and coordination, and the number of events (disruptions) per procedure have been shown to adversely affect morbidity and mortality.[7-10] For aortic procedures, Lear et al. have demonstrated an association between the number of major intra-operative failures per procedure and patient outcomes, such as unplanned return to theatre, postoperative complications and in-hospital mortality.[11]

The increasing awareness of the importance of preventing medical errors combined with the growing complexity of endovascular interventions has activated the use of endovascular VR simulation. Research has shown that medical VR simulation is effective in training physicians at various levels of experience and shortening the learning curves, with transfer of these endovascular skills to the OR.[12-18] To be optimally effective, this simulation-based training should be integrated within a full proficiency-based stepwise curriculum, with cognitive training completed prior to initiation of practical skills simulation.[19-21]

The latest development in the field of endovascular simulation is patient-specific VR rehearsal (PsR). It enables the interventionalist and the whole endovascular team to evaluate and practice the case before treating the actual patient. As such, PsR not only facilitates procedural planning (cognitive rehearsal) and technical practice (psychomotor rehearsal) but also enables team rehearsal. Previous research by our group has established that PsR prior to carotid artery stenting (CAS) is feasible and

that it may improve preoperative planning and preparation of the endovascular team.[22, 23] Recently, this novel technology became available for the endovascular repair of thoracic aortic pathology (TEVAR) and infrarenal aortic aneurysms (EVAR). This thesis sets out to evaluate PsR prior to endovascular aortic aneurysm repair in the clinical setting and addresses its potential benefits and limitations.

Although many high-stake industries (e.g. the military, aerospace industry) have already implemented rehearsals in which difficult or dangerous tasks are practiced beforehand, it is not part of routine medical practice at present.
To facilitate implementation of new technology in any high performance industry, this technology should be easily accessible, simple and practical in use, and disrupt as little as possible the routine clinical practice. Therefore, the first study evaluated the feasibility of using patient-specific TEVAR rehearsal in a real life setting and explored the potential hardware or software problems that could limit its immediate implementation. **Chapter 2** shows that the process of creating patient-specific TEVAR simulations is feasible using standard CTA data as input and that this process is reproducible for different thoracic aortic pathologies (thoracic aortic aneurysm, acute traumatic aortic injury, and penetrating aortic ulcer). The simulations exhibit a high degree of realism with respect to the angiographic images of the landing zones and device deployment. Furthermore, the rehearsals can be used in the clinical setting and are valuable for preoperative evaluation of the case. However, it was noted that the time needed to create the simulation is highly dependent on the quality of the CTA data. Artefacts such as contrast filling defects in hemodynamically unstable patients may result in poor simulations, and CT scans not including the abdominal aorta and iliac arteries result in technical failures. Additionally, the incidence of endoleaks in the simulated scenarios is based upon guidelines provided by the manufacturer of the stent graft used in the simulation, and does not always reflect real life. Software improvements are crucial to address these issues and enable implementation of this technology in routine clinical practice.

Another incentive for implementing new technology in daily clinical practice is the potential benefit it may offer for the endovascular therapists, the team and the patient. One of the most evident benefits of PsR is the opportunity for physicians and their team to evaluate the case preoperatively and assess how specific endovascular

tools and devices may interact with the anatomy of an actual patient. In the case of an EVAR procedure, it is relevant to identify the optimal fluoroscopy angles for visualization of the landing zones and to select the appropriate size and length of stent graft to obtain technical success.

Chapter 3 describes the results of ten real patients undergoing an EVAR procedure, preceded by PsR. The rehearsals were conducted as 'whole' team rehearsals and involved the interventionalist, assistant, scrub and circulating nurse, and anaesthetist that were also present in the subsequent real intervention on the patient. To evaluate the feasibility of implementing this technology in daily clinical practice, the procedures were performed in three independent hospital institutions. To evaluate if PsR could indeed influence the treatment plan, the interventionalists were asked to review the preoperative CT imagery and indicate their tool and fluoroscopy preferences before and after the rehearsal. The study showed that PsR prior to EVAR indeed influenced the treatment plan. This was most notable for optimal fluoroscopy C-arm position to visualise the proximal and distal landing zones. In one case, the interventionalist changed his treatment plan to use a stent graft with suprarenal instead of infrarenal fixation, because of the occurrence of a type 1a endoleak in the simulation. Overall team members rated the rehearsals as realistic and effective at improving preoperative planning and practice, and for preparation of the entire team. This study therefore confirms that PsR constitutes a practical and effective tool to plan cases preoperatively, evaluate different approaches, identify potential hazards and increase confidence within the team.

What this study did not yet prove is if the aforementioned benefits actually lead to an increase in clinical safety and procedural efficiency, i.e. if patients actually benefit from physicians and team members conducting PsR.

To address this question, a multicentre randomised controlled trial (RCT) was initiated. Hundred patients with an infrarenal or iliac aneurysm suitable for endovascular exclusion were randomised to preoperative patient-specific EVAR rehearsal or to the control group.

Preoperative rehearsals were performed by the endovascular team, consisting of the lead implanter, the assisting interventionalist and the scrub nurse. Both experienced and inexperienced teams were included.

The research described in **Chapter 4** demonstrated that PsR indeed reduces the number of minor and major errors during the real EVAR intervention. The majority of errors were related to technical issues, e.g. unfamiliarity with the procedure, the equipment or techniques used during the procedure. Additionally, there was a reduction in the errors causing delay, which may lead to improved procedural efficiency. These findings were similar for rehearsals performed by experienced as well as inexperienced teams, and for complex as well as non-complex aneurysm repair. The reduction in procedural errors suggests that PsR is a valuable and effective tool for preoperative practice, planning and team briefing.

Preoperative planning of EVAR procedures using dedicated 3D planning and sizing software has become common practice, with evidence suggesting that accurate planning directly influences EVAR outcomes. [24-26] Additionally, preoperative practice on the simulator enables the endovascular team to get acquainted with the procedural flow, familiarise themselves with the behaviour of a chosen stent graft in a particular anatomy, and identify potential hazards (e.g. endoleaks). Research depicted in **Chapter 5** demonstrated that, although all participating centres used dedicated sizing and planning software, PsR prior to EVAR influences the treatment plan of both experienced and inexperienced interventionalists. This was most notable for optimal fluoroscopy C-arm position and dimensions of the contralateral limb and iliac extensions. A possible explanation is that the interventionalists had more confidence in the results and observations made during PsR, as suggested by the subjective ratings of realism and usefulness of PsR prior to EVAR. The value of PsR as a preoperative planning tool is further supported by the reduction in the number of angiographies needed to visualise the proximal and distal landing zones.

In line with the ‘systems’ approach to patient safety we focused not only on the individual surgeon, but also on the team performance (**Chapter 5**). Effective communication and teamwork among operating theatre staff has been described as paramount for the delivery of safe surgery and is associated with a reduction in morbidity and mortality.[3, 27, 28] Several authors have demonstrated that preprocedural team rehearsal can significantly reduce errors made during vascular procedures.[29, 30] In our study, there was a 35% reduction in communication errors in the group with preoperative PsR. Subjective ratings by all team members indicated that PsR was

regarded as a useful tool to prepare the team, improve communication and encourage confidence prior to the actual intervention.

Although PsR significantly reduces the number of errors during the real EVAR intervention, reduces the number of angiograms needed to accurately position and deploy the stent graft, changes the treatment plan in the majority of rehearsed cases, and subjective ratings by inexperienced and experienced team members indicate that PsR prior to EVAR is helpful to improve technical and non-technical skills, no effect was observed on technical and non-technical performances, nor on technical and clinical success rates. A possible explanation is that the numbers within this RCT may still have been too small to detect a difference in these outcome measures. Additionally, the rating scales used for assessment in this study may not be able to discriminate increasing levels of technical and non-technical performance during an EVAR procedure. Furthermore, only the interventionalist, assistant and scrub nurse were involved during rehearsals, limiting the assessment of the non-technical skills to the interaction between the interventional/surgical and nursing team. As the non-technical skills were rated post-hoc based on video recordings, subtle interactions between team members may have been missed. Finally, patient outcome parameters were only recorded until one month postoperatively. Long-term follow-up is required to evaluate if PsR with subsequent alterations of the treatment plan may decrease the number of secondary interventions or improve long-term outcomes.

The current generation of PROcedure rehearsal software does have some limitations. Firstly, the time for 3D reconstruction of the relevant vasculature and the accuracy of the simulated rehearsal depends on the quality of the CT DICOM data. Furthermore, biomechanical properties such as straightening of the iliac arteries by stiff wires, crossing of heavily calcified lesions, and the positioning of the stent graft against the aortic wall are not always accurately replicated. Additionally, the software only allows rehearsal of an entire procedure. Ideally, the physician and endovascular team should be able to go back and forth, deploy various devices during the same simulation, and practice the most challenging parts of the intervention. Finally, PsR is associated with a considerable cost, e.g. acquisition and maintenance of the simulator and staffing costs.

Future perspectives

Although the research described in this thesis has provided evidence that PsR prior to EVAR improves patient safety and procedural efficiency, ongoing research and software adjustments are necessary to facilitate implementation of this technology in daily clinical practice.

Firstly, the technology should be straightforward and practical in use. Although the 3D reconstruction of the relevant vasculature has improved over the last years, the main limiting factor for creation of the simulation remains the quality of the preoperative CT scan. Importation of segmentations created with dedicated 3D sizing software already used in clinical practice or predefined templates may offer a solution in the near future.

Secondly, physicians should always be able to rely on the results of the simulation and rehearsal. Although there is an ongoing debate about the required level of fidelity for training technical and teamwork skills, PsR inherently necessitates the highest degree of fidelity to provide detailed information on patient-specific reactions to different material and manipulations.[31] The current biomechanical data need to be reviewed and refined, e.g. changes to the in vivo tortuosity of the vasculature by guidewires, catheters, sheaths and stent grafts and the reaction of vessels to dilatation and stenting. The latter may influence the occurrence of endoleaks in the simulation, and may have an impact on the realism of the simulation and the potential to identify possible hazards. Future software developments will therefore have to focus on the integration of additional biomechanical characteristics, for example by using finite element analysis to evaluate the mechanical interaction between endovascular equipment and the vasculature.[32]

Thirdly, time constraints in daily practice may limit the endovascular teams to perform full length, time-consuming rehearsals. Part-task rehearsals, allowing the endovascular team to practice the more challenging steps of the procedure may offer a solution. However, further research is needed to determine which steps are critical in performing a successful EVAR procedure and to evaluate if performing a part-task rehearsal will also improve patient safety and procedural efficiency.

Finally, and perhaps most importantly, the benefits of PsR should outweigh the associated costs. These include the cost for acquisition and maintenance of simulator soft- and hardware, staffing costs, etc. Simulator costs can be distributed, since these can be used for rehearsal and for training individuals or entire endovascular teams, across a range of experience levels, in almost any endovascular procedure. Staffing costs may be addressed by performing rehearsals with the endovascular team during anaesthetic preparation time. Additionally, this technology may be used as a preoperative planning tool to adjust treatment plans and reconfirm stent graft measurements, a potentially cost-saving measure given the high costs of current stent graft devices. Further research is needed to ascertain the cost-effectiveness and financial outcome of PsR prior to EVAR.

In the field of education and training it has been recognised that the value of VR simulation relies on the successful incorporation of the simulation into an entire educational program and not solely on the inherent value of the technology itself. In endovascular surgery, a proficiency-based stepwise training curriculum using generic endovascular VR simulation modules to acquire basic endovascular skills has shown to improve surgical performance in the operating room.[21] Similar to generic VR simulation, patient-specific simulation could also form an integral part of an established training program. For example, the patient-specific EVAR software can be used by the trainee to evaluate the anatomy and determine the required number and sizes of stent grafts, where after s/he performs the rehearsal to assess the accuracy of the measurements and practice the case. As such, it may facilitate the transfer of skills acquired in the laboratory environment to treat patients in the actual angiosuite.

Besides as a preoperative briefing tool, PsR can also be used as a debriefing tool when complications or adverse events occur or to create and conduct unannounced in situ simulations, or in urgent settings to implement protocols to treat ruptured AAA by endovascular means.[33] By re-enacting the actual operative circumstances in simulation, it can be used to analyse errors and provide objective, formative feedback, enabling continued training for the endovascular team. However, the role of PsR as an advanced training and debriefing tool, and the exact manner in which

the PsR technology should be incorporated into these training curricula needs further investigation.

In conclusion, the studies described in this thesis indicate that setting up a patient-specific rehearsal is feasible for various anatomies in different hospital settings.
PsR performed prior to EVAR is a technology that can be used reliably and effectively by teams with various experience in patients with diverse aneurysm characteristics. Preoperative EVAR rehearsals may not only optimise preoperative planning, briefing and preparation of the endovascular team but more importantly reduce the errors and delays during the procedure, thereby improving patient safety and procedural efficiency. Further research should explore the role of PsR as an advanced training and debriefing tool, evaluate how PsR prior to EVAR may be implemented in daily clinical practice and if these rehearsals are cost-effective.

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7

Summary in English and Dutch

Summary

In most vascular surgery centres, endovascular treatments have now superseded open surgical repair to treat atherosclerotic and aneurysmal pathologies. However, endovascular technologies are rapidly evolving and require a different skills set compared to open surgery. Furthermore, these procedures are often performed by multidisciplinary teams in a complex high-tech environment. These aspects are reflected in a higher rate of errors during endovascular procedures.
Additionally, working hour restrictions, greater emphasis on operating room efficiency, and concerns for patient safety issues have resulted in reduced training opportunities and do necessitate alternative training modalities. These challenges have instigated a rise in the use of endovascular VR simulation. Research has shown that endovascular simulation is an effective tool for teaching, training and practicing endovascular techniques to physicians at various levels of experience.

The most recent advancement in medical simulation science is the development of patient-specific VR rehearsal. This new technology allows the incorporation of patient-specific image data into the simulations, offering life-like replications of the patient's anatomy. It enables the physician and team to rehearse the endovascular repair of thoracic aortic pathology (TEVAR) and infrarenal aortic aneurysms (EVAR) on a virtual patient prior to treat the actual patient.
The main objective of this thesis is to assess the value of patient-specific rehearsal as a practical preoperative planning and briefing tool to increase patient safety.

An important consideration when implementing new technology into existing workflow patterns, is if it is practical in use and does not overly disrupt established medical practice routines. Therefore, we evaluated the feasibility of using patient-specific TEVAR and EVAR software in a real life setting and explored the potential hardware or software problems that could limit its implementation. The studies depicted in **Chapter 2** and **3** showed that it is feasible to create realistic patient-specific simulations and perform the rehearsals in different hospital settings. The 3D reconstruction, which forms the basis of the simulation, was identified as the most variable and time consuming step in the creation process. For patient-specific

TEVAR rehearsal, software improvements were considered to be mandatory to enable implementation in routine clinical practice.

These adjustments have already been implemented for the patient-specific EVAR rehearsal software, allowing us to evaluate the potential benefits of performing patient-specific rehearsal prior to EVAR. In **Chapter 3**, we demonstrated that these rehearsals, performed by the endovascular team, could influence the treatment plan. This was most notable for optimal fluoroscopy C-arm position to visualise the target landing zones. Subjectively, the realism, utility to evaluate the case, and the potential to increase team performance were rated highly by all team members involved.

A subsequent multicentre randomised controlled trial evaluated if these potential benefits actually lead to an increase in patient safety and procedural efficiency. Preoperative patient-specific rehearsal with the endovascular team indeed reduced the number of minor and major errors during the real EVAR intervention. Additionally, there was a reduction in the errors causing delay, which may lead to improved procedural efficiency. These findings were similar for rehearsals performed by experienced as well as inexperienced teams, and for complex as well as non-complex aneurysm repairs (**Chapter 4**).

Although all participating centres used dedicated sizing and planning software, patient-specific rehearsal prior to EVAR significantly influenced the treatment plan of experienced as well as inexperienced interventionalists, especially with regards to the optimal fluoroscopy angle to deploy the stent graft. This was also illustrated by a significant reduction in the number of angiographies performed to visualise the proximal and distal landing zones in the group with preoperative patient-specific rehearsal. Subjective ratings by all team members indicated that PsR is a useful technology to prepare the team, improve communication and encourage confidence prior to the actual intervention (**Chapter 5**).

In conclusion, patient-specific rehearsal is a practical tool that can be used reliably and effectively by teams with various experience for patients with diverse aneurysm characteristics. It constitutes a valuable tool to optimise preoperative planning, briefing and preparation of the endovascular team. In addition, patient-specific

rehearsal prior to EVAR reduces the errors and delays caused by error during the actual procedure, thereby improving patient safety and procedural efficiency. Further research should explore the role of patient-specific rehearsal as an advanced training and debriefing tool, to evaluate how this technology may be implemented in daily clinical practice and if these rehearsals may be cost-effective.

Samenvatting

De endovasculaire behandeling van vaatziekten kent sedert jaren een opmars, en is tegenwoordig in de meeste vasculaire centra de voorkeursbehandeling voor een groot aantal vasculaire aandoeningen. Desondanks wordt beschreven dat bij endovasculaire ingrepen meer fouten gebeuren dan bij open ingrepen. Een mogelijke verklaring hiervoor ligt in het feit dat endovasculaire technieken relatief nieuw en snel evolutief zijn, en dat andere vaardigheden vereist zijn dan bij de klassieke open chirurgie. Bovendien worden deze ingrepen vaak uitgevoerd door een multidisciplinair team in een hoogtechnologische omgeving. Verder hebben de verminderde werkuren, de toegenomen nadruk op het efficiënt gebruik van operatiezalen en personeel, en de groeiende bezorgdheid omtrent de veiligheid van de patiënt geleid tot een afname van de opleidingsmogelijkheden. Deze uitdagingen vormden op vele plaatsen de inspiratie voor het aanpassen en moderniseren van de chirurgische opleiding, waarbij een belangrijke rol toegekend werd aan virtual reality (VR) simulatoren. Meerdere wetenschappelijke studies hebben inmiddels aangetoond dat endovasculaire VR simulatie een doeltreffend middel is om nieuwe endovasculaire technieken aan te leren en te trainen, en dit zowel voor artsen zonder endovasculaire ervaring als voor ervaren chirurgen.

De meest recente technologische evolutie op het vlak van endovasculaire VR simulatie is de mogelijkheid om patiënt-specifieke simulaties uit te voeren. Hierbij wordt de CT scan van de patiënt geïncorporeerd in de simulatie, waardoor realistische virtuele reconstructies van de specifieke anatomie gemaakt kunnen worden. Deze simulaties laten de arts en het endovasculaire team toe om de endovasculaire behandeling van aandoeningen van de thoracale aorta (TEVAR) en van infrarenale aneurysmata (EVAR) te oefenen op een virtuele patiënt alvorens de echte patiënt te behandelen.
Het doel van dit proefschrift is evalueren welke mogelijkheden patiënt-specifieke simulatie de arts en het team biedt als instrument om een geplande EVAR of TEVAR ingreep voor te bereiden, en of het uitvoeren van deze simulaties voor de eigenlijke ingreep ook daadwerkelijk een invloed heeft op de veiligheid van de patiënt tijdens de ingreep.

Om een nieuwe technologie succesvol te introduceren in de medische praktijk moet deze aan verschillende voorwaarden voldoen, zoals gemakkelijk inpasbaar zijn in de dagelijkse routine. De studies voorgesteld in **Hoofdstuk 2** en **3** toonden aan dat het mogelijk is om realistische patiënt-specifieke TEVAR en EVAR simulaties te creëren en de procedure vervolgens preoperatief te oefenen met het endovasculaire team, en dit in verschillende ziekenhuisomgevingen. De 3D reconstructie, die de basis vormt van de simulatie, bleek de meest variabele en tijdrovende stap in het gehele proces. Voor patiënt-specifieke TEVAR simulatie werd aangegeven dat software aanpassingen noodzakelijk zijn vooraleer implementatie in de dagelijkse praktijk overwogen kan worden.

Deze software aanpassingen werden reeds uitgevoerd voor patiënt-specifieke EVAR simulatie, wat het mogelijk maakt om de potentiële voordelen van het uitvoeren van preoperatieve patiënt-specifieke EVAR simulatie te evalueren. In **Hoofdstuk 3** tonen we aan dat deze preoperatieve simulatie, die uitgevoerd werd door het volledige endovasculaire team, het behandelingsplan kan beïnvloeden. Dit is het meest opvallend voor het bepalen van de optimale plaatsing van de C-arm om de landingszones voor de endoprothese in kaart te brengen, wat het mogelijk maakt om de stent accuraat te positioneren en ontplooien. Subjectief gezien ervaart het team patiënt-specifieke EVAR simulatie als een nuttig en realistisch instrument om de casus te evalueren en het team preoperatief voor te bereiden op de geplande ingreep.

Een volgende studie evalueerde of deze voordelen ook daadwerkelijk een invloed hebben op de veiligheid van de patiënt en efficiëntie van de uitgevoerde ingreep. In een multicentrisch gerandomiseerd onderzoek toonden we aan dat patiënt-specifieke EVAR simulatie, uitgevoerd door het endovasculaire team minder dan 24 uur voor de eigenlijke operatie, het aantal fouten tijdens deze ingreep significant vermindert. Verder was er ook een daling in het aantal fouten die een vertraging veroorzaken, wat resulteert in een verhoogde efficiëntie van de procedure. Deze bevindingen werden vastgesteld bij zowel ervaren als onervaren teams, en voor zowel complexe als eenvoudige EVAR procedures (**Hoofdstuk 4**).

Hoewel alle deelnemende centra in dit onderzoek software gebruikten die speciaal ontworpen is voor het correct opmeten van het aneurysma en het plannen van de procedure, werd na patiënt-specifieke EVAR simulatie in de meerderheid van de gevallen het behandelingsplan toch nog aangepast, en dit voornamelijk voor wat betreft de optimale C-arm plaatsing. Dit was opnieuw het geval voor zowel ervaren als onervaren chirurgen, en werd eveneens geïllustreerd door een significante daling in het aantal angiografieën die nodig waren om de stent te positioneren en correct te ontplooien. Patiënt-specifieke EVAR simulatie werd door de teamleden beschouwd als een waardevol instrument om de communicatie binnen het team te verbeteren, het vertrouwen van de teamleden te verhogen en de voorbereiding van het team te optimaliseren (**Hoofdstuk 5**).

Uit dit onderzoeksproject kunnen we besluiten dat patiënt-specifieke simulatie een betrouwbaar en praktisch instrument is om de arts en het endovasculair team voor te bereiden op de geplande ingreep. Bovendien werd aangetoond dat preoperatieve patiënt-specifieke EVAR simulatie het aantal fouten en vertragingen tijdens de eigenlijke procedure vermindert, wat een invloed heeft op patiëntveiligheid en de efficiëntie van de uitgevoerde procedure. Dit geldt zowel voor ervaren als onervaren teams, en voor zowel complexe als eenvoudige procedures. Verder onderzoek zal moeten uitwijzen of patiënt-specifieke simulatie ook een rol kan spelen in de opleiding van chirurgen, of het gebruikt kan worden voor debriefing, of deze technologie ook daadwerkelijk geïmplementeerd kan worden in de dagelijkse praktijk, en of deze preoperatieve simulaties kosteneffectief zijn.

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Appendices

Appendix 1: Subjective questionnaire

	Not at all				Very much	N/A
REALISM						
1. The procedure simulation of EVAR is realistic	1	2	3	4	5	
2. The simulated aortic angiographic images were realistic	1	2	3	4	5	
3. The simulated iliac images were realistic	1	2	3	4	5	
4. The ease/difficulty of contralateral limb catheterization was realistic	1	2	3	4	5	
5. Stent graft deployment was realistic	1	2	3	4	5	
6. Ballooning the landing zones and overlap zones was realistic	1	2	3	4	5	
TECHNICAL ISSUES						
The simulation aids in …						
1. The sequence/strategy of device deployment	1	2	3	4	5	
2. The choice of the landing zones	1	2	3	4	5	
3. The choice of the stent graft body length	1	2	3	4	5	
4. The choice of the contralateral limb length	1	2	3	4	5	
5. The choice of optimal fluoroscopy angle for the neck and body	1	2	3	4	5	
6. The choice of optimal fluoroscopy angle for the contralateral limb placement	1	2	3	4	5	
7. A decrease in total procedure time	1	2	3	4	5	
8. A decrease in total fluoroscopy time	1	2	3	4	5	
9. A decrease in total contrast use	1	2	3	4	5	
10. Providing information on potential endoleaks	1	2	3	4	5	
This model has …						
11. Altered my preconceived thought of how the procedure would be performed	1	2	3	4	5	
12. Altered my preconceived choice of endovascular material	1	2	3	4	5	
13. Been useful for me to practice the “real” case prior to performing it on the patient	1	2	3	4	5	
14. Helped me gather important information and evaluate potential difficulties	1	2	3	4	5	
15. Helped me choose the right C-arm position for the real case	1	2	3	4	5	

TEAMWORK AND COMMUNICATION ISSUES						
The simulation …						
1. Aided the coordination and cooperation between team-members	**1**	**2**	**3**	**4**	**5**	
2. Increases the team's preparedness for the real intervention	**1**	**2**	**3**	**4**	**5**	
3. Aided in the overall team performance	**1**	**2**	**3**	**4**	**5**	
4. Was useful for the team to practice the "real" case prior to performing the real case on the patient	**1**	**2**	**3**	**4**	**5**	
5. Increased patient safety	**1**	**2**	**3**	**4**	**5**	
6. Enhanced my communication with the other team members	**1**	**2**	**3**	**4**	**5**	
7. Enhanced my confidence for the real intervention	**1**	**2**	**3**	**4**	**5**	

Overall comments:

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Appendix 2: ICECAP record

PATIENT IDENTIFIER NUMBER: ___ ___ ___

Imperial College Error CAPture record (ICECAP)

Definitions:

Error: any issue/event that had the potential to prevent the procedure from continuing in an idyllic manner. Errors may or may not cause harm or delay. The term 'error' may include wrong acts/omissions/inefficiencies/delays/safety failures/problems that cause harm/delay or have the potential to cause harm/delay.

Equipment: unavailable (item is not immediately available for use, is not on scrub tray), failure/fault (item is not working correctly), configuration (the setting on the item needs to be changed), desterilized (the item is desterilized and therefore needed to be replaced).

Communication: misleading (one team member communicates with misleading instruction), lack of (one team member does not communicate effectively with another), discord (2 or more team members disagree on plan of action), does not hear/misheard.

Procedure-Independent Pressures: absence (of team member), distraction (e.g. communications not specifically regarding the procedure, noise), external pressures (this may be on the team member in the form of phone calls/ bleeps, being busy with another task or being required at another case). It may also refer to pressures on the workspace, e.g., another team needs to use the theatre.

Technical factors: psychomotor (e.g. dropping an instrument, cutting a vessel that should not have been cut), unfamiliar with procedure (actions required during operation), equipment, technique (e.g. knot tying, making anastomosis). Unfamiliarity could result from lack of experience/training/planning. Where there is anticipated inefficiency/delay due to juniors learning under supervision, this is not counted as error and does not need to be recorded.

Safety Issues: Checks not done (patient identification, equipment expiry dates or counts post-surgery), active violation (not wearing protective clothing, dangerous action e.g. cutting diathermy wire).

Patient Factors: Unusual anatomy, variations in physiology (e.g. hypotension, patient with COPD), compliance (if the patient is not under GA)

Other: These are any errors that occurred that do not fit into the other categories.

Category	Examples
1. **Equipment Issues**	Diathermy not working, Doppler not available, swab dropped ont the floor
2. **Communication Issues**	Team member gave unclear instructions, lack of communication between surgeon & anaesthetist
3. **Procedure-independent pressures**	Pagers/phones going off, team member needs to leave to attenc a different task/patient
4. **Technical factors**	Instrument is dropped, wrong vessel cut, difficulty with particular technique
5. **Safety issues**	Patient ID/equipment expiry checks not done, protective clothing not worn, violation of infection control guidelines
6. **Patient-related issues**	Unusual anatomy, patient hypotensive, patient with severe COP patient- not under GA- is uncompliant

1. Equipment Issues

☐ 1. (if applicable) "**Radiological equipment:** any equipment unavailable, faulty, not configured correctly or desterilised?"
☐ 2. "**Surgical equipment:** any equipment unavailable, faulty, not configured correctly or desterilised?"
☐ 3. "**Anaesthetic equipment:** any equipment unavailable, faulty, not configured correctly or desterilised?"
☐ 4. "Were there any **drugs or medication-related issues**?'
☐ 5. "Were there **any other** equipment-related issues that have not already been mentioned?"

Record errors/inefficiencies/safety failures below:

Error #	Equipment category:	Type of equipment problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ Radiological ☐ Surgical ☐ Drugs/medication ☐ Other	☐ Unavailable ☐ Failure/fault ☐ Configuration ☐ Desterilised		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

2. Communication

☐ 1. "**Misleading.** Did anyone experience communication that was misleading or unclear?"
☐ 2. "**Lack of**. Did anyone experience a lack of communication?"
☐ 3. "**Discord.** Were there any significant disagreements between team members about the plan of action etc?"
☐ 4. "**Does not hear/misheard.** Was any information/instruction communicated that was not heard/ misheard by other team members?"

Record errors/inefficiencies/safety failures below:

Error #	Type of communication proble	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estima delay caused by this issue?
1	☐ **Misleading** ☐ **Lack of** ☐ **Discord** ☐ **Does not hear/misheard**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ **Misleading** ☐ **Lack of** ☐ **Discord** ☐ **Does not hear/misheard**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ **Misleading** ☐ **Lack of** ☐ **Discord** ☐ **Does not hear/misheard**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ **Misleading** ☐ **Lack of** ☐ **Discord** ☐ **Does not hear/misheard**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ **Misleading** ☐ **Lack of** ☐ **Discord** ☐ **Does not hear/misheard**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ **Misleading** ☐ **Lack of** ☐ **Discord** ☐ **Does not hear/misheard**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ **Misleading** ☐ **Lack of** ☐ **Discord** ☐ **Does not hear/misheard**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

3. Procedure-Independent Pressures

☐ 1. "**Absence.** Were any team members absent who should have been here, or did any team member need to leave due to other pressures?"
☐ 2. "**Distraction.** Were there any distractions, e.g. from pagers or phones, interruptions etc?"
☐ 3. "**External pressures.** Were there external pressures, such as external emergencies, equipment or theatre needed for a different case?"

Record errors/inefficiencies/safety failures below:

Error #	Type of procedure-independent problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ **Absence** ☐ **Distraction** ☐ **External pressures**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ **Absence** ☐ **Distraction** ☐ **External pressures**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ **Absence** ☐ **Distraction** ☐ **External pressures**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ **Absence** ☐ **Distraction** ☐ **External pressures**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ **Absence** ☐ **Distraction** ☐ **External pressures**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ **Absence** ☐ **Distraction** ☐ **External pressures**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ **Absence** ☐ **Distraction** ☐ **External pressures**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

4. Technical Issues

☐ 1. "**Psychomotor.** Did any team member experience a psychomotor issue, such as dropping an instrument or psychomotor difficulty with a particular technique?"
☐ 2. "Was anyone **unfamiliar** with:
☐ the **procedure**, ☐ any of the **equipment**, ☐ any of the **technique**s used?"

Record errors/inefficiencies/safety failures below:

Error #	Type of technical problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ **Psychomotor** ☐ **Unfamiliarity with:** ☐ **procedure** ☐ **equipment** ☐ **technique**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ **Psychomotor** ☐ **Unfamiliarity with:** ☐ **procedure** ☐ **equipment** ☐ **technique**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ **Psychomotor** ☐ **Unfamiliarity with:** ☐ **procedure** ☐ **equipment** ☐ **technique**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ **Psychomotor** ☐ **Unfamiliarity with:** ☐ **procedure** ☐ **equipment** ☐ **technique**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ **Psychomotor** ☐ **Unfamiliarity with:** ☐ **procedure** ☐ **equipment** ☐ **technique**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ **Psychomotor** ☐ **Unfamiliarity with:** ☐ **procedure** ☐ **equipment** ☐ **technique**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ **Psychomotor** ☐ **Unfamiliarity with:** ☐ **procedure** ☐ **equipment** ☐ **technique**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

5. Safety Issues

☐ 1. "**Checks not done.** Were any safety checks omitted, such as checking patient identification, anesthetic equipment, WHO Surgical Safety checklist (if applicable)?"
☐ 2. "**Active violation of safety regulations.** Were there any active violations of safety regulations, such as not wearing protective clothing, violating infection control guidelines etc?"

Record errors/inefficiencies/safety failures below:

Error #	Type of safety problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ **Checks not done** ☐ **Active violation of safety regulations**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ **Checks not done** ☐ **Active violation of safety regulations**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ **Checks not done** ☐ **Active violation of safety regulations**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ **Checks not done** ☐ **Active violation of safety regulations**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ **Checks not done** ☐ **Active violation of safety regulations**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ **Checks not done** ☐ **Active violation of safety regulations**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ **Checks not done** ☐ **Active violation of safety regulations**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

6. Patient-related Issues

☐ 1. "**Unusual anatomy.** Were any problems experienced due to this patient having unusual anatomy, e.g. location of vessels?"
☐ 2. "**Physiology problems.** Were there any problems relating to this patient's physiology, e.g. hypotension, severe COPD etc.?"
☐ 3. "**Compliance.** Were there any issues with patient compliance?" (Only applicable if patient not under GA)

Record errors/inefficiencies/safety failures below:

Error #	Type of patient-related problem:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1	☐ **Unusual anatomy** ☐ **Physiology problems** ☐ **Compliance**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2	☐ **Unusual anatomy** ☐ **Physiology problems** ☐ **Compliance**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3	☐ **Unusual anatomy** ☐ **Physiology problems** ☐ **Compliance**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4	☐ **Unusual anatomy** ☐ **Physiology problems** ☐ **Compliance**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5	☐ **Unusual anatomy** ☐ **Physiology problems** ☐ **Compliance**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6	☐ **Unusual anatomy** ☐ **Physiology problems** ☐ **Compliance**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7	☐ **Unusual anatomy** ☐ **Physiology problems** ☐ **Compliance**		☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

7. Other Issues

☐ 1. "Were there any other errors/inefficiencies/safety failures that have not already been mentioned?"

Record errors/inefficiencies/safety failures below:

Error #	If there were any other errors/delays/inefficiencies/safety failures that occurred, please note them here:	Details: provide further information including people/item involved, circumstance	Did this issue predispose the patient to injury or harm?	What was the estimate delay caused by this issue?
1			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
2			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
3			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
4			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
5			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
6			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour
7			☐ Yes, actual harm occurred as a direct consequence of this issue ☐ Corrective measures needed to prevent harm. ☐ No harm	☐ No delay ☐ < 1 minute ☐ < 15 minutes ☐ < 1 hour ☐ > 1 hour

Appendix 3: Definitions of success

	Definition
Primary success	Success obtained without the need of an additional or secondary endovascular or surgical intervention
Assisted primary success	Success achieved with the use of an additional or secondary *endovascular* procedure
Secondary success	Success obtained with the use of an additional or secondary *surgical* procedure (e.g. the performance of a femoral-femoral bypass for treatment of a unilateral limb occlusion of a bifurcated graft)
Technical success	Technical success relates to periprocedural events that occur from the initiation of the procedure and extend through the first 24-hour postoperative period. It is defined as: - Successful access to the arterial system using a remote site - Successful deployment of the endoluminal graft with secure proximal and distal fixation - Absence of either type I or III endoleak - Patent endoluminal graft without significant twist, kinks, or obstruction
Initial clinical success	Initial clinical success encompasses 30-day data. Successful deployment of the endovascular device at the intended location, without: - Death as a result of aneurysm-related treatment - Type I or III endoleak - Graft infection or thrombosis - Aneurysm expansion (diameter > 5mm) - Aneurysm rupture - Conversion to open repair - Graft dilatation (≥ 20% by diameter) - Graft migration - Failure of device integrity

Adapted from Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg 2002;35(5):1048-60.

Appendix 4: Modified Global Rating Scale: generic endovascular skills

Respect for tissue (stenosis or occlusion)	**1** Frequently used unnecessary force on tissue or caused damage by inappropriate use of material	**2**	**3** Careful handling of tissue but occasionally caused inadvertent damage.	**4**	**5** Consistently approached tissues appropriately with minimal damage.
Time and motion	**1** Make unnecessary moves.	**2**	**3** Efficient time/motion but some unnecessary moves.	**4**	**5** Clear economy of movement and maximum efficiency.
Knowledge of endovascular material	**1** Frequently asked for the wrong tool or used an inappropriate material	**2**	**3** Knew names of most endovascular toolsl and used appropriate material	**4**	**5** Obviously familiar with endovascular material and their names.
Handling of endovascular material	**1** Repeatedly awkward moves and unsure with loss of access, poor stability of the tools and inaccurate positioning of balloon/stent	**2**	**3** Competent use with hardly any loss of access, moderate stability of tools and good positioning of balloon/stent but appeared stiff and awkward occasionally	**4**	**5** Fluid movements with stability of the tools, maintenance of access and perfect positioning of balloon/stent
Flow of intervention	**1** Frequently stopped intervention or needed to discuss the next move.	**2**	**3** Demonstrated some forward planning and reasonable progression of procedure.	**4**	**5** Obviously planned course of intervention with efficiency from one move to another
Knowledge of procedure	**1** Insufficient knowledge. Looked unsure and hesitant.	**2**	**3** Knew all important steps of the intervention.	**4**	**5** Demonstrated familiarity with all steps of the intervention.
Overall performance	**1** Very poor	**2**	**3** Competent	**4**	**5** Clearly superior
Quality of final product	**1** Very poor	**2**	**3** Competent	**4**	**5** Clearly superior

Appendix 5: Procedure-specific Rating Scale EVAR

Access: Introduction guide wires and diagnostic catheter	**1** Does not use guide wire to support diagnostic catheter, not advanced into suprarenal aorta, looses position during exchanges, no screening.	**2**	**3** Appropriate introductory site. Stiff guide wire and diagnostic catheter positioned. Appropriate set up for introduction of main body. Checked orientation of contralateral limb.	**4**	**5** Handles guide wire and diagnostic catheter expertly. Stiff wire and diagnostic catheter are in place. Excellent set up for main body introduction.
Aortic angiogram - Positioning main body	**1** Bad angle to view the proximal landing zone, inappropriate wires have been selected and diagnostic catheter not positioned at appropriate level. Unstable introduction of the main device, no screening.	**2**	**3** Appropriate C- arm position to land closely to renal arteries. Stable introduction of the main device while screening. Angiogram taken with breath hold and in magnification if appropriate.	**4**	**5** Perfect positioning of C arm to cover infrarenal neck with minimal of radiation. Safe advancement of the main body while screening. Perfect angiogram prior to deployment.
Deployment main body	**1** Inadequate size or placement of stent-graft, lost position during deployment. Unsafe withdrawal of the diagnostic catheter, contralateral limb poorly orientated.	**2**	**3** Accurate size and placement of stent-graft body with proper orientation of contralateral limb.	**4**	**5** Excellent covering of proximal neck with ideal stent-graft, stable deployment, checks angio to ensure position in relation to renal arteries and safe removal of pigtail.
Contralateral cannulation	**1** Inappropriate choice and use of selective catheter and guide wire while cannulating contralateral limb. Losing position during exchanges, bad angle to view the gait	**2**	**3** Appropriate choice and use of guide wires and selective catheters. Good angle to view the gait and verifies intraluminal position.	**4**	**5** Excellent choice and usage of guide wire and selective catheter. Perfect angle to view the gait and verification of intraluminal position.
Deployment contralateral limb, ipsilateral limb (if appropriate) and extensions	**1** No C arm adjustment to identify origin of contralateral internal iliac artery. Advancement and deployment (unstable) of limb without screening, overlap not appropriate.	**2**	**3** Accurate size, length and placement of contralateral device/extension while screening after adjustment of C arm position.	**4**	**5** C arm adjustment to identify contralateral internal iliac artery. Perfect delivery and stable deployment with optimal overlap of the contralateral device while screening. Delivers extensions if required.
Final/last angiogram and management of endoleaks or stenosis	**1** Angiogram not extended. Endoleaks are not detected nor treated with appropriate techniques.	**2**	**3** Angiogram with extended run to check position of stent-graft and to identify endoleaks. Solves primary endoleaks with appropriate techniques (moulding balloon, extensions ....)	**4**	**5** .Excellent angiogram with superb handling of primary endoleaks.
Quality of final product	**1** Unacceptable, wrong choice and positioning of stent graft, side branches covered unintentionally, proximal or distal landing zone not covered sufficiently, type I or III endoleak present, residual stenoses (>50%) and/ or severe kinking	**2**	**3** Average	**4**	**5** Superior. Accurate choice and placement of stent graft with good overlap and optimal covering of proximal and distal landing zones. No type I or III endoleaks. Side branches patent. No kinking or stenoses.
Pass rating	Would you feel confident in allowing this person to exclude an infrarenal AAA by endovascular means, under supervision, on a real patient?			Yes / No	

Appendix 6: Observational Teamwork Assessment for Surgery (OTAS)

Intra-Operative OTAS	Examplar Behaviours	Notes	Rating 0-6
	Surgical team		
Communication	- Asks team if all prepared to begin the operation - Requests and instructions to team communicated clearly and effectively - Provides information to whole team on progress - Informs team of technical difficulties/changes of plan → no communication of problems **-1** - Yelling, inappropriate comments **-1** - Use of names **+1**		
Coordination	- Contribute to smooth exchange of instruments and provisions with SN - Coordinate use of equipment e.g. will need pump for angio → if not communicated **-1** - Gives prior notification of requirements → anticipation **+1**		
Cooperation/ Back-up behaviour	- Responds to requests and questions form N-team and A-team - Supports others and compensates for lack of experience → providing help when needed **-1** - Asks for help when needed **+1** - Helps, supports or takes over when needed **+1**		
Leadership/ Following	- Instructions and explanations provided to assistants - Supervision provided when needed → if not present to provide support when needed **-1** - Assertive in controlling noise and distractions in theatre → noise **-1** - Advises A-team or N-team to call for additional help if required → asking for help when needed **+1** - No leadership **=1**		
Monitoring/ Situational Awareness	- Asks A about pt condition - Asks SN if materials ok → if materials are not present **-1** - Knowledge use of device → if much explanation of device representative needed **-1** - Knowledge of procedure steps → if no clear knowledge of steps **-1** - Delay because lack of planning procedure **=1**		
	Nursing team		
Communication	- SN acknowledges and confirms surgeon's requests, through verbal or non-verbal (e.g. eye contact) - SN provides clear and audible requests for provisions to CN - Yelling, inappropriate comments **-1** - Providing explanation to colleagues **+1** - Discussing problems with surgical team **+1**		
Coordination	- CN checks provisions prepared and ready for SN during operation - A CN is always present to provide backup to SN → CN not always in room **-1** - SN anticipates S requirements for instruments → anticipation of next step **+1**		
Cooperation/ Back-up behaviour	- SN responds effectively to requests from S-team and provides smooth exchange of instruments - CN responds to instructions and requests from SN → if materials are not provided after request **-1** - Providing support when needed **+1**		
Leadership/ Following	- Informs S-team of any concerns in equipment → if problems not clearly communicated **-1** - Minimizes noise and distractions in theatre → noise **-1**		
Monitoring/ Situational Awareness	- Final checks on equipment and diathermy connections - CN monitors the needs of the SN and responds appropriately → not paying attention **-1** - CN knows materials and location of materials → if not **-1** - SN observes procedure closely → thinking with team **+1**		

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Dankwoord - Acknowledgements

Eindelijk. Na het schrijven en herschrijven van talloze versies zit het er op. Of toch bijna. Vooraleer ik deze allerlaatste versie naar de printer stuur, wens ik iedereen te bedanken die rechtstreeks of onrechtstreeks heeft bijgedragen tot het tot stand komen van dit doctoraat.
Een aantal mensen wil ik echter in het bijzonder noemen.

In de eerste plaats wil ik mijn promotor Professor Frank Vermassen bedanken.
Prof, dank je voor de kans om dit onderzoek onder jouw begeleiding uit te voeren, voor het vertrouwen, voor de vrijheid om dit op mijn eigen manier in te vullen, voor de deur die altijd open staat ondanks je drukke agenda, voor je duidelijke inzichten, je enthousiasme en je positivisme. Het is voor mij nog steeds onbegrijpelijk hoe je zo snel gedetailleerde en nuttige feedback kunt geven. Ik heb veel van je geleerd, en hoop dit ook in de toekomst verder te doen.

Ik wil ook mijn co-promotor Professor Isabelle van Herzeele bedanken.
Isabelle, jij heb mij binnengeloodst in de wondere wereld van de simulatie, publicatie en presentatie. Dankzij jouw expertise en onvermoeibare inzet is dit proefschrift geëvolueerd tot wat het nu is. Dank je voor het minutieus nalezen en aanvullen van alle artikels en het beoordelen van de vele video's. Jouw goed doordachte en mooi gebrachte presentaties zijn en blijven een voorbeeld voor mij.

De leden van de examencommissie wil ik graag bedanken voor de tijd en aandacht die zij hebben genomen om dit proefschrift te lezen en te beoordelen. De kritische en constructieve opmerkingen hebben zonder twijfel de kwaliteit van dit werk verbeterd.

Gratitude goes out to the co-authors of the different scientific publications for their valuable feedback, including Professor Mario Lachat, Dr. Johan Duchateau, Mr. Colin Bicknell, Professor Joep Teijink, Dr. Jan Heyligers, Dr. John Rundback, and Mr. Rajesh Aggarwal.

Thank you to all the PAVLOV group members for their willingness to enrol participants, their help during the data collections, and their warm hospitality. A special thanks to Zoran Rancic, Lyubov Chaykovska and Nung Rudarakanchana for

cheering up the evenings I spent abroad and offering me a place to sleep (when strikes prevented me from getting back home).

Many thanks to Nathalie Moreels, Heidi Maertens and Eva-Line Decoster for all the video ratings, a never-ending job. Thank you to Rachael Lear, Celia Riga and Colin Bicknell for sharing their expertise in the field of medical error and for all the assessments.

The simulations involving patients could not have been accomplished without the participation of the individual operative team members at Ghent university Hospital, Zurich university hospital, St. Maarten hospital, St. Elisabeth hospital, Catharina hospital, and St. Mary's Hospital. My gratitude goes out to all the study participants and patients in Ghent, Zurich, Duffel, Eindhoven, Tilburg and London for their time and effort put into the different research projects.

Dank aan alle huidige en voormalige collega's van de dienst thoracale en vasculaire heelkunde voor jullie vriendschap, interesse, gezelligheid en opbeurende woorden die ik zo af en toe nodig had om dit werk te voltooien. Dankzij jullie ondersteuning kon ik naast het klinische werk ook tijd vrijmaken om dit proefschrift af te werken.

Saskia, Els en Tessa, dank voor alle administratieve hulp, voor jullie organisatorische talenten, maar vooral ook voor de leuke babbels tussendoor die me de nodige afleiding bezorgden.

Tenslotte was dit werk onmogelijk geweest zonder mijn vrienden en familie.

Mijn vrienden wil ik bedanken voor hun interesse en steun in de afgelopen jaren. Dank je voor jullie begrip als ik weer eens tegen een deadline aanliep.

Cristina en Johan, Nikolaas en Ann-Sofie, mijn schoonfamilie. Jullie aandacht en interesse, de liefdevolle opvang van onze dochters, de leuke koffiemomenten en de ontspannende babbels hebben er mede voor gezorgd dat dit boek geschreven kon worden.

Mama en papa, dank voor de onbezorgde jeugd en alles wat jullie voor mij gedaan hebben. Dankzij jullie heb ik alle kansen gehad. Papa, de vele discussies die we voerden hebben mij gemaakt tot wie ik ben. Mama, jouw nuchtere kijk en doorzettingsvermogen zijn een voorbeeld voor mij. Dank om zo goed voor ons te zorgen. Friedl, dank voor je luisterend oor. Je bent een fantastische zus!

Lieve Clara en Annette, mijn twee grootste schatten. Jullie toveren elke dag een glimlach op mijn gezicht en herinneren me aan wat écht belangrijk is. Ik geniet elke dag van jullie.

Lieve Thomas, in dit dankwoord eindig ik met jou, omdat jij degene bent die verreweg het meest te verduren heeft gehad tijdens dit avontuur. Jij was er altijd voor mij met liefde, begrip en veel geduld. Je was mijn uitlaatklep, mijn boksbal, mijn klankbord, mijn toeverlaat. Dank je om een fantastische papa (en soms tegelijkertijd ook mama) te zijn voor onze dochters. Zonder jou was dit niet mogelijk geweest. Ik kijk uit naar ons volgende avontuur.

Gent, maart 2017

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Curriculum Vitae

Personal information

Name:	Liesbeth Maria Desender
Date of birth:	18/08/1979
Civil status:	Married to Thomas Martens, mother of Clara and Annette
Correspondence:	Department of Thoracic and Vascular Surgery Ghent University Hospital De Pintelaan 185 9000 Ghent Belgium Liesbeth.desender@ugent.be

Education

Secondary school:	1991-1995	Latin-Mathematics, Sint-Bernarduscollege, Nieuwpoort
	1995-1997	Mathematics-Science, Immaculata instituut, De Panne
Bachelor degree:	1997-2000	Faculty of Medicine, Ghent University (Cum laude)
Masters degree:	2000-2004	Faculty of Medicine, Ghent University (Magna cum laude)
Doctoral Training:	2013-present	Doctoral schools of Life Sciences and Medicine, Ghent University

Surgical training

General Surgery:	2004-2006	AZ Maria Middelares, Ghent
	2006-2008	Ghent University Hospital
	2008-2009	AZ Maria Middelares, Ghent
	2009-2010	Ghent University Hospital
Vascular and Thoracic Surgery:	2010-2014	Ghent University Hospital

Current position

Consultant Thoracic and Vascular Surgeon, Department of Thoracic and Vascular Surgery, Ghent University Hospital

Certifications

Electrocardiography	2002	Ghent University
Radioprotection	2004	Ghent University
General Surgery	2010	Ghent Univerity
Vascular Surgery	2013	Belgian Society for Vascular Surgery

Memberships

Belgian Society for Vascular Surgery
European Society for Vascular Surgery (2011-2014: Belgian national representative and Board member)
Dutch Society for Simulation in Healthcare
European Society of Thoracic Surgeons

Grants

Pfizer Educational Grant (2010)
Technical Support Grant from Simbionix Ltd, Cleveland, USA
Educational Grant from W.L. Gore & Assoc, Inc, Sunnyvale, California, USA
Educational Grant from Medtronic Vascular, California, USA

Publications

A1 Publications in international journals included in the Science Citation Index

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L. Desender, I. De Laet, F. Vermassen, J. De Waele. Tertiary peritonitis and tertiary abdominal compartment syndrome: a perfect match? World Congress Abdominal Compartment Syndrome, Antwerp, Belgium, 23th March 2007.

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F. Berrevoet, L. Desender, M. Dezza, I. Colle, X. Rogiers, R. Troisi, B. de Hemptinne. Low morbidity using composite mesh for incisional hernia repair after liver transplantation. Annual Scientific Meeting of the Belgian Transplantation Society.

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E. Reynvoet, L. Desender, F. De Ryck, F. Vermassen. Video assisted thoracoscopic surgery for bronchopulmonary carcinoid tumor. 13th Belgian Surgical Week, Spa, Belgium, 9th May 2012.
Winner 1st prize Trainer versus Trainee session.

I. Van Herzeele, L. Desender, W. Willaert, F. Vermassen. World's first case-specific rehearsal prior to EVAR. LINC symposium, Leipzig, Germany, 25th January 2012.

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Winner 2nd prize free paper session

I. Van Herzeele, L. Desender, C. Randon, F. De Ryck, F. Vermassen. European Experience with a Novel Transcervical Access Neuroprotection System for Carotid Revascularization. Multidisciplinary European Endovascular Therapy Conference, Rome, Italy, 13th June 2012.

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L. Desender, Z. Rancic, R. Aggarwal, M. Glenck, M. Lachat, F. Vermassen, I. Van Herzeele. Patient-Specific Rehearsal prior to Endovascular Aneurysm Repair: a Pilot Study. TCT conference, Miami, USA, 22nd October 2012.

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L. Desender, I. Van Herzeele, M. Janssen, F. Vermassen. Initial presentation of an acute aortic syndrome: sudden-onset paraplegia. Multidisciplinary European Endovascular Therapy Conference, Rome, Italy, 11th June 2013.

T. Martens, L. Desender, I. Van Herzeele, F. Vermassen. Endovascular Repair in Marfans Patients: is it feasible? Multidisciplinary European Endovascular Therapy Conference, Rome, Italy, 11th June 2013.

I. Van Herzeele, L. Desender. Optimal rehearsal for endovascular teams prior to aneurysm repair. Medtronic Benelux Symposium, Mechelen, Belgium, October 24th 2013.

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Invited Lectures

De chirurgische dilemma's en behandelingsmogelijkheden van geïnfecteerde vaatprothesen en endoprothesen. Najaarsvergadering Koninklijke Belgische Vereniging voor Vaatchirurgie, Le Touquet, France, 10th October 2009.

Alternatives for Branched Iliac Stent Grafting. Prijs Endovasculaire Werkgroup. Belgium, 16th June 2011.
Winner 3rd prize

Vascular Surgery: Training in Belgium. ESVS Annual Meeting, Athens, Greece, 22nd September 2011.

Patient-Specific VR Simulation for Endovascular Procedures. Wetenschapsdag Ghent University, Ghent, Belgium, 14th March 2012.

Case Rehearsal prior to EVAR is not a Waste of Time! Veith Symposium, New York, USA, 16th November 2012.

Patient-Specific Rehearsal prior to EVAR. Lustrum Congress Dutch Society of Simulation in Health Care, Amsterdam, The Netherlands, 20th March 2013.

Patient-tailored Team Rehearsal for EVAR. 35th Charing Cross Symposium, London, United Kingdom, 8th April 2013.

Procedure Rehearsal in Endovascular Surgery. 35th Charing Cross Symposium, London, United Kingdom, 9th April 2013.

Patient-Specific Simulated Rehearsal of Endovascular Procedures significantly improves Operative Performance. 8th European Symposium of Endovascular Biomaterials, Strasbourg, France, 10th May 2013.

Iliac and SFA interventions: what to use and why? XXVIII Annual Meeting ESVS, Stockholm, Sweden, 23rd September 2014.

Optimal sizing, planning and preparation for EVAR. Veith symposium, New York, USA, 19th November 2014.

Role of surgery for intrathoracic cysts. Eindejaarsmeeting Belgische Vereniging voor Pneumologie, Luik, Belgium, 5th December 2014.

Dunbar syndrome. Werkgroep Klassieke vaatheelkunde, Mechelen, Belgium, 3rd December 2015.

Value of procedure rehearsal for EVAR procedures. Interdisciplinary Endovascular Aortic symposium, Barcelona, Spain, 13th September 2016.