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Simulation-based Endovascular Training: Ready for Prime Time?

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Ghent 2016

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

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This thesis was financially supported by a Clinical Doctoral Grant from the Fund for Scientific Research - Flanders, Belgium.

“Practice does not make perfect. Only perfect practice makes perfect.”

Vince Lombardi 1913-1970

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Abbreviation list

ACGME	Accreditation Council for Graduate Medical Education
ACS	American College of Surgeons
ALARA	As Low As Reasonable Achievable
APDS	Association of Program Directors in Surgery
EIA	External Iliac Artery
EWTD	European Working Time Directive
CIA	Common Iliac Artery
DSA	Digital Subtraction Angiography
FES	Fundamental Endovascular Skills/Fundamentals of Endoscopic Surgery
FLS	Fundamentals of Laparoscopic Surgery
GOALS	Global Operative Assessment of Laparoscopic Skills
GRS	Global Rating Scale
IC	Interventional Cardiology
IR	Interventional Radiology
MCQ	Multiple-Choice Questionnaire
MIS	Minimally-Invasive Surgery
OR	Operating Room
OSATS	Objective Structured Assessment of Technical Skills
OTAS	Observational Teamwork Assessment for Surgery
PAD	Peripheral Arterial Disease
PROSPECT	PROficiency-based StePwise Endovascular Curricular Training
PTA	Percutaneous transluminal angioplasty
SFA	Superficial Femoral Artery
SPSS	Statistical Package for the Social Sciences
SSC	Surgical Safety Checklist
TASC	TransAtlantic InterSociety Consensus
VR	Virtual Reality
VS	Vascular surgery
WHO	World Health Organization

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General introduction and thesis outline

Learning process in endovascular procedures

In the 1990's there has been a revolution in the treatment of atherosclerotic arterial disease by the introduction and expansion of endovascular interventions. The word 'endovascular' is derived from the Latin words 'endo' meaning 'within' and 'vasculi', which means 'vessels'. During endovascular treatment guidewires, balloons, stents and other tools are manipulated inside blood vessels using X-ray guidance to treat arterial lesions (Figure 1).

Figure 1 shows an endovascular intervention. Tools are inserted via an arterial puncture in the groin of the patient.

Standard open surgical procedures were converted to endovascular interventions, characterised by a minimally invasive approach with reduced tactile feedback and an increased need for hand-eye coordination, manually handling endovascular tools whilst viewing its position on a two-dimensional screen.[1] Despite these distinctive technical and cognitive challenges, endovascular interventions show multiple clinical and financial advantages over open procedures including reduced postoperative pain, limited scar tissue formation and shorter hospital stay.[2] However, a learning curve has to be overcome to obtain these complex minimally invasive procedural skills and if endovascular procedures are performed by inexperienced interventionalists, it may be associated with higher complication rates.[3]

The learning curve is the number of procedures it takes for an average physician to perform the procedure successfully and independently (Figure 2). In endovascular surgery, between 5 and 40 cases may have to be carried out depending on the type of endovascular procedure, patient characteristics and the innate abilities of the physician.[3] The figure below graphically represents how learning influences the performance over time for a given surgical procedure, showing an initial sharp increase in skills retention that gradually plateaus because less new information is obtained after each attempt. During the initial phase of this learning process the operating time is prolonged and more errors tend to occur, leading to increased blood loss, complication rate and overall morbidity.[4]

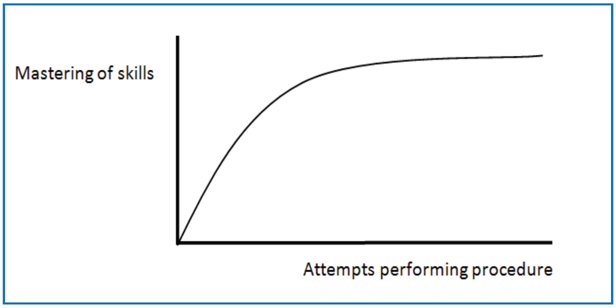

Figure 2: Learning curve for surgical procedure.

In order to avoid these complications and to achieve the previously mentioned advantages of minimally invasive procedures, vascular surgeons need to obtain competence levels and master the cognitive, technical and human factor skills to carry out endovascular interventions successfully.

Evolution in surgical education

Traditionally, surgeons were trained according to the model ‘see one, do one, teach one’, introduced by William Halsted[5], referring to apprenticeship learning by observing the physician and gradually mastering surgical tasks during clinical practice. However, it has been argued that this model is no longer feasible or acceptable in the 21th century.[6, 7] The last decade there has been a growing focus on patient safety.[8] It is now considered unethical to learn and practice new surgical techniques on patients and standardised proficiency levels are needed to credential physicians before performing complex interventions.[9, 10] Patients demand to be treated by proficient surgeons and not by inexperienced trainees. Appropriate knowledge, technical and non-technical skills should be acquired prior to treat real patients in order to carry out minimally invasive procedures successfully and safely.

Furthermore, as described above, the surgical discipline increasingly uses minimal invasive interventions such as endovascular therapeutic and diagnostic procedures that require a different tool and skills set compared to open surgical procedures. Training of these particular crafts is more challenging than teaching open vascular skills since trainees cannot rely on previously obtained skills during their surgical education and only physicians with endovascular experience can successfully manipulate the tools during the intervention.

Additionally, trainees have to master a broad range of surgical procedures including a variety of minimally invasive techniques within a shorter time period in comparison to previous generations due to the implementation of the European Working Time Directive (EWTD), reducing working hours and consequently decreasing training time.[11, 12] Using effective and pervasive teaching tools, trainees might have the ability to dedicate their time for more efficient learning, as opposed to participating passively with limited conscious focus during set times and dates, such as mandatory half-day seminars. Finally, teaching basic skills during a real intervention in the current economical climate does not only prolong the operating time but also increases complication risks, resulting in higher perioperative costs.[13]

These changes vastly limit practice opportunities for trainees and raise concerns about ensuring the quality of surgical healthcare in the future. Effective educational tools including multimedia-based and hands-on surgical tools have been studied to complement training on the ward and in the operating room[6] and to shorten the learning curve and reduce the complications in actual patients.[14]

Multimedia-based surgical training tools

Multimedia-based or e-learning technology is defined as any platform available on the Internet or otherwise, whose content, sequence, and pace are controlled by the learner, and whose source of information is separated from the learner in both space and time.[15] This technology provides numerous advantages over traditional teaching methods. Online textbooks, podcasts and other multimedia-based curricula are increasingly replacing printed text and didactic lectures, offering trainees the flexibility to use the resources when they are maximally engaged, at their own convenience, free of time and geographic constraints, to optimise learning.

E-learning provides the possibility to deliver educational content to large groups of trainees and surgeons in various cities, countries or continents using a single platform. These boundaries are often difficult to overcome with simulation-based curricula or didactic lectures, which require trained expert instructors, expensive equipment or other resources.[16]

Access to web-based curricula also tend to be less expensive, by avoiding publishing costs or costs to reimburse the clinical time of the tutors[17, 18] Other advantages are the opportunity to standardise curricula, to be independent of the availability of faculty, patients or rare cases, and the ability to assess learners repeatedly and longitudinally provide them with immediate and ongoing formative feedback until they achieve proficiency.[19] The availability and effectiveness of e-learning tools in surgical education will be extensively discussed in the second chapter of this thesis.

Hands-on surgical training tools

Over the last decade, animal models, human cadaver training and simulation-based methods have been suggested to master surgical skills outside the operating room.[20]

Animal laboratories provide training with the use of anesthetised pigs to help trainees over the steepest part of the learning curve.[21] Endovascular interventions in a fully functioning arterial system can be performed[22]; however procedures are limited to only a few types of endovascular interventions after artificial induction of pathology.[23-25] Piglab training seems to be equivalent to Virtual Reality (VR) simulation training for endovascular iliac artery procedures[21], however evidence is extremely limited, with no studies evaluating effectiveness of transfer of porcine lab training to surgical performance in clinical environment.[20]

Human cadaver training offers practice opportunities to perform several minimally invasive procedures without the ethical and legal implications of animal models[20], however to permit endovascular practice postmortem intravascular circulation needs to be established, allowing physicians to deliver materials, train implantation techniques and bypass significant arterial stenosis.[26] Cadaveric procedural anatomic courses have shown to improve operative knowledge for several general surgery procedures[27]; however the value and effectiveness of human cadavers in endovascular training has not been assessed in current literature.

Simulation-based tools are available for hands-on training of surgical skills in a simulated environment. This technique replicates an intervention that can be demonstrated and learned and allows evaluation of progress using assessment parameters that are automatically registered.[28] To train minimally invasive techniques high or low fidelity simulators can be used. High fidelity refers to the level of realism of the simulation; the anatomical structures look realistic and respond appropriately as they are moved or retracted by the virtual instruments. Most tools act as in real-life. This is contrasted by a low-fidelity or synthetic system where no internal structures are represented.[29] Low-fidelity simulators seem to be appropriate to learn and practice basic skills, whereas high-fidelity equipment is indicated for practicing advanced skills[29, 30], increasing cognitive load during skills acquisition in highly contextualised learning environments.[31, 32]

High fidelity simulators or virtual reality simulators are used in high-reliability fields such as military, aviation, nuclear and oil industry, because they allow practice of complex and hazardous activities in a safe, secure, computer-generated environment. In laparoscopic and endoscopic medical fields, VR simulation has proven effective for training and assessment of technical performance.[33-35] It has also been shown to decrease procedural time and radiation dose in the field of interventional radiology.[36] Similarly, for endovascular skills training, VR simulators are ideal since the endovascular tools can be reused including stents, balloons and stent-grafts.[20] The simulator allows practice of C-arm and table manipulation, hand-eye-foot coordination and imaging techniques in a radiation-free environment. This simulated environment permits sensory interaction, giving the impression of actually performing a real-life endovascular intervention.[37]

The first advanced endovascular VR simulator was described fifteen years ago by Dawson, leading to development of several endovascular simulators, which continue to be updated and improved by implementing new high-tech facilities.[38] It has been shown that today's currently available brands of VR simulators are equally effective in providing high-fidelity reproductions of the endovascular environment, incorporating the necessary features for a high-fidelity experience, including haptic technology, vessel reconstruction, physiology feedback and performance feedback.[39] Based upon previous experiences, user friendliness and availability, the dual leg Angio Mentor (Simbionix, Cleveland, Ohio, USA) was selected to be used in this research (Figure 3). The software of this simulator covers a range of modules to practice treatment of peripheral, aortic and coronary arteries.

Figure 3: Angio Mentor (Simbionix, Cleveland, Ohio, USA).

Improvement of technical performance after VR simulation training is explained by the concept of 'transferability of skills', meaning that the skills obtained in one context can be transferred into another context that shares similar characteristics.[40] Transfer of acquired skills from the simulated environment to the operating room is powerful and effective for both experienced surgeons and novices.[36, 41] By transferring surgical skills to bedside procedures and the operating room, surgical simulation training has shown to improve patient outcomes.[34, 35, 42-44] It has for example been proven that simulation based training can significantly reduce catheter-related bloodstream infections in patients.[45]

Characteristics of a surgical curriculum

Surgical skills are categorised into three main areas: cognitive (knowledge), technical (clinical) and non-technical (human factor) skills.[46] To be effective, skills training should incorporate these key skills in a surgical curriculum.[7] Focus should not only be on knowledge and technical skills, but also non-technical skills such as teamwork, leadership and communication should be addressed, since literature indicates that human factor errors lead to most errors and adverse patient outcomes in health care.[47, 48] There is a three-stage progression towards skills acquisition.[7] During the first cognitive stage, the trainee intellectualises the tasks, familiarising with the various endovascular tools and imaging techniques. Practice and feedback is required to progress to the second integrative stage, where performance is seen to flow with fewer interruptions, before the final autonomous phase is achieved, where the surgeon operates without external input.

A curriculum consists of a set of courses aiming to achieve specific *learning objectives*, defining milestones that trainees need to master at various stages of their training. These learning objectives should clearly state the competences that have to be achieved and specify the level of expertise that must be obtained.[49] The Royal College of physicians and surgeons implemented CanMEDS, a framework for training based upon 6 areas of medical practice; stating a surgeon should be a scholar, professional, communicator, collaborator, leader and health advocate.[50]

To achieve high quality educational outcomes, a curriculum should be *competence-based or proficiency-based*.[43] Using the concept of proficiency-based training, the physician practices until predefined expert-levels of performance are achieved. This is in contrast to current time-based training in which a surgeon is considered competent after completing a predefined training period performing a certain number of interventions. Opposed to this time-based training, proficiency-based curricula stimulate skills acquisition and skills transferability to the operating room.[14, 40] In the USA, surgical trainees are required to complete the Fundamentals of Laparoscopic Surgery (FLS) and the Fundamentals of Endoscopic Surgery (FES) for the American Board of Surgery, which are surgical training curricula with validated competence-based simulation components (Table 1).[51]

Task	Allowable Errors	Proficiency Time (s)	No. of Repetitions Required
Peg transfer	No dropped pegs outside the field of view	48	2 consecutive + 10 nonconsecutive
Pattern cut	All cuts within 2 mm of the line	98	2 consecutive
Ligating loop	Up to 1 mm accuracy area, no knot insecurity	53	2 consecutive
Extracorporeal suture	Up to 1 mm accuracy area, no knot insecurity	136	2 consecutive
Intracorporeal suture	No model avulsion	112	2 consecutive + 10 nonconsecutive

Table 1: Proficiency-based curriculum FLS manual skills training

A *stepwise or modular approach* allows the development of proficiency-based surgical curricula for various procedures. This modular system was described by McClusky et al. and is based upon 5 steps: knowledge acquisition, psychomotor assessment and initial acquisition, integration of knowledge and psychomotor skills, supervised real-world application and mastery.[52] Acquiring cognitive skills should always precede technical skills training. A modular education model requires integration of appropriate and valid assessment tools to evaluate the skills after each step within the program.

To adequately evaluate the skills acquisition and measure level of proficiency in each of the six CanMEDS areas of medical practice, *appropriate assessment* methods should be defined. As described above, current assessment methods mainly focus on registration of a completed training period with achievement of a minimum number of interventions to ensure proficiency. However, these represent surrogate measures of performance and are insufficient to determine clinical competence.[53] Therefore, standardised and objective assessment methods are needed to train and evaluate operative performance.

Prior to including VR simulation in an endovascular educational program for training and assessment of surgical trainees, the validity of the simulator should be demonstrated. *Validity* is the extent to which the tool teaches or evaluates what it is intended to measure. There are five steps of validation. The first step is *face validity*, which describes to what extent the test resembles accurately to real interventions. This form of validity is assessed by expert review of the content of the simulator to see if it is appropriate. It must be noted that a realistic simulation does not necessarily imply an effective training or assessment model.[54] *Content validity* refers to the extent to which the content of the examination corresponds to the content of the tested domain. The next step is *construct validity,* describing to what extent the test measures the correct parameters and allows discrimination between multiple levels of expertise. *Concurrent or discriminative validity* refers to the degree to which the results of the examination correlate with a previously validated measure for that domain. In endovascular simulation, face validity, content validity and construct validity has been shown; however simulator metrics do not show concurrent validity. This results in the need for adjuvant assessments using OSATS-derived rating scales in endovascular VR simulation. Finally, *predictive validity* describes if the test is able to predict future performance in the operating room.

Besides demonstrating the concept of validity, both feasibility and reliability of the tool should also be addressed. *Feasibility* refers to the possibility that something can be accomplished or carried out, whereas *reliability* includes precision, internal consistency and reproducibility of a test. The *inter-rater reliability* reflects the level of agreement between independent observers.

A variety of assessment tools are available, which can be broadly classified as non-observational and observational. VR simulators provide a non-observational assessment by automatically and instantly recording assessment parameters that are available at the end of each exercise. However, there is a lack of evidence to support the validity of these metrics and additional observational assessments should be used to evaluate the quality of performance. 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.[55] This OSATS is often modified to ensure that it can be used to evaluate a specific surgical procedure e.g. the Global Operative Assessment of Laparoscopic Skills (GOALS).[56] In this thesis the OSATS derived rating scales for endovascular skills have been used.[57] Additionally, structured expert feedback concerning strengths and weaknesses can be provided guided by the elements addressed by these rating scales.

This expert *feedback component* is essential to enhance skills acquisition (Figure 5). Formative expert feedback is a constructive evaluation process to improve the learning technique by providing beneficial learning opportunities. This is in contrast with summative feedback that assesses if standards have been achieved, such as an exam. Since physicians are used to provide summative feedback, both trainee and supervisor experience difficulties in receiving and providing formative feedback, thus impeding training. Dedicated time for adequate formative assessment by expert supervisors during simulation-based practice and in the workplace is crucial to successfully train young surgeons[58], since practice does not make perfect, but perfect practice makes perfect. Formative feedback should automatically and ideally be given at the end of each training session to stimulate skills retention.[59]

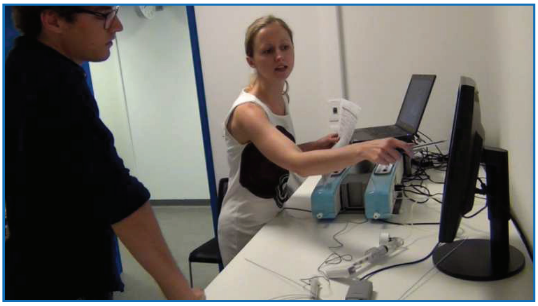

Figure 5 illustrates structured formative feedback after a training session.

Costs for surgical education

Although simulation training has been introduced into surgical education almost two decades ago and improvement of operating performance has been proven for several simulation-based curricula[34, 35, 42, 44, 60], physicians remain critical, mainly because simulation training is considered to be expensive caused by material and personnel resources.[61, 62]

Endovascular VR simulation training may seem to be expensive compared to synthetic low fidelity simulation tools; however, there is a limit to the re-use of a low fidelity model resulting in increased costs related to disposable tools. If compared to the other types of high fidelity training, VR training is less expensive than practice on live animals and human cadavers.[20, 63] Endovascular training in the porcine lab implies significant logistic and material costs of which the largest item cost is the use of intravascular stents.[63] Similarly, these high costs are inevitable to organise human cadaver training using postmortem circulation by advanced reperfusion techniques imperative to allow endovascular practice.[26]

Furthermore, VR simulation training requires a lower expense compared to opportunity training during real-life surgical interventions, prolonging operating room time and resulting in increased costs due to the training process.[64-66]

VR simulation-based training has proven to be cost-efficient for training in catheter insertion technique, effectively reducing complication rates and avoiding additional costs of care due to reduced catheter-related bloodstream infections after simulation-based education.[60, 67] Nevertheless, due to increasing financial pressure on surgical departments, high-level evidence of clinical and economical effectiveness is required for acceptance and implementation of surgical simulation curricula.[62] Therefore, each surgical curriculum needs to provide evidence whether or not it addresses the learning objectives in a cost-efficient manner.[68]

Aim and outline of this thesis

The objective of this thesis was to design and validate a structured proficiency-based curriculum consisting of e-learning and hands-on simulation training to learn and practice endovascular skills required to treat symptomatic atherosclerotic arterial lesions in the lower limbs. We aimed to confirm transferability of these skills to the hybrid angiosuite and critically assess the costs of this surgical training program.

To allow comprehensive evaluation of a proficiency-based (assessment using expert scores instead of training period or number of performed procedures) stepwise (knowledge training prior to practice of technical skills) structured (standardised exercises independent of clinical pathology presented in clinical practice) endovascular training program including hands-on VR simulation and multimedia-based training in surgical skills, the following research questions were analysed in this thesis:

1. Do multimedia-based learning tools provide an effective educational method for surgical training? **(Chapter 2)**
2. What Fundamental Endovascular Skills (FES) should be achieved in an endovascular training program, based upon the opinion of an interdisciplinary panel of experts in endovascular procedures (interventional cardiologists, interventional radiologists and vascular surgeons)? **(Chapter 3)**
3. How to develop a proficiency-based stepwise endovascular training (PROSPECT) program to train cognitive, technical and human factor skills and is it feasible to obtain proficiency levels? (**Chapter 4**)

4. Do the endovascular skills acquired in a proficiency-based stepwise endovascular training program (PROSPECT) transfer to real life and lead to higher quality performances? (**Chapter 5**)
5. Does a hands-on simulation component in an endovascular proficiency-based curriculum add educational value in comparison with a curriculum that only includes e-learning with regards to skills acquisition, transferability of skills and skills retention? (**Chapter 5)**
6. How large is the financial investment needed to implement an endovascular proficiency-based curriculum with e-learning and simulation-based? (**Chapter 6**)

The current state of multi-media based training in surgical disciplines is presented in a systematic review in **Chapter 2**.

In the initial phase of this study Fundamental Endovascular Skills (FES) were defined by a multidisciplinary transatlantic consensus among endovascular interventionalists. This process is described in **Chapter 3** and provides the learning goals for endovascular skills training.

Chapter 4 describes the development and validation of a PROficiency-based StePwise Endovascular Curricular Training (PROSPECT) program educating minimally invasive treatment of symptomatic atherosclerotic iliac and femoral arteries.

This program was implemented in a Randomised-Controlled Trial (RCT) assessing transferability of skills and operating room performance in **Chapter 5**. Skills acquisition was compared in three groups: one group received traditional clinical education without additional training, the second group continued traditional education and studied four e-learning modules, and the last group completed the entire PROSPECT program with both e-learning and hands-on simulation training complementary to their clinical activities.

Finally, the cost of this PROSPECT program in endovascular training was evaluated and discussed in **Chapter 6**.

2

E-learning for Surgical Training: A systematic review

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Abstract

Objective

To evaluate the effectiveness of e-learning as a teaching tool compared to no intervention and other methods of surgical training.

Background

Internet and software-based platforms (e-learning) have gained popularity as teaching tools in medical education. However, despite their abundance and widespread use, there is limited evidence to support their effectiveness for surgical training.

Methods

A systematic literature search of bibliographic databases was performed up to August 2015. Studies were included if they were randomized-controlled trials assessing the effectiveness of an e-learning platform for teaching any surgical skill, compared to no intervention or another method of training.

Results

From 4704 studies screened, 87 were included with 7871 participants enrolled, comprising of medical students (52 studies), residents and fellows (51 studies), attending physicians (2 studies), and nurses (6 studies). E-learning tools were used for teaching cognitive (71 studies), psychomotor (36 studies), and non-technical skills (8 studies). Tool features included multimedia (84 studies), interactive learning (57 studies), feedback (27 studies), assessment (26 studies), virtual patients (22 studies), virtual reality environment (11 studies), spaced education (7 studies), community discussions (2 studies), and gaming (2 studies). Overall, e-learning showed either greater or similar effectiveness compared to no

intervention (29 and 4 studies, respectively), or compared to non-e-learning interventions (29 and 22 studies, respectively).

Conclusions

Despite significant heterogeneity amongst platforms, e-learning is at least as effective as other methods of training and can be a powerful tool for surgical curricula. Nevertheless, the effectiveness of this technology remains contingent on adherence to best practices in education.

Introduction

In light of the various factors that have changed surgical practice, such as growing concerns for patient safety[69], introduction of new technologies, focus on cost-effectiveness[70], and work-hour restrictions[71], surgical education has evolved significantly. As a result, educators face challenges when attempting to provide effective learning experiences for trainees, while simultaneously providing high quality surgical care to patients.

To achieve these paradigm-shifts and overcome the various obstacles of today's training environment, Internet and software-based resources have gained increasing popularity.[72] The pervasiveness and widespread accessibility of the World Wide Web, portable devices (e.g. smartphones and tablets), multimedia platforms, software programming and other disruptive technologies present new possibilities for delivering evidence-based educational material optimally, efficiently, and cost-effectively.[73] These so-called "e-learning" tools range anywhere from online textbooks access, to cognitive simulators, and online curricula with varying extents of multimedia and user-engagement.

E-learning technology can be used to stimulate multiple visual and auditory perceptual pathways of the human mind when attempting to understand events with complex temporal and spatial relationships, such as a surgical procedure[74] thereby rendering it a potentially powerful instrument for surgical training. In addition, e-learning provides an unparalleled level of accessibility that is not restricted by location, faculty availability, time-restrictions, user costs, or other resources necessary to organise and deliver an effective curriculum.[62, 75]

Developing effective e-learning teaching tools can be highly resource-intensive, requiring a significant investment of time, cost and expertise for the initial design of the platform and its educational content, while adhering to best practices in surgical education using a theory-driven approach. Therefore, to justify this investment and to encourage educators and surgical societies to continue developing such tools, it is imperative to demonstrate its educational value. While the association between internet-based instruction and educational outcomes has been suggested in a systematic review from 2008[76], there has since been a proliferation of Internet and software-based platforms that have surfaced with more advanced and complex user interfaces.[76, 77] Furthermore, given the highly procedural nature of surgical specialties compared to that of other domains in medicine, the evidence to support its use for surgical training remains unclear.

The aim of this study was to systematically review the literature to evaluate and critically appraise the evidence supporting the use of e-learning as a tool for surgical education compared to either no intervention or other methods of training amongst healthcare professionals.

Methods

A systematic literature search was performed for all articles published up to August 2015 by adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) standards.[78] This study was registered in the International prospective register of systematic reviews PROSPERO on March 20, 2014 (registration number CRD42014008954).

Randomized controlled trials (RCT) were included if they reported on the effectiveness of e-learning technology to teach a surgical skill to any healthcare professional at any stage of training or practice (medical students, residents, fellows, attending surgeons, nurses and other allied healthcare workers) in comparison to either no intervention or other method(s) of training.

E-learning technology was defined as any platform available on the Internet or otherwise, whose content, sequence, and pace are controlled by the learner, and whose source of information is separated from the learner in both space and time.[15] Platforms with a hands-on technical training component, including the use of hardware other than a standard computer monitor, keyboard, mouse or touch-screen device were excluded. All non-RCTs were also excluded. In order to evaluate the true effectiveness of e-learning, studies that incorporated e-learning as part of a broader curriculum were only included if the comparison group was subjected to the same curriculum with the exception of e-learning.

Using Kirkpatrick's four-level model for evaluating training programs[79], studies solely reporting self-reported opinions (level 1) without evaluating learning (level 2), transfer of acquired competencies into job behaviors (level 3), or patient outcomes (level 4) were excluded (Figure 1). There were no exclusions based on surgical specialty, year, language of publication, or surgical skill, as long as the e-learning tool was deliberately designed to target any Accreditation Council for Graduate Medical Education (ACGME) core competency in relation to surgery.[80]

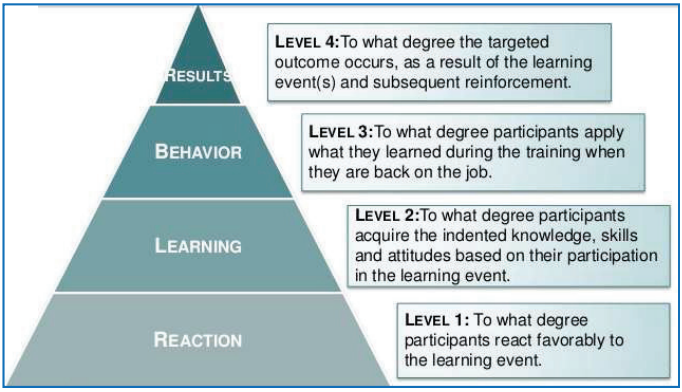

Figure 1: Kirkpatrick's training evaluation model

Search Strategy

Bibliographic databases (MEDLINE, EMBASE, BIOSISPreviews, ERIC, The Cochrane Library, PubMed, Web of Science and Scopus), conference proceedings and grey literature were searched for relevant articles. The search strategy used text words and relevant indexing to capture the concept of e-learning for surgical training. The full MEDLINE strategy (Appendix 1) was applied to all databases, with modifications to search terms as necessary. Further studies were identified in Web of Science and Scopus (July 2015) by carrying out citation searches for studies citing included studies, as well as by examining their reference lists. The ClinicalTrials.gov trial registry was searched to identify relevant research in progress. Health Technology Assessments were also identified via the Centre for Reviews and Disseminations' HTA Database. Conference proceedings from the International Conference on Residency Education, the Association for Surgical Education, and the Association of Program Directors in Surgery were also searched until 2015. Finally, the Journal of Surgical Education was hand-searched for relevant articles from 2000-2015.

Initially, two authors (HM and AM) independently screened all studies for relevance and eligibility based on title and abstract. Any inconsistencies or disagreements were resolved by discussion and consensus. Articles judged to meet the inclusion criteria were withheld for further full-text evaluation. Agreement between reviewers was assessed using kappa statistic.

Data Extraction and Synthesis

Data was systematically extracted to include characteristics of the study design and methodology, participants, the e-learning platform, comparison interventions, timeframe and frequency of delivery of curricular content, metrics and assessment tools to evaluate performance, all primary and secondary outcomes that provide Kirkpatrick level 2 and greater assessment, and results of statistical analyses comparing e-learning treatment arms to other treatment arms. Characteristics of e-learning platforms were also qualitatively analysed using an inductive thematic analysis methodology in order to synthesise features related to instructional design.[81]

Outcomes were segregated and analysed according to various themes in order to evaluate the impact of specific features on outcomes. Data was further classified and analysed according to various comparison groups, Kirkpatrick levels of assessment, and surgical skills that were taught and evaluated. Kirkpatrick level 2 was further divided into levels 2a (written or oral examination) and 2b (performance-based assessment in a non-clinical simulated environment). Surgical skills were broadly categorised into technical skills, cognitive skills (e.g. procedural or disease-related knowledge, pattern recognition), and non-technical interpersonal skills (e.g. communication, leadership, teamwork, professionalism).

Given the significant heterogeneity of e-learning technologies and educational content, pooled comparisons and meta-analyses were not performed.

Quality Assessment

Study quality was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) standards to evaluate the execution of methods, reporting of results and the likelihood that additional research would affect confidence level in the estimate of effect.[82, 83] Limitations in study quality and potential risk of bias were evaluated using the CONSORT checklist for RCTs.[84] Outcome bias in relation to methods of performance assessment was evaluated using accepted standards for validity evidence.[85]

Results

The initial search strategy yielded 2741 studies for potential inclusion after removal of duplicates. After screening, 137 studies were selected for full-text review. An additional 1963 studies were screened from reference lists, bringing the total number of studies that underwent full-text review to 145, of which 87 were ultimately included for analysis. Appendix 2 provides a detailed listing of references. Reasons for exclusion included: wrong study population (i.e. non-healthcare professionals; 6 studies), wrong focus (i.e. not evaluating e-learning or unrelated to surgery; 10 studies), no comparison group or non-randomised comparison group (6 studies), duplicates not initially excluded during screening (18 studies), and insufficient information about the intervention to determine if it fulfilled the criteria to be considered an e-learning tool (10 studies). Agreement between reviewers for inclusion of identified studies during screening and full-text review was 100%. Figure 2 depicts details of the study inclusion algorithm.

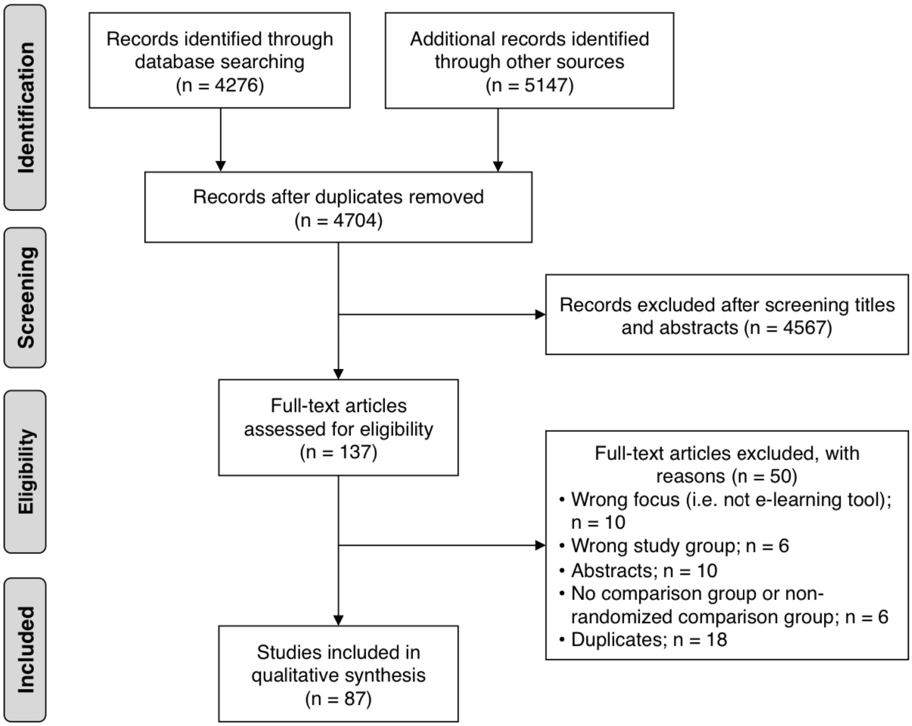

Figure 2: Study selection flow diagram

A total of 87 RCTs were included, involving 7871 participants enrolled. Number of enrolled subjects ranged from 15 to 480, with a median of 60 (IQR 35-100). Thirty-three studies compared e-learning to no intervention, while the rest compared e-learning to various educational interventions (Table 1). Most e-learning tools were designed to teach either cognitive skills (71 studies), such as procedural or disease-related knowledge and pattern recognition, or psychomotor skills for surgical tasks (36 studies). Eight studies evaluated e-learning for teaching non-technical skills, such as communication, leadership, team dynamics and professionalism.

The majority of studies evaluated learning and acquisition of skills through written/oral examinations (mostly in the form of multiple-choice examinations; 66 studies), or using performance-based assessments in a non-clinical simulated environment (31 studies; Kirkpatrick level 2). Only 2 studies evaluated transfer of acquired competencies to the clinical environment (Kirkpatrick level 3), and no studies assessed changes in patient outcomes (Kirkpatrick level 4). Table 1 summarises study characteristics.

Table 1: Characteristics of included studies

Study Characteristics	No. Studies (No. Participants)*
Study design	
• Single-center	62 (4289)
• Multi-center	24 (3141)
• Cluster randomized trial	1 (441)
Treatment arms	
• 2	72 (6743)
• 3	10 (584)
• 4	5 (544)
Participants†	
• Medical students	52 (5012)
• Junior residents	35 (2876)
• Senior residents and/or fellows	28 (2177)
• Attending surgeons	2 (132)
• Nurses	6 (344)
Discipline and specialty	
• Fundamentals of surgery	14 (1478)
• General/abdominal surgery	16 (1293)
• Urology	10 (1837)
• Trauma/critical care	8 (378)
• Orthopedic surgery	8 (768)
• Otolaryngology	7 (428)
• Obstetrics/gynecology	6 (242)
• Cardiothoracic surgery	6 (475)
• Ophthalmology	5 (543)
• Nursing	3 (270)
• Plastic surgery	3 (99)
• Vascular surgery	1 (53)
• Pediatric surgery	1 (60)
Surgical skills taught through e-learning	
• Technical (psychomotor) skills training	36 (2567)
• Cognitive skills training (e.g. basic knowledge, procedural knowledge, pattern recognition)	71 (6627)
• Non-technical skills training (i.e. communication, leadership, team dynamics, professionalism)	8 (500)

Comparison group (e-learning vs.)	
• Nothing	33 (2915)
• Didactic teaching	18 (1004)
• Textbook/literature	17 (1207)
• Simulation	16 (1194)
- Bench-top model	9 (646)
- Mannequin	3 (141)
- Cadaver	3 (371)
- Virtual reality	1 (36)
• Small-group sessions with facilitator	7 (903)
• Online supplement	5 (1374)
• Video	3 (271)
• Clinical training	1 (28)
Outcomes assessment	
• Kirkpatrick level 2a: written/oral examination	66 (6428)
• Kirkpatrick level 2b: performance-based assessment (simulation)	31 (1962)
• Kirkpatrick level 3: performance-based assessment (*in-vivo*)	2 (176)
• Kirkpatrick level 4: patient outcomes	0 (0)

*Number of studies and participants reported from a total of 87 and 7871, respectively.
†Includes total number of studies that included each group of participant.

Fifty-six studies evaluated the effectiveness of e-learning as an adjunct to a more comprehensive curriculum that also involved other methods of teaching. All platforms were made available on a personal computer either as installed software or a web-accessible tool, one of which was specifically designed for mobile devices using touch screen technology. Fifty-eight studies reported total training time on the e-learning platform, most of which included less than 2 hours (42 studies), or 3-24 hours (7 studies) of training. The other 9 studies provided 1-7 days (2 studies), 1-4 weeks (6 studies) or 1 year (1 study) of training.

Overall, e-learning interventions showed either greater or similar effectiveness compared to no intervention (29 and 4 studies, respectively), or compared to non-e-learning interventions (29 and 22 studies, respectively) (Table 2).

Table 2: Outcomes for various e-learning tools, sorted according to comparator group and study outcomes. Number of studies and participants are reported as total and according to each Kirkpatrick level of assessment.

Comparison Group*	No. Studies (No. Participants)†			
	Total	Kirkpatrick 2a	Kirkpatrick 2b	Kirkpatrick 3
All Studies				
• E-learning > control	58 (5806)	45 (4738)	20 (1479)	2 (176)
• E-learning = control	26 (1401)	19 (1108)	10 (401)	0 (0)
• E-learning < control	3 (664)	2 (582)	1 (82)	0 (0)
Nothing				
• E-learning > control	29 (2796)	21 (1902)	12 (1074)	0 (0)
• E-learning = control	4 (119)	1 (37)	3 (82)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Didactic				
• E-learning > control	7 (456)	6 (436)	2 (89)	0 (0)
• E-learning = control	11(548)	10 (488)	2 (81)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Textbook/article				
• E-learning > control	13 (858)	10 (729)	4 (209)	2 (176)
• E-learning = control	4 (349)	3 (256)	1 (93)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Simulation				
• E-learning > control	9 (703)	5 (512)	5 (273)	0 (0)
• E-learning = control	6 (350)	4 (227)	4 (210)	0 (0)
• E-learning < control	1 (141)	1 (141)	0 (0)	0 (0)
Small-group with instructor				
• E-learning > control	4 (351)	3 (293)	2 (116)	0 (0)
• E-learning = control	1 (29)	0 (0)	1 (29)	0 (0)
• E-learning < control	2 (523)	1 (441)	1 (82)	0 (0)
Online supplements				
• E-learning > control	4 (1274)	4 (1274)	0 (0)	0 (0)
• E-learning = control	1 (100)	1 (100)	0 (0)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Video				
• E-learning > control	3 (271)	3 (271)	1 (69)	0 (0)
• E-learning = control	0 (0)	0 (0)	0 (0)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Clinical				
• E-learning > control	0 (0)	0 (0)	0 (0)	0 (0)
• E-learning = control	1 (28)	0 (0)	1 (28)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)

* "E-learning > control": performance of e-learning group was significantly greater than the non-e-learning group; "E-learning = control": performance of e-learning group was equivalent to the non-e-learning group; "E-learning < control": performance of e-learning group was significantly worse than the non-e-learning group; †Number of studies and participants reported from a total of 87 and 7871, respectively.

Amongst the studies that compared e-learning to non-e-learning interventions, most studies showed greater effectiveness using e-learning teaching tools compared to independent reading of a textbook chapter or article, simulation-based curricula, small-group seminars run by a facilitator, online supplemental material, a teaching video, or clinical exposure. However, the majority of studies comparing e-learning to didactic lecture-based curricula showed non-inferiority of one method over another.

Only 3 studies showed significantly lower performance in the e-learning group.[86-88] Two of these studies evaluated e-learning after a single training session of 1-2 hours in comparison to a small group session with individualised feedback by an instructor to teach knot tying, and bench-top simulation using cadaveric specimens to teach anatomy, for the same duration of training. The third study evaluated the effectiveness of a web-based monthly journal club compared to a moderated in-person journal club to teach critical appraisal skills over a period of 8 months. While the e-learning group scored significantly lower on the post-intervention examination, only 18% of subjects actually received any training, compared to the moderated group, which had considerably greater compliance with the intervention.

E-learning tools were used to teach a very broad range of skills related to surgical practice (Table 3), with a strong emphasis on cognitive competencies, ranging from those focused on basic knowledge of a surgical disease or procedure, to the higher-order perioperative and intra-operative cognitive functions. Most of these studies showed either greater performance (48 studies) or equivalent performance in the e-learning group compared to controls (21 studies).

Table 3: Outcomes for various e-learning tools, sorted according to surgical skill and study outcomes. Number of studies and participants are reported as total and according to each Kirkpatrick level of assessment.

Surgical Skill Training*	No. Studies (No. Participants)†			
	Total	Kirkpatrick 2a	Kirkpatrick 2b	Kirkpatrick 3
Psychomotor				
• E-learning > control	22 (1834)	12 (889)	15 (1219)	2 (176)
• E-learning = control	13 (651)	8 (411)	7 (288)	0 (0)
• E-learning < control	1 (82)	0 (0)	1 (82)	0 (0)
Cognitive				
• E-learning > control	48 (4884)	41 (4491)	11 (605)	2 (176)
• E-learning = control	21 (1161)	18 (1080)	6 (189)	0 (0)
• E-learning < control	2 (582)	2 (582)	0 (0)	0 (0)
Non-technical				
• E-learning > control	4 (338)	3 (318)	2 (102)	0 (0)
• E-learning = control	4 (162)	2 (111)	3 (111)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)

* "E-learning > control": performance of e-learning group was significantly greater than the non-e-learning group; "E-learning = control": performance of e-learning group was equivalent to the non-e-learning group; "E-learning < control": performance of e-learning group was significantly worse than the non-e-learning group;

†Number of studies and participants reported from a total of 87 and 7871, respectively.

Thirty-six studies covered educational objectives targeting psychomotor skills required to perform a variety of surgical tasks, such as knot tying, catheter insertions and laparoscopic procedures. Twenty-two studies evaluated post-curriculum performance in a simulated environment (box trainer, laparoscopic simulator, animal model), while two trials examined transfer of skills to real life interventions.[89, 90] The other 12 studies, while designed to teach a combination of both cognitive and psychomotor skills related to a surgical procedure, only assessed cognitive outcomes using written or oral examinations.

Of the 24 studies that evaluated performance in either a simulated or clinical environment, nine trials found that e-learning-based training improves technical skills, while 14 trials did not show a significant difference compared to the non-e-learning control group. One trial showed greater performance for teaching knot tying using a moderated in-person session with a facilitator who provided individualised feedback.

Eight studies also attempted to use e-learning to teach non-technical interpersonal aptitudes related to surgery, demonstrating either equivalent performance (4 studies; 1 compared to no intervention, 3 compared to another intervention) or superior performance (4 studies; 2 compared to no intervention, 2 compared to another intervention).

A total of 10 themes of e-learning platform characteristics were identified in relation to instructional design (Table 4): multimedia (including videos, images, animations), interactive learning, formative feedback on prior performance or while using the platform, assessment, virtual patients, virtual reality, spaced education, community-based learning, and gaming. Outcomes for each theme are summarised in Table 5.

Table 4: Themes and characteristics of e-learning tools

Theme	Theme Definition	No. Studies (No. Participants)*
Multimedia component	• Videos • Images • Animations	84 (7063)
Interactive component	• Learner interaction with platform requiring decision-making and judgment	57 (5494)
Feedback	• Learner obtains feedback on surgical skills on prior performance or performance while using platform	27 (3254)
Assessment component	• Learner is assessed through the platform with formative or summative evaluation	26 (3173)
Virtual patients	• Case-based scenarios	22 (1889)
Virtual reality	• Highly immersive simulated environment	11 (790)
Spaced education	• Interval reinforcement of content	7 (1780)
Community-based learning	• Learning through web-based discussion groups with colleagues (e.g. blogs)	2 (522)
Gaming	• Learning through structured and organized play	2 (175)
Not reported		1 (20)

*Number of studies and participants reported from a total of 87 and 7871, respectively.

Table 5: Outcomes for various e-learning tools, sorted according to characteristic theme and study outcomes. Number of studies and participants are reported as total and according to each Kirkpatrick level of assessment.

Theme*	No. Studies (No. Participants)†			
	Total	Kirkpatrick 2a	Kirkpatrick 2b	Kirkpatrick 3
Multimedia component				
• E-learning > control	56 (5439)	44 (4391)	19 (1459)	2 (176)
• E-learning = control	26 (1401)	19 (1108)	10 (401)	0 (0)
• E-learning < control	2 (223)	1 (141)	1 (82)	0 (0)
Interactive				
• E-learning > control	45 (4599)	36 (3782)	12 (1133)	1 (126)
• E-learning = control	15 (897)	12 (816)	4 (102)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Feedback				
• E-learning > control	23 (3026)	22 (2973)	3 (151)	0 (0)
• E-learning = control	4 (228)	3 (198)	2 (51)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Assessment component				
• E-learning > control	22 (2945)	21(2892)	3 (151)	0 (0)
• E-learning = control	4 (228)	3(198)	2 (51)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Virtual patients				
• E-learning > control	17 (1580)	16 (1527)	1 (53)	0 (0)
• E-learning = control	5 (309)	3 (256)	2 (53)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Virtual reality				
• E-learning > control	9 (660)	8 (607)	2 (93)	0 (0)
• E-learning = control	2 (130)	1 (100)	1 (30)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)
Spaced education				
• E-learning > control	6 (1339)	6 (1339)	0 (0)	0 (0)
• E-learning = control	0 (0)	0 (0)	0 (0)	0 (0)
• E-learning < control	1 (441)	1 (441)	0 (0)	0 (0)
Community-based learning				
• E-learning > control	1 (81)	1 (81)	0 (0)	0 (0)
• E-learning = control	0 (0)	0 (0)	0 (0)	0 (0)
• E-learning < control	1 (441)	1 (441)	0 (0)	0 (0)
Gaming				
• E-learning > control	1 (145)	1 (145)	0 (0)	0 (0)
• E-learning = control	1 (30)	0 (0)	1 (30)	0 (0)
• E-learning < control	0 (0)	0 (0)	0 (0)	0 (0)

***** "E-learning > control": performance of e-learning group was significantly greater than the non-e-learning group; "E-learning = control": performance of e-learning group was equivalent to the non-e-learning group; "E-learning < control": performance of e-learning group was significantly worse than the non-e-learning group;

†Number of studies and participants reported from a total of 87 and 7871, respectively.

Study quality of included studies, as determined by the GRADE classification, was highly variable (Table 6). Most studies comparing e-learning to either no intervention or another teaching method were high quality (15 and 35 studies respectively). Nevertheless, the majority of studies lacked full conformity to CONSORT criteria for RCTs, including failure to report loss of follow-up (60 studies), and inappropriate randomisation with adequate allocation concealment (28 studies). Only 29 studies reported skill retention beyond 1 day after the educational content was fully delivered (1-7 days: 1 study, 1-4 weeks: 11 studies, 1-6 months: 12 studies, 7-12 months: 4 studies, >1 year: 1 study).

The mean dropout rate was 8% (SD 15%) and 8% (SD 16%), for the intervention and control groups respectively. Only 18 trials evaluated performance outcomes using blinded assessment. It was not clearly stated whether or not the assessors were blinded in 11 trials, while 4 trials did not blind the assessors. Validity evidence for methods of assessment varied considerably, with 32 studies (37%) using instruments that had limited evidence supporting the interpretation of assessment scores.

Table 6: Quality and recommendations of included studies according to comparison groups

Quality Indicator	No. Studies (No. Participants)*†							
	Nothing (N=33)	Didactic (N=18)	Text/ Article (N=17)	SIM (N=16)	Small Group (N=7)	Online Supp (N=5)	Video (N=3)	Clinical (N=1)
Design limitations								
• Not serious	21 (1711)	12 (529)	12 (810)	10 (649)	3 (557)	4 (1274)	1 (69)	1 (28)
• Serious	12 (1204)	6 (475)	5 (397)	6 (545)	4 (346)	1 (100)	2 (202)	0 (0)
Consistency								
• Consistent	33 (2915)	18 (1004)	17 (1207)	16 (1194)	7 (903)	5 (1374)	3 (271)	1 (28)
• Inconsistent	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Directness of evidence								
• Direct	31 (2806)	17 (944)	15 (935)	16 (1194)	7 (903)	5 (1374)	3 (271)	1 (28)
• Indirect	2 (109)	1 (60)	2 (272)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Study quality limitations								
• Not serious	21 (2255)	11 (594)	13 (883)	12 (990)	4 (343)	4 (1274)	3 (271)	1 (28)
• Serious	11 (637)	7 (410)	4 (324)	3 (144)	2 (119)	1 (100)	0 (0)	0 (0)
• Very serious	1 (23)	0 (0)	0 (0)	1 (60)	1 (441)	0 (0)	0 (0)	0 (0)
GRADE score								
• High	15 (1380)	7 (281)	11 (753)	9 (619)	2 (116)	4 (1274)	1 (69)	1 (28)
• Moderate	10 (1122)	7 (477)	4 (223)	4 (401)	2 (227)	0 (0)	2 (202)	0 (0)
• Low	8 (413)	4 (246)	2 (231)	2 (114)	3 (560)	1 (100)	0 (0)	0 (0)
• Very low	0 (0)	0 (0)	0 (0)	1 (60)	0 (0)	0 (0)	0 (0)	0 (0)
Outcome bias (validity evidence)								
• Low bias	8 (917)	1 (20)	3 (160)	4 (242)	3 (528)	4 (1274)	1 (172)	1 (28)
• Moderate bias	14 (1214)	8 (437)	7 (586)	4 (252)	3 (230)	0 (0)	1 (69)	0 (0)
• Strong bias	10 (767)	9 (547)	6 (360)	8 (700)	1 (145)	1 (100)	1 (30)	0 (0)
• Unclear bias	1 (17)	0 (0)	1 (101)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Overall recommendation								
• Clear benefits‡	16 (1607)	5 (330)	12 (778)	6 (410)	3 (261)	3 (1037)	3 (271)	0 (0)
• No benefits	3 (131)	7 (334)	2 (285)	5 (401)	1 (82)	1 (237)	0 (0)	1 (28)
• Unclear benefits	12 (996)	6 (340)	3 (144)	5 (383)	3 (560)	1 (100)	0 (0)	0 (0)
• Clear benefits only for certain subgroups	2 (181)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

SIM = simulation-based curriculum; Online Supp = online supplement
*Number of studies and participants reported from a total of 87 and 7871, respectively.
†Results segregated according to comparison groups
‡Clear Benefits: e-learning is superior to the comparison group

Discussion

Pervasive electronic teaching tools that are readily available through the Internet and portable devices have become increasingly popular. Given their accessibility and potential for immersive and experiential learning, this technology can help address many limitations of today's surgical training paradigm. In order to justify the investment necessary to develop and regularly update electronic and web-based curricula, and to guide educators, researchers and program directors to channel their efforts and resources appropriately, it is important to demonstrate the educational value of such technologies. This systematic review shows that most e-learning platforms are effective teaching tools for developing a broad range of surgical competencies– at least in a simulated environment and in comparison to no other intervention. However, the evidence to support the superiority of e-learning over other educational interventions and curricula remains limited, with significant heterogeneity in terms of platform design, content and features, and outcomes. Furthermore, only two RCTs actually demonstrated transfer of skill to the clinical environment, and there was no evidence to show improvement in patient outcomes.

At its core, e-learning tools are limited to teaching cognitive processes, be it the knowledge base necessary to develop mental models, or the cognitive elements necessary to perform psychomotor tasks. It would therefore seem intuitive that, while e-learning may never completely replace all other methods of education, it could serve as an adjunct to improve the effectiveness of a curriculum – especially when the curriculum has a dominant cognitive component that can feasibly be packaged into web-accessible modules. These modules should ideally be complemented with other activities such as simulation-based training to develop the entire spectrum of surgical competency, often resulting in highly effective training curricula.[91] For instance, several online teaching tools have been developed to teach the steps of a specific surgical task (e.g. knot-tying). While these may help significantly with the initial cognitive phase of psychomotor skill acquisition[92], more advanced phases require a degree of automaticity and effortless thinking that can only be attained through repeated and focused practice, through simulation and clinical exposure. This is supported by the fact that two studies showed improvements in outcomes only in a subset of participants– namely junior trainees, without any improvement in performance amongst their more senior or experienced colleagues.[93, 94] In addition, whether superior or not to the more traditional textbooks or didactic lectures, e-learning can help relieve faculty constraints and help channel limited resources to where they may be better suited. Finally, most studies only evaluated short-term performance with no data on long-term skill retention, and amongst those comparing e-learning to other interventions, the majority (9 studies) showed equivalent long-term performance. It is important to emphasise that most of these studies evaluated 1-2 hours of training with e-learning, suggesting that in order for such technologies to have a lasting impact; learners should have ongoing and repeated access to curricular content.

There are also several limitations to e-learning technology, many of which have surfaced through 3 RCTs that reported worse performance amongst subjects who received an e-learning curriculum compared to either simulation-based training or small-group moderated sessions.[86-88] In one study attempting to teach knot-tying skills, the control group received ample individualised feedback by an instructor as opposed to watching a video that provided standardised instructions. In other words, access to multimedia alone is not sufficient for deep learning. This highlights the importance of using a technology in the appropriate context as part of a goal-directed curriculum that adheres to principles of educational psychology, including focused and immediate feedback. Another study emphasised the fact that the e-learning group had a significantly lower participation (less than 20%). While this dropout rate was an anomaly, it demonstrates the importance of compliance in spite of the fact that computer-based learning is generally associated with high user satisfaction. Educators should therefore strive to achieve high levels of participation to ensure that curricular goals are actually being met.

Twenty-seven studies evaluated the outcomes of e-learning platforms that provided either some degree of assessment or formative feedback (either from previous training or while using the platform), with the majority demonstrating superior performance with e-learning. Research in expertise suggests that achievement of proficiency is heavily dependent on provision of focused feedback, immediate and ample opportunities for repetition, focused practice and emphasis on difficult aspects and areas of weakness.[95] By modeling case scenarios according to expert behaviours, learners can practice the correct skills deliberately, as opposed to indiscriminately. E-learning can provide an interactive learning environment with immediate assessment and feedback, and additional targeted practice to improve a particular element of one's performance.

Another predominant theme that became apparent in this review included the incorporation of spaced education over a prolonged period. With the exception of the study by McLeod et al that evaluated the effectiveness of a year-long monthly online journal club which had a high dropout rate[87], all six other RCTs that evaluated the impact of online spaced education showed a greater improvement on post-curriculum multiple-choice examinations compared to control groups (no comparison: two studies; other interventions:

four studies). These results are consistent with other simulation-based curricula suggesting that distributed practice with ongoing learning decreases performance decay that occurs overtime compared to a single training session.[16, 96, 97]

The results of this study are limited by the quality of the included studies, and despite including only RCTs that used objective performance metrics (Kirkpatrick level 2 and greater), many studies had methodological flaws. Nevertheless, GRADE scores were generally high, assessment tools had a moderate level of validity evidence, and given the large number of studies from a variety of surgical specialties, it was possible to assess the overall effectiveness of e-learning – at least with regards to short-term performance improvements in a non-clinical environment.

There remains a large gap in the literature evaluating the impact of this technology on long-term retention, transfer of competencies to a clinical setting, and changes in patient outcomes. Also, most studies tended to evaluate a combination of surgical skills and the metrics used to evaluate performance were not always specific or optimal to assess those acquired skills e.g. written examination to evaluate technical performance in knot tying. Lastly, the significant heterogeneity amongst different e-learning platforms makes it difficult to generalise its overall effectiveness. However, the rich breadth of curricula allowed us to scrutinise the various features that can be incorporated into e-learning instruments and make recommendations on how to optimise its design to promote more effective learning.

Researchers, educators and surgical societies wishing to disseminate curricular content to a broad audience using computer-based platforms can use these recommendations as a roadmap to channel resources appropriately, optimise learning, and ultimately contribute to better patient outcomes.

3

Transatlantic Multispecialty Consensus on Fundamental Endovascular Skills: results of a Delphi consensus study

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Eur J Vasc Endovasc Surg. 2016 Jan;51(1):141-9.

Abstract

Objectives

Aim of this study was to establish a consensus on Fundamental Endovascular Skills (FES) for educational purposes and development of training curricula for endovascular procedures. The term “Fundamental Endovascular Skills” is widely used, however current literature does not explicitly describe what skills are included in this concept. Endovascular interventions are performed by several specialties that may have opposing perspectives on these skills.

Design

A two-round Delphi questionnaire approach was used. Experts from interventional cardiology, interventional radiology and vascular surgery from the USA and Europe were invited to participate.

Materials

An electronic questionnaire was generated by endovascular therapists with educational background who did not participate in the subsequent rounds. The questionnaire consisted of 50 statements describing knowledge, technical and behavioral skills during endovascular procedures.

Methods

Experts received the questionnaires by email. They were asked to rate the importance of each skill on a Likert scale from 1 to 5. A statement was considered fundamental when more than 90% of the experts rated it 4 or 5 out of 5.

Results

Twenty-three of 53 experts invited agreed to participate: 6 interventional radiologists (2 USA, 4 Europe), 10 vascular surgeons (4 USA, 6 Europe) and 7 interventional cardiologists (4 USA, 3 Europe). There was 100% response rate in the first round and 87% in the second round. Results showed excellent consensus among responders (Cronbach's alpha = 0.95 first round; 0.93 second round). Ninety percent of all proposed skills were considered fundamental. The most critical skills were determined.

Conclusions

A transatlantic multispecialty consensus was achieved about the content of "Fundamental Endovascular Skills" among interventional radiologists, interventional cardiologists and vascular surgeons from Europe and the USA. These results can serve as directive principles for developing endovascular training curricula.

Introduction

Endovascular procedures have become the standard treatment of care for several patients with symptomatic cardiac and vascular disease.[98-101] As a result, endovascular skills' training programs are increasingly required. Knowing the various endovascular tools, technical skills different from open surgery, appropriate decision making and communication are essential to treat patients safely by endovascular means.[102, 103]

Current literature does not define these key skills.[104] Furthermore, interventional cardiologists, interventional radiologists as well as vascular surgeons perform endovascular interventions while they may consider different endovascular skills to be fundamental.

The objective of this research was to identify the key skills that should be achieved in a Fundamental Endovascular Skills (FES) program, based upon the opinion of a panel of experts in endovascular procedures (interventional cardiology, interventional radiology and vascular surgery) using responses to serial questionnaires according to a modified Delphi technique. This approach has previously been used in an international expert consensus on a framework for simulation-based surgical training curriculum[105], to define principles for developing a radiology curriculum[106], to provide guidelines for training and assessment of non-technical skills[107] and to define the key steps for a standardised laparoscopic curriculum.[108] A multispecialty consensus concerning competence assessment[109], case selection prior to carotid artery stenting[110] and patient management have also been achieved using this modified Delphi technique.[111-114]

Defining FES may enable endovascular specialists to create and provide a common educational ground for endovascular training. The results of this study may not only influence tutors but may also guide program directors, healthcare institutions and policy makers to improve patient safety by acquirement of fundamental knowledge and technical skills before approaching actual patients. The key skills can be assessed to certify that an endovascular specialist has the FES before being enrolled in any advanced endovascular training program.[72] Finally, device manufacturers and simulation companies may use these fundamental skills to guide the design of their training modules.

Materials and methods

Study design

The Delphi technique is an approach used to gain consensus among a panel of experts.[115] Delphi consensus methodology was used because this technique is characterized by anonymity of the panel ensuring that each participant has an equal possibility to provide and change their opinion in the course of the process.[116] The standard Delphi technique is a structured and interactive communication forecasting method that relies on the opinion from an expert panel.[117] Participants evaluate statements and further re-evaluate these statements in subsequent Delphi rounds based upon anonymous group responses until consensus has been reached.[116] Emailed questionnaires were used to avoid face-to-face interactions in order to eliminate undue influence from individuals. Written consent was obtained from all participants by e-mail. The study was set up to permit an initial design of two rounds, with further rounds as required, depending upon the level of consensus achieved following analysis of data from the second round.

Questionnaires

Electronic questionnaires providing multiple statements were designed. The questionnaire was based upon the endovascular literature, the knowledge, skills and attitude framework for surgical training.[118] It was finalised after a thorough discussion among four attending physicians, experienced in endovascular treatment and/or educational research (RA, SM, FV and IVH). None of these individuals participated in the subsequent rounds.

The questionnaire consisted of 50 statements describing the three main skills required during endovascular procedures: *knowledge, technical skills* and *attitudes* concerning perioperative functioning and communication. Participants were asked to rate the importance of these statements using a 1-5 Likert scale.

Experts

Interventional cardiology and angiology, interventional radiology and vascular surgery experts from USA and Europe were invited to participate. These experts were asked to collaborate on a voluntary basis and were eligible if they perform more than 100 peripheral endovascular procedures yearly as the primary operator and are involved in training junior colleagues. It is commonly accepted that the minimum requirement in a Delphi consensus is 5-10 participants from each professional group.[117]

Data analysis

The level of participants' agreement to the statement was drafted on a five-point Likert scale comprising 'Strongly disagree', 'Disagree', 'Neutral', 'Agree' and 'Strongly agree'.

The skills rated 4 (agree) or 5 (strongly agree) on the five-point Likert scale were considered to be a FES that should be included in an endovascular training program. In previous Delphi studies, consensus was mostly defined as more than 80% of the experts supported an element.[119, 120]

The first round was sent out to the experts who agreed to participate on March 17th 2014. A 4-week answering period was provided, during which a reminder was sent at 2-week intervals to non-responders. Similarly, the second round was sent out to the same group of experts on May 5th 2014. The questionnaire consisted of the same statements providing the distributions of scores (mean score and standard deviation) for each question from the first round. In the second round, the experts were instructed to re-consider the statements presented in the first round.

For statistical analysis SPSS 22.0 (Statistical Package for the Social Sciences, IBM Company, US) was used. The Cronbach's alpha test was used to determine the internal consistency in the first and second round of the Delphi survey. The results were analysed using non-parametric tests. Wilcoxon signed ranks test was used to compare ratings of the elements between the first and second round. To compare groups for differences between specialties and nationalities the Kruskal-Wallis test was used. A sensitivity analysis was performed to determine the robustness of the results. The results of round 1 and 2 were compared for only those participants who rated both rounds (N = 20, Cronbach's alpha = 0.96). To determine the ranking of the statements mean values of the experts' ratings were used.

Results

Twenty-three of the 53 (43%) invited experts agreed to participate in the survey. The panel consisted of 6 interventional radiologists (2 USA, 4 Europe), 10 vascular surgeons (4 USA, 6 Europe) and 7 interventional cardiologists and angiologists (4 USA, 3 Europe). Three experts performed between 100 and 200 procedures each year (1 interventional radiologist, 2 vascular surgeons). The majority (twelve experts) performed between 200 and 500 procedures yearly (3 interventional radiologists, 4 interventional cardiologists, 5 vascular surgeons). Seven performed between 500 and 1000 procedures on a yearly basis (2 interventional radiologists, 2 interventional cardiologists, 3 vascular surgeons) and one interventional cardiologist performed more than 1000 procedures each year. Thirteen experts were currently working in a teaching hospital, nine experts in an academic setting and one expert in a non-teaching clinic. The number of responses in rounds one and two were respectively 23 (100%) and 20 (87%). When submitted, full responses to all questions were received. In this survey, the group was very positively skewed, therefore a statement was considered a FES when more than 90% of the experts rated it 4 or 5 out of 5.

Consensus was achieved in 90% of the discussion subjects. There was a strong internal consistency among the experts in both rounds (Cronbach's alpha =0.95 first round; Cronbach's alpha =0.93 second round).

The panel agreed that all statements concerning *knowledge* should be included in an endovascular curriculum, except for the principles of radiation safety and ALARA (As Low as Reasonably Achievable) principles. The top 5 most important Fundamental Endovascular Skills for knowledge are 'Knowledge of the vascular anatomy', 'Benefits and limitations of endovascular procedures', 'Knowledge of indications for open and endovascular treatments', 'Risk associated with various procedural phases' and 'Interpretation of the imaging findings (normal and pathological)'.

Twenty-four out of the 26 *technical skills* were considered fundamental skills. The top 3 FES in terms of technical performance are 'Select an appropriate access site and approach (i.e. retrograde, antegrade)', 'Insert selected guide wire correctly to appropriate level with proper care for obstruction, side branches and vessel trauma' and 'Evaluate the lesion and run-off (if unknown) prior to treat lesion'. In contrast, 'Administration of the accurate dose of heparin' and 'Performing an angiogram to check the lesion after angioplasty in multiple projections' were not considered fundamental among the experts. Only 'administration of the accurate dose of heparin' and 'performing an angiogram to check the lesion after angioplasty in multiple projections' were not included.

Twelve out of 14 *attitudes* were scored highly by the participants. The top 3 FES for attitude are 'Know own limitations and call for help from his/her supervisor', 'Check patient records (blood results, medication,…) prior to start the procedure', 'Check informed consent that has been obtained prior to start the procedure in the angiosuite'. 'Ensuring the endovascular team is wearing radioprotective clothing' and 'Ensuring the side is marked prior to start the procedure' were not considered FES. The overall responses to the questions in both rounds are shown in Appendix III. The statements are organised according to level of importance, based upon the mean score of the experts.

Considering both fundamental and non-fundamental skills, a statistically significant difference was found between the 3 participating specialties in 12 of 50 questions (Table 1). Only one of the non-fundamental skills was rated differently between the specialties: 'Ensuring the side is marked prior to start the procedure'. However, this significant difference in rating of this statement was only noted in the first round (4.33 Radiology vs. 5.00 Cardiology vs. 4.60 Surgery; P=0.044).

Table 1: Statements rated differently across specialties

Statement	Interventional radiology (N = 6) Mean (SD)	Interventional cardiology (N = 7) Mean (SD)	Vascular surgery (N = 10) Mean (SD)	P value
Select an appropriate access site and approach (i.e. retrograde, antegrade)				
Round 1	4,17 (0.41)	4,86 (0.38)	4,90 (0.32)	**0.006**
Round 2	4,83 (0.41)	5,00 (0.00)	4,89 (0.33)	0.663
Feed the working catheter over the guide wire to the appropriate level i.e. catheter does not pass beyond the tip of the guide wire				
Round 1	4,17 (0.41)	4,86 (0.38)	4,90 (0.32)	**0.006**
Round 2	4,67 (0.52)	5,00 (0.00)	4,89 (0.33)	0.295
Insert balloon catheter across lesion while keeping guide wire steady				
Round 1	4,01 (0.63)	4,86 (0.38)	4,60 (0.69)	**0.040**
Round 2	4,50 (0.55)	5,00 (0.00)	4,67 (0.50)	0.205
Choose and prepare appropriate supportive (working) catheter				
Round 1	3,83 (0.75)	5,00 (0.00)	4,60 (0.52)	**0.007**
Round 2	4,17 (0.75)	4,60 (0.55)	4,67 (0.71)	0.292
Use fluoroscopy guidance during balloon angioplasty				
Round 1	4,33 (0.52)	5,00 (0.00)	4,80 (0.42)	**0.024**
Round 2	4,50 (0.55)	5,00 (0.00)	4,67 (0.50)	0.205
Decompress balloon fully before repositioning or removal				
Round 1	4,17 (0.41)	5,00 (0.00)	4,90 (0.32)	**0.001**
Round 2	4,50 (0.55)	4,80 (0.45)	4,78 (0.44)	0.459

Navigate guide wire supported by working catheter using road map to cross the lesion				
Round 1	4,17 (0.41)	4,86 (0.38)	4,60 (0.52)	**0.048**
Round 2	4,50 (0.55)	4,80 (0.45)	4,67 (0.71)	0.546
Check patient records (blood results, medication,...) prior to start the procedure				
Round 1	4,17 (0.98)	5,00 (0.00)	4,20 (0.63)	**0.030**
Round 2	4,67 (0.52)	5,00 (0.00)	4,67 (0.50)	0.348
Give briefing to endovascular team (anaesthetist, nurses,...) prior to start the procedure				
Round 1	4,50 (0.55)	5,00 (0.00)	5,00 (0.00)	**0.009**
Round 2	4,50 (0.55)	4,60 (0.89)	4,78 (0.44)	0.552
Proper and safe positioning of patient on table in angiosuite				
Round 1	4,50 (0.55)	5,00 (0.00)	5,00 (0.00)	**0.009**
Round 2	4,83 (0.41)	5,00 (0.00)	4,78 (0.44)	0.549
Ensure the side is marked prior to start the procedure				
Round 1	4,33 (0.52)	5,00 (0.00)	4,60 (0.52)	**0.044**
Round 2	4,33 (0.52)	5,00 (0.00)	4,67 (0.71)	0.079
Insert stent if appropriate (type, length and size) across lesion, keeping wire steady				
Round 1	4,17 (0.75)	4,86 (0.38)	4,70 (0.48)	0.108
Round 2	4,00 (0.89)	5,00 (0.00)	4,78 (0.44)	**0.037**

Table 1: Statements rated differently between the two Delphi rounds across specialties. Statistically significant values are in bold.

On the other hand, significant differences were noticed between experts from Europe and the USA for 5 skills (Table 2). European physicians tended to rate the importance of these statements higher than colleagues from the USA. One of the non-fundamental skills was rated differently across continents: 'Performing an angiogram to check the lesion after angioplasty in multiple projections'. During the first Delphi round there was no significant difference, however during the second survey physicians from the USA rated this skill significantly lower than physicians from Europe (4.25 USA vs. 4.92 Europe; P=0.011).

Table 2: Statements rated differently across continents

Statement	Europe (N = 13)	USA (N = 10)	P value
Check informed consent prior to start the procedure in angiosuite			
Round 1	4,54 (0.78)	3,50 (1.18)	**0.028**
Round 2	4,42 (0.52)	3,50 (0.96)	**0.019**
Communicate effectively with patient			
Round 1	4,54 (0.52)	3,80 (0.92)	**0.042**
Round 2	4,33 (0.49)	4,12 (0.64)	0.461
Knowledge of optimal medical treatment of PAD			
Round 1	4,54 (0.52)	4,90 (0.32)	0.068
Round 2	4,92 (0.29)	4,12 (1.36)	**0.036**
Check intraluminal position of the catheter after crossing lesion with contrast			
Round 1	4,77 (0.44)	4,80 (0.42)	0.862
Round 2	5,00 (0.00)	4,62 (0.52)	**0.025**
Perform angiogram in multiple projections to evaluate lesion			
Round 1	4,77 (0.44)	4,80 (0.42)	0.862
Round 2	4,92 (0.29)	4,25 (0.71)	**0.011**

Table 2: Statements rated differently between the two Delphi rounds across nationalities. Statistically significant values are in bold. PAD=Peripheral Arterial Disease.

Statistically significant differences between ratings in the first and second Delphi round were found for 3 statements: ‘Select an appropriate access site and approach (i.e. retrograde, antegrade)’ (4.52 vs. 4.90; P=0.025), ‘Feed the working catheter over the guide wire to the appropriate level i.e. catheter does not pass beyond the tip of the guide wire’ (4.48 vs. 4.70; P=0.046) and ‘Check patient records (blood results, medication...) prior to start the procedure’ (4.53 vs. 4.75; P=0.033).

To determine the impact of the 20 experts only responding to both Delphi rounds, a sensitivity analysis was performed, showing consistent results when analysing only the data of experts who responded to both rounds.

Discussion

Endovascular procedures to treat cardiovascular disease are increasingly applied and require specific core skills to treat patients safely and obtain good outcomes. The present study has explored what cognitive skills, technical skills and attitudes are considered fundamental during endovascular procedures using the Delphi technique. In two rounds a transatlantic multispecialty consensus was achieved on what skills should be included in every basic endovascular training curriculum. It should be noted there was almost always an increase in ratings from the first to the second round, but these skills were already rated important in the first round. These high ratings reveal the importance of implementing these skills in endovascular training curricula. Based upon the expert ratings, the most important skills could be determined for each of the 3 categories.

Fundamental knowledge skills

The top 5 most important FES for *knowledge* implement that every endovascular specialist independent of their specialty should be actively involved in the outpatient clinic to see and evaluate cardiovascular patients, be able to initiate or optimise medical treatment and to decide what type of treatment is indicated per individual patient. Likewise, each endovascular team member should know the imaging facilities and the endovascular tool kit that is routinely used in the angiosuite or operating room.

On the other hand, 'The principles of radiation safety and ALARA principles' were not considered to be fundamental. This is no surprise since Bordoli et al. have suggested that there might be a lack of formal radiation safety training in the US for vascular surgery residents.[121] In some countries a radiology technician is present during every endovascular intervention to adjust the C-arm, to use the aortic pump, but also to ensure that each team member is protected by wearing lead aprons. Therefore, these interventionalists might not consider radiation safety as a fundamental knowledge skill because it is the responsibility of the radiology technician. However, in the literature there is sufficient evidence that operator-controlled imaging significantly reduces radiation exposure e.g. during endovascular aneurysm repair.[122-124] Furthermore, radiation education has shown to be effective in reducing radiation exposure[125] and recommendations for basic knowledge training of X-ray physics and image production were defined. Software is continuously being developed and improved and with the routine use of fusion in the hybrid angiosuite the exposure of patients and operators to radiation is significantly reduced. The use of roadmap to cross the lesion can be replaced by overlaying a reference image obtained from a Digital Subtraction Angiography (DSA) run. This is not conferring any additional radiation since the roadmap is using high radiation and moreover it may even be decreasing the exposure to the operators since the DSA can be obtained with power injector with the operator away from the radiation source. Worldwide there is an increasing attention to improve radiation safety by demanding that personnel using any radiation equipment have to obtain a certificate proving that they know the ALARA principles.[126]

Fundamental technical skills

The top three principles of technical performance are the key to success in any endovascular procedure e.g. in an occlusion of the popliteal artery an ipsilateral antegrade approach is preferred and in obese patients retrograde contralateral femoral access might be preferable.

On the other hand, the administration of heparin was considered less important possibly influenced by the fact that this is a routine step, often initiated and followed up by the anesthesiologist or anesthesiology nurse. Although evaluation of the results after Percutaneous transluminal angioplasty (*PTA*) in multiple projections is important, especially in complex lesions, this was not considered a basic endovascular skill. It is not our intention that an endovascular interventionalist becomes a technician because in first place he/she should become and remain an excellent clinician. It should be noticed that many of the fundamental skills selected are focusing on clinical parameters.

Fundamental attitude and behavior skills

The panel agreed that ‘Ensuring the endovascular team is wearing radio protective clothing’ and ‘Ensuring the side is marked prior to start the procedure’ are not FES. Radio protective clothing focuses again on the importance of radiation safety, thus considered non-fundamental similarly to the statements concerning ALARA principles as explained above. Ensuring that the intervention side is marked might be considered as part of the surgical safety checklist and therefore not a specific endovascular skill.[127]

Inter-specialty and inter-continental differences

Interventional radiologists scored the statements systematically lower in the first round, however based upon the median scores of the endovascular colleagues they rated the statements higher in the second round, leading to a better consensus. Inter-specialty differences had no impact on the decision to consider a skill fundamental or not, since there were no significant differences in the ratings of the specialists in the second round. These statements rated differently across specialties are mostly describing technical skills. This in contrast to the dissimilarities in ratings across continents, which are mostly statements concerning non-technical skills. European interventionalists seem to find these human factor skills more important.

Limitations

A selection bias cannot be excluded since only 43% (23 of 53) of the invited experts agreed to participate in this study. The survey was possibly too well prepared leaving no room for suggestions or changes by the participants. Since the experts all work in different hospitals, it is possible that their answers are influenced by local traditions besides their specialty.

Despite these limitations, the survey was designed by leaders in the endovascular field with experience in education and highly experienced interventional cardiologists, interventional radiologists and vascular surgeons carrying out peripheral endovascular procedures have participated from both USA and Europe.

This study has led to the identification of the top 5 most important FES in terms of *knowledge*, the top 3 Fundamental endovascular *technical performances* and top 3 Fundamental endovascular *attitude skills*. This study is the first report that has attempted to define these skills. The problem now remains how to integrate these FES into daily training programs in the world.

As we all know insufficient knowledge about the endovascular tools and how to cross a lesion safely (fundamental cognitive skill) may lead to vessel perforation and failure. If a trainee is not aware of the patient's history and lab results (fundamental attitude skill), uncontrolled bleeding when removing the sheath may cause serious adverse events. The World Health Organization (WHO) has already successfully addressed some of these issues by the introduction of the surgical safety checklist in the operating room[128], however these are not always respected.

How do you train and assess these FES in daily life? Should these skills immediately be learned and practiced on real patients or should these be obtained prior to treat real patients e.g. using simulation-based training with formative feedback. To provide high quality endovascular training programs, a curriculum addressing the fundamental endovascular skills outside of the operating room or angiosuite should be developed and validated. These trainings should be carefully organised in order to avoid a reduction in patient exposure since the implementation of the European Working Time Directive.

Conclusion

Specific endovascular skills' training is required to improve the quality of care in endovascular treatment. The first step toward training is defining what FES should be achieved in an endovascular training program. Consensus has been reached about the FES that should be taught across various endovascular specialties in the USA and Europe.

The findings can be used to optimise clinical education and to develop structured endovascular training programs including cognitive, technical and attitude training. Cognitive skills identified by this consensus should be taught and assessed prior to any technical skills and attitude training. Key technical skills may be learnt and practiced using simulation modules prior to learn and practice in real cases.

4

Development of a PROficiency-based StePwise Endovascular Curricular Training (PROSPECT) program

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J Surg Educ. 2016 Jan-Feb;73(1):51-60.

Abstract

Objectives

Focus on patient safety, work-hour limitations and cost-effective education is putting pressure to improve curricula to acquire minimal invasive techniques during surgical training. This study aimed to design a structured training program for endovascular skills and validate its assessment methods.

Design

A PROficiency-based StePwise Endovascular Curricular Training (PROSPECT) program was developed, consisting of e-learning and hands-on simulation modules, focusing on iliac and superficial femoral artery atherosclerotic disease. Construct validity was investigated. Performances were assessed using multiple-choice questionnaires (MCQ), valid simulation parameters, Global Rating Scorings (GRS) and Examiner Checklists. Feasibility was assessed by passage of two final-year medical students through this PROSPECT program.

Setting

Ghent University Hospital, a tertiary clinical care and academic center in Belgium with General Surgery residency program.

Participants

Senior-year medical students were recruited at Ghent University Hospital. Vascular surgeons were invited to participate during conferences and meetings if they had performed at least 100 endovascular procedures as primary operator during the last 2 years.

Results

Twenty-nine medical students and 20 vascular surgeons participated. Vascular surgeons obtained higher MCQ scores (median 24.5-22.0 vs. 15.0-12.0; P<0.001). Students took significantly longer to treat any iliac or femoral artery stenosis (3.3-14.8 vs. 5.8-30.1 min.; P=0.001-0.04) while in more complex cases, fluoroscopy time was significantly higher in students (8.3vs. 21.3 min.; P=0.002; 7.3 vs. 13.1 min.; P=0.03). In all cases vascular surgeons scored higher on GRS (51.0-42.0 vs. 29.5-18.0; P<0.001) and Examiner Checklist (81.5-75.0 vs. 54.5-43.0; P<0.001). Hence, proficiency-levels based on median expert scores could be determined. Two students completed the program and passed for each step within a 3-month period during their internships.

Conclusions

A structured, stepwise, proficiency-based valid endovascular program to train cognitive, technical and human factor skills has been developed and proven to be feasible. A randomised controlled trial has been initiated to investigate its effect on performances in real-life, patient outcomes and cost-effectiveness.

Introduction

The increase of minimally invasive interventions, the need to learn new skills, and continuous technological and scientific advances pose unique challenges for surgical education. Additionally, implementation of residents' working hour restrictions, increased focus on patient safety and cost-effective training methods are affecting the curricula of surgical trainees.[129-131] Therefore, simulation-based training has been introduced to allow skills acquisition in a structured manner in a safe training environment where trainees may learn and practice endovascular skills.[62, 132, 133] Literature shows that these skills do transfer to the clinical environment[34, 35, 68, 134] and may lead to improved patient outcomes.[45, 135]

Current training programs are still largely time-based and focus on the caseload at the hospital while simulation-based training has the ability to offer structured training programs and to focus primarily on the trainee. Ideally, trainees should not practice during a fixed period or during mass training courses but should be allowed access to structured repetitive practice to achieve proficiency.[62, 96, 136] This proficiency-based or mastery training focuses on training to expert-derived performance criteria and allows maximal skill acquisition and skill transfer to the operating room or angiosuite.[45, 137] Similar to other high-risk fields e.g. aviation, nuclear industry; these advantages have led to the development of proficiency-based curricula including simulation in medical education.[138-142]

Several simulation-based surgical curricula have been recognised and certified by official organisations and societies, such as the Fundamentals of Laparoscopic Surgery (FLS) certification program[143], the American College of Surgeons/Association of Program Directors in Surgery (ACS/APDS) skills curriculum[14] and the Fundamentals of Endoscopic Surgery (FES).[144] However, endovascular skills training is still mainly offered as mass courses or for research purposes. To learn and maintain endovascular skills, proficiency-based structured curricula including simulation training are still lacking.

Therefore, the aim of this study was to design, validate and demonstrate the feasibility of a PROficiency-based StePwise Endovascular Curricular Training (PROSPECT) using e-learning and simulation.

Materials and methods

Study population

Forty-nine subjects (29 final-year medical students and 20 experts) were recruited to participate in this study. The medical students were recruited at Ghent University Hospital. Vascular surgeons (experts) were asked to participate during national conferences and meetings. An 'expert' was arbitrarily defined as an endovascular specialist who performs at least 100 endovascular procedures as the primary operator yearly. Twenty-seven subjects (17 medical students and 10 experts) participated to demonstrate the construct validity of the MCQ about the four e-learning modules. Twenty subjects (10 medical students and 10 experts) carried out the simulated cases to evaluate the construct validity of the simulation modules. Two medical students went at their own pace through the PROSPECT program to proof its' feasibility. Having received verbal and written information, all participants were asked to sign an informed consent. This study has been approved by the Ethics Committee of Ghent University Hospital.

<u>Design and development</u>

A comprehensive simulation curriculum for endovascular management of symptomatic atherosclerotic vascular disease in the lower limbs (Rutherford classification 2-5; stenosis of iliac/superficial femoral artery disease) was designed. Learning objectives were based upon a standardised framework[105] and a Delphi consensus that has defined the content of “Fundamental Endovascular Skills” among interventional radiologists, interventional cardiologists and vascular surgeons in Europe and the USA. The overall objective is to learn, practice and acquire the cognitive, technical and human factor skills required to treat a patient with a stenotic symptomatic lesion TASC A or B in the iliac artery and/or superficial femoral artery. This curriculum addresses the three core components of knowledge, technical skills and non-technical skills in a modular approach.[145] Each module consists of web-based learning as well as training and assessment in simulated environment.[143] Endovascular surgeons with an educational background supervised and reviewed the entire process.

Training

Cognitive training was offered by means of four web-based learning modules that were based upon lectures, workshops and current literature. The e-learning modules introduce the trainee into the world of vascular atherosclerotic diseases, the endovascular tools used, explain the flow of the intervention and how to properly plan and execute an endovascular procedure. The modules start with basic endovascular skills, move to more complex procedures and finally address human factor skills.[14] These modules allow the trainee to learn endovascular procedures in a structured stepwise fashion, independent of clinical activity and individual patient characteristics. Three endovascular experts reviewed the content and layout. This interactive method is easily accessible and allows the trainee to study anywhere, anytime at his own pace.

Technical endovascular skills training and assessment was carried out on the ANGIO Mentor^{TM} Express System (Simbionix USA Corp., Cleveland, Ohio, USA). It is a part-task Virtual Reality device, consisting of a haptic device, a laptop and 2 LCD screens. The haptic device allows the user to perform endovascular procedures, insert and manipulate guide wires, deploy balloons, stents and stent grafts. The system is called part-task simulator since technical skills necessary to perform an arterial puncture are e.g. not addressed. Two consultants graded independently the level of complexity of all iliac and femoral cases on the simulator and selected five cases that were implemented in the program, including non-complex and complex cases. (Figure 1)

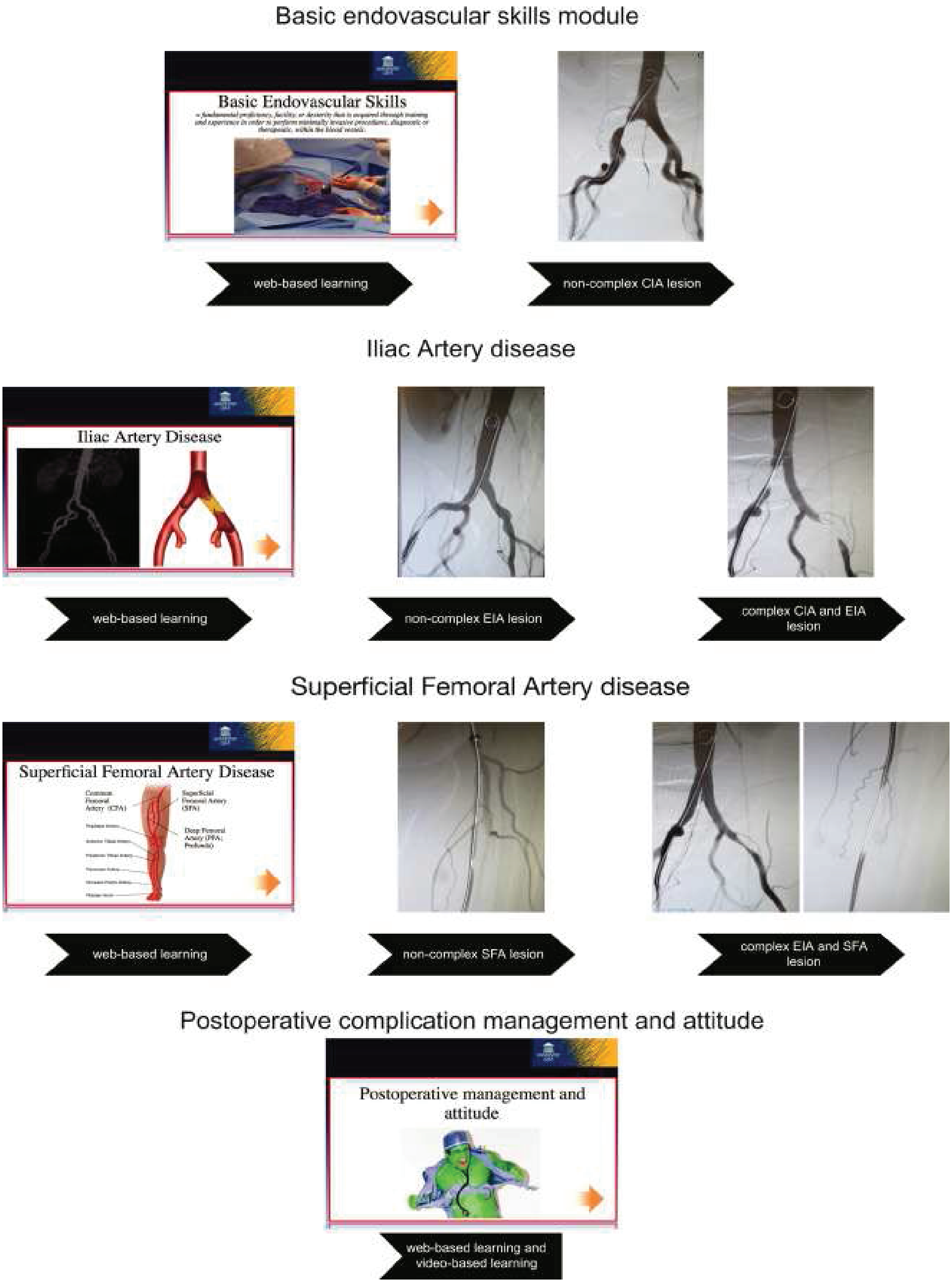

Figure 1. Flow of the PROSPECT program. The four stepwise modules of PROSPECT are illustrated. Web-based learning focusing on knowledge skills and non-technical skills is followed by simulation exercises to train technical skills.

Evidence suggests that most preventable medical errors are not caused by inadequate knowledge or technical skills but are often due to problems in transferring knowledge into real-world conditions.[146, 147] Therefore, human factor skills such as situational awareness, communication, decision-making and teamwork are important aspects of surgical performance. However, existing training curricula mainly focus on technical skills training, except for the ACS/APDS skills curriculum.[14] Currently, attention is shifting to include these soft skills into surgical education. In this curriculum, the key human factor skills are taught throughout video-based learning. These videos were developed by experts in team training and assessment during simulation-based team training courses: communication, coordination, cooperation/back-up behaviors, leadership and situational awareness, illustrating good and poor behaviors during endovascular procedures.[148]

Assessment

Proficiency-based curricula are neither time-based nor number-based but trainees will practice until a pre-defined performance-level has been achieved. Repetitive practice with formative feedback is needed to achieve this proficiency-level.[59, 96] Therefore, adequate assessment methods are mandatory. Construct validity of each assessment tool used in this training program was evaluated prior to design this stepwise, proficiency-based training curriculum. Construct validity defines whether a model can differentiate between different levels of experience and thus be used to assess performance.[149, 150] Proficiency-levels of skills were defined as the median scores of the experts.

Cognitive skills

Multiple-choice questionnaires were created to ensure trainees had acquired the appropriate knowledge by going through the web-based modules prior to any technical skills training. Vascular surgeons in practice and senior year medical students completed the MCQ tests for each module in order to assess construct validity.

Technical Skills

Vascular surgeons and final year medical students performed the five simulated cases in a random order. Hand movements and fluoroscopy screens were videotaped and post-hoc evaluated independently by two vascular surgeons using the previously validated Global Rating Score (GRS) and Examiner Checklist.[151, 152] Simulation assessment parameters were automatically recorded, however only valid parameters were included in the curriculum.

Simulation training is organised according to the trainee's schedule. After each simulation session trainees were allowed to ask questions and structured formative feedback was provided using the Global Rating Score and the Examiner Checklist. Daily, a maximum of three training sessions were allowed per trainee, with at least one hour of rest between sessions to ensure skill memorisation.[57, 138, 151]

Human factor skills

Evaluation of human factor skills performance during the simulated cases was not possible since they were carried out by an individual and not by an endovascular team. Nevertheless, principles of non-technical skills were included in the multiple-choice questionnaires.

Flow of the program (Figure 1)

The first module started with an e-learning module concerning basic endovascular skills as described above. When the median MCQ score of the experts was achieved, trainees were allowed to learn and practice the endovascular treatment of a simulated stenosis in the ipsilateral CIA using a variety of tools. During the simulation exercise, trainees were being observed and assessed. Structured formative feedback was provided. If the proficiency-level of technical skills was obtained on two consecutive simulations, trainees were allowed to proceed to the next module. In the second e-learning module trainees studied atherosclerotic iliac artery disease and treatment. When the MCQ proficiency-level was achieved, trainees learned how to treat a simulated non-complex ipsilateral EIA lesion, followed by a complex simulation exercise treating bilateral iliac artery lesions. After successfully completing this iliac module, trainees were allowed to proceed to SFA e-learning module. After passing the MCQ test, non-complex and complex SFA lesions were treated on the VR simulator. Finally, a fourth e-learning module explains trainees the importance of non-technical skills during endovascular procedures, teamwork and complication management.

Feasibility

Two sixth-year medical students were invited to go through the training program to evaluate the feasibility of the predefined proficiency-levels for knowledge and technical skills. A pre-post test was carried out, consisting of a cognitive part (20 MCQ) and a simulation exercise treating bilateral iliac artery lesions.

Statistical analysis

For statistical analysis SPSS 22.0 (Statistical Package for the Social Sciences, IBM Company, US) was used. The values for the different groups deviated significantly from the Gaussian distribution ($P < 0.05$), therefore non-parametric tests were used for all statistical analyses. Mann-Whitney U test was carried out to compare performances between two groups. Cronbach's alpha test was used to determine inter-rater reliability. Wilcoxon signed ranks test was used to compare scores before and after the curriculum.

Results

Design and development of PROSPECT

E-learning

Seventeen medical students and ten vascular surgeons in practice (experts) completed the MCQ. Experts scored significantly higher for each MCQ in comparison with medical students, confirming construct validity. Questions were categorised by level of difficulty to standardise all tests. Proficiency-levels for knowledge were determined based upon the median expert score (Table 1). Time spent for designing and expert reviews of the e-learning modules took respectively an estimated 384 hours and 12 hours.

Table 1: Validity of the MCQ's

Module	Students (N = 17) (Median, IQR)	Experts* (N = 10) (Median, IQR)	P value
Basic endovascular skills	15.0 (12.0-16.0)	24.5 (21.8-25.3)	**< 0.001**
Iliac artery disease	16.0 (13.5-17.0)	22.0 (20.8-24.5)	**< 0.001**
Superficial femoral artery disease	12.0 (09.0-14.5)	23.0 (21.0-25.0)	**< 0.001**
Postoperative management and attitude	15.0 (14.0-17.0)	22.0 (21.0-24.0)	**< 0.001**

Table 1 shows the median scores out of 30 questions for each module. IQR= interquartile range. Mann-Whitney U test was used to test for differences between groups (vascular surgeon consultants and medical students).

Simulated cases

Demographics of the ten medical students and ten vascular surgeons in practice are illustrated in Table 2. Based on their simulated performances some simulator metrics and video-based scorings have been validated.

Total procedure time (min), total contrast used (mL), total fluoroscopy time (min), number of catheters used and number of roadmaps taken during the procedure were able to differentiate level of experience. Students took significantly longer to treat iliac and femoral stenoses (3.3-14.8 vs. 5.8-30.1 min; P=0.001-0.04). In complex cases, fluoroscopy time was significantly higher in the student group (8.3 vs. 21.3 min; P=0.002; 7.3 vs. 13.1 min; P=0.03). Table 2 illustrates the baseline measures across student and expert groups.

Table 2: Demographics and Baseline Measures across Student and Expert Groups

Variable	Parameter	Student (N=10)	Expert (N=10)	p value
Demographics	Age, y(median)	24	38	-
	(Range)	*23-25*	*36-45*	
	Gender, n	M:F 6:4	M:F 6:4	-
	Handedness, n	R:L8:2	R:L9:1	-
	Vision corrected	Y:N9:1	Y:N6:4	-
Simulation metrics	**Total procedure time, min, median *(range)***			
	Basic angiography	5.8 *(5.1-7.4)*	3.3 *(2.5-5.3)*	**0.01**
	Iliac artery non-complex	10.4 *(9.5-12.9)*	8.5 *(5.2-10.5)*	**0.04**
	Iliac artery complex	30.1 *(26.1-43.7)*	14.8 *(11.2-20.0)*	**0.001**
	SFA non-complex	26.2 *(20.2-31.5)*	13.3 *(10.7-20.7)*	**0.01**
	SFA complex	27.1 *(22.3-38.7)*	14.1 *(12.6-15.9)*	**0.001**
	Pre-post test module	25.7 *(20.5-39.5)*	14.7 *(9.4-16.7)*	**0.001**
	Total amount of contrast, mL, median *(range)*			
	Basic angiography	19.5 *(18.0-27.5)*	19.0 *(14.5-26.0)*	0.44
	Iliac artery non-complex	39.0 *(20.0-49.0)*	29.5 *(21.5-39.0)*	0.60
	Iliac artery complex	79.0 *(39.5-104.0)*	49.0 *(39.0-64.5)*	0.36
	SFA non-complex	144.0 *(73.5-206.5)*	59.0 *(43.0-91.0)*	**0.02**
	SFA complex	129.0 *(85.8-215.3)*	68.0 *(59.5-73.5)*	**0.01**
	Pre-post test module	94.0 *(43.0-106.5)*	63.5 *(52.0-69.5)*	0.32
	Total Fluoroscopy time, min, median *(range)*			
	Basic angiography	1.9 *(1.1-3.5)*	1.4 *(0.5-2.5)*	0.22
	Iliac artery non-complex	3.4 *(2.7-7.4)*	3.3 *(1.5-4.3)*	0.36
	Iliac artery complex	21.3 *(11.4-25.9)*	8.3 *(5.2-12.8)*	**0.002**
	SFA non-complex	10.7 *(7.6-15.5)*	6.3 *(3.4-10.9)*	0.08
	SFA complex	13.1 *(9.5-16.7)*	7.3 *(5.3-8.8)*	**0.03**
	Pre-post test module	11.3 *(10.1-19.6)*	6.7 *(3.4-8.8)*	**0.001**

Number of catheters used, n, median *(range)*			
Basic angiography	NA	NA	NA
Iliac artery non-complex	NA	NA	NA
Iliac artery complex	4.5 *(2.8-9.3)*	2.0 *(1.0-3.5)*	**0.02**
SFA non-complex	2.0 *(1.0-2.0)*	1.0 *(1.0-2.0)*	0.78
SFA complex	2.0 *(1.0-3.0)*	2.0 *(1.5-2.5)*	0.60
Pre-post test module	1.5 *(1.0-5.3)*	1.0 *(1.0-2.0)*	0.41
Number of roadmaps, n, median *(range)*			
Basic angiography	3.0 *(2.0-4.3)*	2.0 *(2.0-3.0)*	0.19
Iliac artery non-complex	4.0 *(3.5-6.0)*	4.0 *(3.0-5.0)*	0.28
Iliac artery complex	7.5 *(4.5-12.8)*	6.0 *(5.8-7.5)*	0.35
SFA non-complex	16.0 *(13.0-25.0)*	10.0 *(6.0-11.5)*	**0.01**
SFA complex	16.0 *(9.8-21.8)*	8.0 *(7.0-9.0)*	**0.01**
Pre-post test module	10.0 *(9.3-11.8)*	7.0 *(6.8-10.0)*	**0.02**

Mann-Whitney U test was used to test for differences between groups. Significant values are in bold.

Post-hoc video analyses evaluated quality of performances using the Examiner checklist and Global Rating Scores (Table 3) and revealed higher scores obtained by vascular surgeons in all cases using GRS (51.0-42.0 vs. 29.5-18.0; P<0.001) and Examiner Checklist (81.5-75.0 vs. 54.5-43.0; P<0.001). A high inter-rater reliability (> 0.8) was found between the two independent raters (Table 3). Proficiency-levels of skills were determined for all these valid assessment methods based upon the median expert scores.

<u>Table 3</u>: Validity and inter-rater reliability of the video-based scores; (α = Inter-rater reliability)

	Examiner Checklist (of 85)				Global Rating Scale (of 55)			
Simulation cases	**Student (N=10)** Median range	**Expert (N=10)** Median range	**p value**	**α**	**Student (N=10)** Median range	**Expert (N=10)** Median range	**p value**	**α**
Basic Angiography	54.5	81.5	**<0.001**	0.98	29.5	51.0	**<0.001**	0.98
	48.3-63.3	79.0-82.0			24.3-32.8	47.3-52.0		
Iliac artery Non-complex	47.5	81.0	**<0.001**	0.98	23.0	50.0	**<0.001**	0.99
	42.3-54.8	78.5-82.0			20.8-26.3	46.5-52.8		
Iliac artery Complex	45.5	75.0	**<0.001**	0.97	19.0	42.0	**<0.001**	0.98
	43.0-53.8	70.3-77.8			15.3-22.8	36.5-49.0		
SFA Non-complex	43.0	76.5	**<0.001**	0.98	19.5	43.0	**<0.001**	0.99
	34.3-52.0	67.3-80.3			15.0-21.8	35.8-49.0		
SFA Complex	44.5	76.5	**<0.001**	0.98	20.0	42.5	**<0.001**	0.97
	40.3-48.8	66.0-79.3			15.3-24.5	36.5-45.3		
Pre-post test Module	46.0	75.0	**<0.001**	0.99	18.0	44.5	**<0.001**	0.99
	31.0-50.8	72.3-78.0			13.0-21.3	40.5-49.0		

Mann-Whitney U test was used to test for differences between vascular surgeon experts and medical students. Cronbach's alpha test was used to determine inter-rater reliability.

Feasibility

Two last-year medical students with interest in vascular surgery and interventional radiology completed the curriculum during their internships to assess if it is feasible to reach the pre-defined proficiency levels in the curriculum. Total time needed to complete this proficiency-based curriculum was 69 and 77 days from the moment the student received the first e-learning module until he completed the final test. Depending on the difficulty of the simulation case, it took between two and six attempts to achieve the proficiency level twice (Table 4). A total faculty time of 3 hours per trainee was needed to supervise the simulation sessions and provide formative feedback after each simulated session.

Table 4: Number of simulation sessions needed to achieve the proficiency levels

	Attempt	Student 1	Student 2
Module 1 Simulation case	Session 1	9.26 minutes	7.33 minutes
	Session 2	5.25 minutes	4.33 minutes
	Session 3	4.01 minutes	3.10 minutes (Pass)
	Session 4	3.15 minutes (Pass)	3.00 minutes (Pass)
	Session 5	2.50 minutes (Pass)	
Module 2 Simulation case 1	Session 1	8.27 minutes (Pass)	5.30 minutes
	Session 2	5.33 minutes (Pass)	6.47 minutes (Pass)
	Session 3		4.50 minutes (Pass)
Module 2 Simulation case 2	Session 1	20.10 minutes	15.28 minutes
	Session 2	22.08 minutes	13.18 minutes (Pass)
	Session 3	15.60 minutes	12.00 minutes (Pass)
	Session 4	16.00 minutes	
	Session 5	11.00 minutes (Pass)	
	Session 6	10.15 minutes (Pass)	
Module 3 Simulation case 1	Session 1	13.10 minutes	9.38 minutes (Pass)
	Session 2	10.48 minutes (Pass)	6.02 minutes (Pass)
	Session 3	9.48 minutes (Pass)	
Module 3 Simulation case 2	Session 1	18.30 minutes	18.37 minutes
	Session 2	10.44 minutes	12.57 minutes (Pass)
	Session 3	15.00 minutes (Pass)	11.33 minutes (Pass)
	Session 4	12.42 minutes (Pass)	

Table 4 provides the number of sessions for each student and how long it took to complete each session.

A progression was seen on the pre-post test for both cognitive and technical skills. There was an increase in knowledge score after completing the PROSPECT curriculum (11.5 vs. 16.5; P=0.18). Similarly, a positive evolution was seen in technical skills on the GRS (13.0 vs. 45.0; P=0.18) and Examiner Checklist (33.0 vs. 78.0; P=0.18).

Discussion

The FLS, ACS/APDS skills curriculum, the training curriculum for laparoscopic cholecystectomy and the proficiency-based knot-tying and suturing curriculum use multiple modules to learn surgical skills in a stepwise fashion.[14, 138, 139, 143] Similarly, PROSPECT was designed based upon a scientific method to enhance efficient and safe surgical education of endovascular procedures in the lower limbs.

PROSPECT will allow trainees to acquire endovascular skills in a safe environment and stepwise structured approach to maximise the efficiency of the learning process prior to treat real patients. The trainee completes four modules: ‘Basic Endovascular skills’, ‘Iliac Artery disease’, ‘Superficial Femoral Artery disease’ and ‘Postoperative complication management and attitude’ in order to achieve competency in basic simulated endovascular interventions. Each module offers first knowledge training through an online accessible learning tool. Validated Multiple Choice Questionnaires ensure that the trainees have the appropriate cognitive skills prior to commence any psychomotor skills training. During simulation exercises trainees learn and practice technical endovascular skills until the proficiency-level of skills has been achieved. These benchmarks are a mixture of validated simulation metrics and live scores using a Global Rating Scale and Examiner Checklist. Similar to previously designed curricula, proficiency-level of skills had to be achieved on two consecutive exercises.[138, 139, 142, 143]

The assessment methods used in this study correspond to performance-based endpoints used in the literature, a combination of valid simulator derived metrics and rating scales.[14, 138, 142] In contrast, Goova et al. used a self-assessment method in the proficiency-based knot-tying and suturing curriculum where trainees scored their own performance based upon a video with explanation.[139] Although this reduces the need for faculty time, it is rather subjective and does not allow personalised formative feedback.

Feedback at the end of a session is known to be more effective than feedback given during practice.[59, 153, 154] Hence, in PROSPECT feedback was standardised and provided after each simulation exercise without offering any assistance during hands-on training.[138, 142] The maximum number of training sessions per day was three with at least one hour apart, because spacing practice of skills facilitates skill acquisition and retention.[138, 155]

The schedule for training should be flexible and trainee-oriented. PROSPECT proficiency-levels can be achieved during fulltime clinical activities of medical interns. Completion of the program took approximately three months, which is similar to other curricula.[139]

The question remains if these skills acquired via PROSPECT do transfer to real-life, lead to higher quality performances and increased patient safety. Transferability of skills to real-life performances was demonstrated for the FLS curriculum.[143]

Not only knowledge and technical skills training, but also non-technical skills training for endovascular procedures was addressed and provided with e-learning and video-based learning. To date, one of the main concerns about the use of VR simulation is how to implement it into the already busy training programs without affecting the trainees' clinical activity and involvement in real-life cases. Because of the modular nature of the curriculum there is high flexibility to learn the various modules at the trainees' own pace and time schedule. Additionally, the program can easily be organised after night shift work.[156]

Limitations

Literature suggests that comparison of the performance of experts versus novices validates the learner group using the simulator and the taught curriculum, but not necessarily the simulation cases as such. Ideally, more groups with different level of expertise should have been included to demonstrate proficiency.[157] We intend to demonstrate improvement in patient outcome and transfer of skill to the angiosuite in a randomised controlled trial to proof the effectiveness.[62] Furthermore, the simulation sessions did not allow practice and assessment of human factor skills and skills retention was not evaluated. Literature suggests skills decay from 6 weeks to 2 year after training, and technical skills are known to decline faster than knowledge.[158-160] Additionally, skill-maintenance depends on the opportunity to practice the acquired skills. Gershuni et al. found no deterioration if surgical residents can keep on practicing; moreover a slight improvement in mean suturing performance was noted.[161] To avoid skill deterioration refresher training to achieve the proficiency levels at appropriate intervals may be necessary.

Since this was a single center study organised for surgical trainees, it is not clear if this training schedule will be applicable for other specialties such as interventional radiology, in other centers or countries. Finally, the creation of the PROSPECT e-learning modules was time consuming and must be regularly updated since endovascular surgery evolves rapidly.

An educational program to improve the education of surgical trainees should not only be feasible but also cost-effective. Financial support to obtain and maintain a simulator and protected time for tutors may be challenging in the current economic climate. Therefore a cost-effectiveness analysis will be performed once PROSPECT has been integrated in trainees' curricula.[162]

Conclusion

Proficiency-based simulation training may stimulate skill transfer to the operating room, minimising the current challenges in surgical education and improving patient safety. An innovative proficiency-based stepwise endovascular curricular training program including e-learning and simulation training (PROSPECT) has been developed to teach knowledge, technical skills and non-technical skills necessary to perform endovascular procedures successfully and safely.

The impact of PROSPECT on real-life performances will be further studied. A randomised controlled trial has been initiated to compare performances of curriculum trained versus conventionally trained residents in real patients. The effectiveness of PROSPECT will be examined to improve endovascular skills and patient outcomes during real-life performances (Clinical trials.gov trial number NCT01965860).

5

A Proficiency-based Stepwise Endovascular Curricular Training (PROSPECT) program enhances operative performance in real life: A Randomised Controlled Trial

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Abstract

Background

Healthcare evolution requires optimisation of surgical training to provide safe patient care. We performed a Randomised Controlled Trial to evaluate the impact of a Proficiency-based Stepwise Endovascular Curricular training program (PROSPECT) on acquisition of endovascular skills and how these skills transfer to real life interventions.

Methods

Thirty-two surgical trainees were randomised into three groups. Besides traditional training, the first group (N=11) received e-learning and simulation training (PROSPECT), the second group (N=10) only had access to e-learning, whilst the controls (N=11) did not receive supplementary training. Subsequently, all subjects performed two endovascular interventions treating symptomatic iliac and/or superficial femoral artery stenosis in real patients. Technical performances (Global Rating Scale (GRS); Examiner Checklist), operative metrics and patient outcomes were compared; adjusted for case difficulty and trainees' clinical experience. Secondary outcomes included knowledge and technical performance after 6 weeks and 3 months (pre-post-test design).

Results

Fifty-eight endovascular procedures were included. Trainees who completed PROSPECT showed superior technical performance in real life (GRS 39.36±2.05; Checklist 63.51±3.18) with significantly less supervisor takeovers compared to trainees receiving e-learning alone (GRS 28.42±2.15; P=0.001; Checklist 53.63±3.34; P=0.027) or traditional education (GRS 23.09±2.18; P=0.001; Checklist 38.72±3.38; P=0.001). Supervisors felt more confident in allowing PROSPECT-trained physicians to perform basic (P=0.006) and complex (P=0.003)

procedures. No differences in procedural parameters and complications were found. Proficiency-levels were maintained up to 3 months after completion of the program.

Conclusions

This type of structured, stepwise, proficiency-based curriculum including e-learning and simulation-based training should be integrated early into (endo)vascular training programs to enhance trainees' endovascular performance.

Introduction

Surgical education is challenged worldwide by the advanced healthcare demands to treat patients safely and to better prepare trainees for the operating room experience.[7, 163] Over the past decade competency-based surgical training and curricula standardisation have gained increasing interest, supported by growing evidence of clinical effectiveness.[163] Simulation-based training has been shown to result in reduction of operating time, decrease in perioperative errors[48] and superior patient outcomes in central line placement[45, 164], obstetric emergencies[165, 166], ophthalmologic surgery[167], laparoscopic surgery[35, 91], crisis resource management and team training.[168-172] Simulation-based education can improve patient care and outcomes if provided within a curriculum with proficiency-based goals[7, 43], allowing trainees to practice continually until they have demonstrated mastery of cognitive and technical skills.[173, 174] Based upon this evidence, several curricula such as the Fundamentals of Laparoscopic Surgery (FLS) and Fundamentals of Endoscopic Surgery (FES) have become mandatory to obtain the American Board of Surgery certification.[14, 51]

In the endovascular field, basic endovascular skills acquired during a session of proficiency-based simulation training in superficial femoral artery angioplasty translate into improved operating performance[175] but to be of uniform and consistent value there is a need for implementation of this training method into a structured curriculum with evidence-based learning goals.[176] Therefore, a Proficiency-based Stepwise Endovascular Curricular Training (PROSPECT) program was developed.[177] In this Randomised Controlled Trial (RCT) the transferability of knowledge and technical skills acquired by this PROSPECT program to Operating Room (OR) performances was examined and compared to trainees receiving e-learning alone, or no additional training.

We hypothesise that a structured comprehensive endovascular training curriculum including virtual reality simulation to acquire practical skills will result in superior clinical performance in real life when compared to conventionally educated surgical trainees. Furthermore, we expect that this proficiency-based curriculum may result in a lasting gain of knowledge and technical skills, as measured by a MCQ test and simulation exercise up to three months after the program.

Methods

Study Design

A single-blinded RCT was conducted at an academic center and nine general hospitals from October 2014 to February 2016 (Figure 1).The study followed a parallel group design within which general surgery residents were randomised either to standard education combined with a simulation-based proficiency-based endovascular curriculum, to standard education combined with multimedia-based training modules, or to standard education alone. Standard education refers to conventional training based upon intraoperative learning and self-study. The trial was registered at clinical trials.gov (NCT01965860).

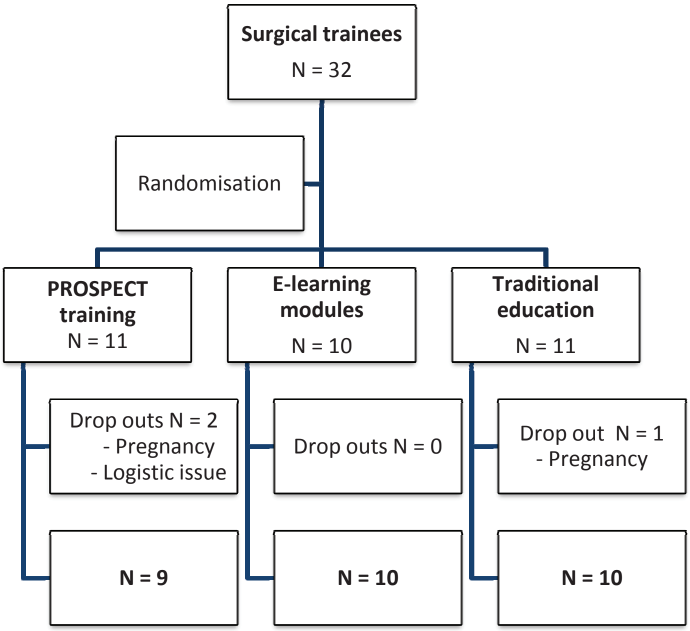

Figure 1: Study flow diagram.

Participants and Randomisation

All surgical trainees at Ghent University, irrespective of their postgraduate level (one to six), were invited to participate in this study. Thirty-two trainees agreed to participate (82% participation rate) and were randomised in three groups using the closed-envelope technique: two intervention groups (PROSPECT group N=11; E-learning group N=10) and one control group (N=11). Randomisation was stratified by postgraduate level.

Fifty-six patients (58 endovascular interventions) were included in this RCT. Patients were eligible if they suffered from symptomatic arterial disease in the lower limbs (Rutherford classification 2-5; stenosis TASC type A or B of iliac and/or femoral arteries).

Eligible patients were asked to participate by the supervising consultant and an informed consent form was signed by surgical trainees as well as by the patients. All the appropriate institutional review boards approved the study protocol.

Initial assessment

Prior to enrolment, cognitive and technical skill level of every surgical trainee was evaluated to ensure similar baseline experience in all groups. After signing the informed consent, operative experience was assessed using a demographics and experience questionnaire.[57] All participants completed a pretest, consisting of a multiple-choice questionnaire (MCQ) with 20 questions to evaluate cognitive endovascular skills[177] and a simulation exercise treating bilateral iliac artery disease on the ANGIO Mentor™ Express System (Simbionix USA Corp., Cleveland, Ohio, USA). Each trainee was familiarised with the Virtual Reality (VR) simulator according to a standardised protocol prior to technical skills assessment.

Interventions

Trainees randomised in the *PROSPECT group* completed a structured, stepwise proficiency-based endovascular curriculum consisting of cognitive, technical and nontechnical skills training to explain the flow of the intervention and how to plan and execute an endovascular procedure. This competency-based training consisted of four modules, starting with basic endovascular skills training. The second and third modules focus on iliac artery and superficial femoral artery disease treatment, while the fourth module explains postoperative complication management and attitude.

These modules allow the trainee to learn endovascular procedures at their own pace in a structured stepwise fashion, away from clinical activities. Each module consists of an online E-learning part to acquire cognitive and nontechnical skills and supervised hands-on simulation sessions to learn and practice technical endovascular skills. Knowledge was tested after each module using MCQ and technical performance was assessed during every simulation exercise using validated simulator metrics, a Global Rating Scale (GRS) and an Examiner Checklist.[177] Structured feedback was provided after each attempt using the GRS and Examiner Checklist. Every trainee was required to achieve cognitive (once) and technical proficiency-levels (two separate occasions) at each level before advancing to the next module. These benchmarks are based on the median score of experts in the field. A detailed description of the design and construct validity of this program has been published.[177]

Trainees in the *e-learning group* only received cognitive multimedia-based training without access to hands-on simulation based training. Subjects had to complete the MCQ test after each module. If benchmark levels were achieved, the subject was allowed to move on to the next e-learning module.

If randomised in the *control group*, no additional training was provided but these trainees received weekly vascular papers to stimulate engagement in the project.

<u>Conventional training</u>

All groups continued conventional clinical training. Participants were asked to keep a logbook with their interventional experiences, self-study, workshops and conferences during the course of the study. Individual self-study was allowed. All groups had the opportunity to ask questions and receive feedback.

Assessment

Within six weeks after completing training, every surgical trainee performed two endovascular procedures in the OR. All participants were aware of the final assessment parameters of the study. Since arterial puncture was not addressed in the curriculum, the sheath was inserted by the supervising vascular surgeon. After the sheath was in place, the trainee took over and performed the endovascular procedure as deemed appropriate by the supervising consultant who was blinded to the trainee's randomisation status. To ensure patient safety, final decisions about the interventional approach and materials were made by the consultant and the consultant was instructed to take over the intervention if necessary.

All cases were videotaped. A single investigator, non-blinded to the randomisation status (HM) observed the entire procedure to oversee the video-recordings and register operative metrics and number of consultant takeovers.

Technical performance was assessed by the blinded supervising consultant immediately after each intervention using the Examiner Checklist for diagnostic angiography, angioplasty and stenting (procedure specific rating scale) and the Global Rating Scale of endovascular performance (OSATS derived).[57] Additionally, one independent blinded vascular surgeon also assessed the technical skills by scoring the video's post-hoc to allow objective external rating. The inter-rater reliability of both technical skills assessments was determined.

Surrogate measures of performance were operative metrics: total procedure time, fluoroscopy time, number of consultant takeovers, amount of contrast used, radiation dose and perioperative and postoperative complications. Intraoperative complications were recorded in the OR by the observer and supervising consultant. Postoperative complications were recorded during a 30 days follow up period. Procedure time was registered between insertion and removal of the introducer sheath. The medical record of each patient was reviewed to gain information about age, sex, number and type of lesions, medical history and drug use.

The supervising consultant was asked if he/she would allow the trainee to perform a simple or complex endovascular procedure. Additionally, cognitive as well as technical skills were re-assessed 6 weeks and 3 months post-training to evaluate skills evolution and retention.

Outcome measures

The primary outcome measure was the difference in technical and overall performance during the real life procedures between the three groups.

Secondary outcomes included evolution in knowledge (MCQ test) and technical skills (VR simulator) and skills retention after the training program. Additionally all trainees randomised to an intervention group completed a questionnaire about their experience with the e-learning modules and simulation training.

Sample Size Calculation

Prior to the study a power analysis was performed to calculate the number of participants required in each of the three groups. Previous work comparing OSATS derived scores in endovascular interventions shows a Cohen D of 2.[57] Using α of 0.05, a power of 0.80 and an expected dropout rate of 10%, the minimum number of surgical trainees required in each group is 7.

Statistical Analysis

Statistical analysis was performed using SPSS 22.0 (SPSS Inc, Chicago, IL). Descriptive statistics were calculated and expressed as the mean±standard deviation. Parametric tests were used since variables were normally distributed as determined by the Shapiro Wilk test. To compare differences between the three groups the Anova test with Tukey post hoc (continue variables) and the fisher's exact test (categorical variables) were used.

A mixed linear regression with patient as random factor was performed to compare performances between the three groups taking into account both interventions. Analysis was adjusted for case difficulty and clinical experiences of the trainee before and during the period of the study. The supervising consultant scored the case complexity on a Likert scale (1-5). Intra-class correlation coefficient (ICC) was calculated to evaluate interrater-reliability (one using life assessment and one using post-hoc video assessment). Difference on the prepost-test was assessed using the paired T-test. Level of significance was defined as P-value lower than 0.05.

Results

Participant Demographics and Endovascular Experience

Twenty-nine of the thirty-two included surgical trainees completed the program, resulting in a dropout rate of 9%. Two trainees dropped out due to pregnancy and one trainee experienced logistic problems to complete training whilst working in a district hospital (Figure 1). Endovascular experience prior to the study amongst the participants was limited (Table 1).

TABLE 1: Demographics and experience of Study Participants

	PROSPECT intervention group	**E-learning intervention group**	**Conventional control group**	**Overall**	**P-value**
Postgraduate year level					**0.68**
Level 1	2	3	4	9	
Level 2	2	3	1	6	
Level 3	4	1	3	8	
Level 4	0	2	1	3	
Level 5	1	1	1	3	
Level 6	2	0	1	3	
Sex					**0.75**
Male/Female	6/5	4/6	6/5	16/16	
No. endovascular cases assisted					**0.24**
0-5	1	2	2	5	
5-10	2	1	1	4	
10-50	6	5	1	12	
50-100	1	1	5	7	
100-200	1	0	0	1	
> 200	0	1	2	3	

Table 1 illustrates participants' demographic information and endovascular experience prior to inclusion

Initial Assessment

The baseline MCQ test showed similar endovascular knowledge in all groups at inclusion (PROSPECT (mean 14.09 ± 3.11); e-learning (mean 14.90 ± 1.10); control (mean 14.36 ± 2.66); P=0.75). Similarly, no significant differences between groups were noted in technical performance on the VR simulator (Table 2).

TABLE 2: Baseline assessment of technical endovascular skills on the simulator

	PROSPECT	**E-learning**	**Control**	**P-value**
Global Rating Scale **(Max score55)**	20.64 (8.23)	18.10 (5.72)	18.55 (7.57)	0.69
Examiner Checklist **(Max score85)**	44.45 (17.18)	40.10 (14.16)	38.27 (13.45)	0.62
Total procedure time **(Min.)**	18.16 (7.92)	22.79 (7.80)	23.95 (9.06)	0.24
Total Fluoroscopy time **(Min.)**	7.30 (4.50)	11.08 (6.77)	9.80 (4.30)	0.26
Roadmaps **(No.)**	7.45 (2.98)	9.10 (4.98)	9.55 (7.97)	0.67
Completion of the case **(% success rate)**	8 (73%)	9 (90%)	9 (82%)	0.60

Table 2 illustrates baseline technical skills using previously validated rating scales and simulator metrics.

PROSPECT Training

Nine out of eleven trainees included in the PROSPECT group completed the stepwise endovascular training program, achieving proficiency-levels for cognitive and technical skills in each module (Figure 1). It took the trainees a mean of 8.44 months (±2.46) to complete the PROSPECT program during their clinical training.

Overall, trainees required a mean of 13 (±4.10) simulation sessions, corresponding with 4.76 (±2.79) hours of practice to achieve competency. Additionally, it took 8.52 (±2.93) hours to study the e-learning modules, taking into account both simulation and e-learning groups. Prepost-test evaluation shows significant increase in knowledge and technical skills in both intervention groups for most parameters. These results are illustrated in table 3.

TABLE 3: Achievement and maintenance of cognitive and technical endovascular skills (Mean, SD)

		Knowledge (MCQ)	**GRS**	**Examiner checklist**	**Procedure Time**	**Fluoroscopy Time**	**Number of Roadmaps**
PROSPECT	Pretest	14.00	19.78	43.56	20.12	8.22	8.11
		3.39	*7.24*	*15.76*	*6.90*	*4.37*	*2.80*
	Post-test 6w	18.11	49.56	83.22	15.76	8.48	8.33
		1.36	*3.78*	*1.99*	*5.18*	*3.38*	*3.00*
	Post-test 3m	18.25	51.13	82.25	13.44	6.30	6.25
		1.98	*3.44*	*1.75*	*2.67*	*2.57*	*1.83*
	P-value Pre-post	**0.003**	**0.001**	**0.001**	0.089	0.890	0.873
	P-value 6w-3m	0.785	0.328	0.174	**0.045**	0.072	0.170

E-learning	Pretest	14.88	16.25	35.63	24.76	11.97	10.13
		1.13	*4.10*	*11.38*	*6.88*	*7.09*	*5.06*
	Post-test 6w	17.88	32.75	59.25	23.58	11.88	8.25
		0.99	*13.51*	*16.73*	*11.47*	*8.83*	*3.73*
	Post-test 3m	17.71	24.14	51.71	16.30	8.72	6.43
		0.75	*6.65*	*16.31*	*3.60*	*7.21*	*7.19*
	P-value Pre-post	**0.001**	**0.008**	**0.001**	0.731	0.978	**0.008**
	P-value 6w-3m	0.838	0.076	0.086	0.128	0.424	0.486
Control	Pretest	14.00	18.00	37.60	24.72	10.12	10.10
		2.49	*7.75*	*13.98*	*9.17*	*4.39*	*8.17*
	Post-test 6w	15.20	21.20	42.80	23.95	11.65	9.90
		2.70	*7.48*	*15.39*	*7.19*	*4.10*	*3.18*
	Post-test 3m	NA	NA	NA	NA	NA	NA
	P-value Prepost	0.288	0.164	0.190	0.720	0.344	0.932
	P-value 6w-3m	NA	NA	NA	NA	NA	NA

Table 3 illustrates scores achieved during pre-post-test assessments 6 weeks and 3 months after completing the training program. GRS = Global Rating Scale. Differences were assessed using the paired T-test. Statistical significant values are in bold.

Operative performance

Trainees in the PROSPECT group performed significantly better compared to the e-learning or conventional training group as assessed by live scoring using the OSATS derived Global Rating Scale (GRS) and Examiner Checklist. Trainees who completed PROSPECT showed superior technical performance (GRS 39.36±2.05; Checklist 63.51±3.18) compared to surgeons receiving only e-learning (GRS 28.42±2.15; P=0.001; Checklist 53.63±3.34; P= 0.027) or traditional education (GRS 23.09±2.18; P=0.001; Checklist 38.72±3.38; P= 0.001). Five consultants supervised the cases, but the same consultant supervised the majority (71%) of the cases. These live ratings were supported by post-hoc video assessment, showing good inter-rater reliability with the live scores (GRS ICC=0.74; Examiner Checklist ICC=0.78; Case difficulty ICC=0.71).

There were no significant differences between the first and second intervention in any group, however general improvement in scores was noticed: control (Checklist 5.10±13.85; P=0.27; GRS 0.2±9.03; P=0.95), e-learning (Checklist 6.60±17.01; P=0.25; GRS 5.10±11.19; P=0.18), PROSPECT (Checklist 4.22±10.49; P=0.26; GRS 0.56±6.65; P=0.81).

The blinded supervising consultant felt significantly more confident allowing 7 trainees of the PROSPECT group to perform a procedure independently, compared with 4 trainees in e-learning and 3 trainees in the control group (P=0.004). Supervisors felt significantly more confident in allowing simulation-trained physicians to perform basic (P=0.006) and more complex (P=0.003) procedures.

There were significantly less supervisor takeovers in the PROSPECT group during the real life interventions (0.30±0.50) compared to surgeons receiving only e-learning (3.40±0.53; P=0.001) or traditional education (4.18±0.54; P=0.001). Consequently, evaluation of performance parameters showed no significant differences between the three groups (Table 4).

TABLE 4: Assessment of operating room performances (mean, SD)

	PROSPECT	E-learning	Control	P-value			
				General	**PROSPECT vs. E-learning**	**E-learning vs. Control**	**PROSPECT vs. Control**
Global Rating Scale	**39.36**	**28.42**	**23.09**	**0.001**	**0.001**	0.054	**0.001**
	2.05	*2.15*	*2.18*				
Examiner Checklist	**63.51**	**53.63**	**38.72**	**0.001**	**0.027**	**0.001**	**0.001**
	3.18	*3.34*	*3.38*				
Supervisor takeovers	**0.30**	**3.40**	**4.18**	**0.001**	**0.001**	0.241	**0.001**
	0.50	*0.53*	*0.54*				
Procedure time (min)	51.25	53.18	42.60	0.525	0.845	0.267	0.448
	7.09	*7.49*	*7.47*				
Fluoroscopy time (min)	11.97	14.35	11.38	0.238	0.240	0.131	0.798
	1.43	*1.51*	*1.52*				
DAP	44071	61306	61771	0.609	0.347	0.979	0.408
	3.80	*.03*	*.37*				
Number of angiographies	9.04	15.01	10.86	0.362	0.197	0.345	0.730
	3.27	*3.43*	*3.46*				
Contrast used (mL)	65.14	78.77	71.37	0.205	0.077	0.543	0.302
	9.16	*9.61*	*9.73*				

Peri-operative complications	2/58 *3.45%*	4/58 *6.70%*	2/58 *3.45%*	0.743	0.924	0.489	0.512
In-hospital minor AE	2/58 *3.45%*	1/58 *1.72%*	0/58 *0%*	0.769	0.975	0.483	0.593
In-hospital major AE	1/58 *1.72%*	1/58 *1.72%*	1/58 *1.72%*	0.941	0.790	0.893	0.735
30days minor AE	0/58 *0%*	1/58 *1.72%*	3/58 *3.45%*	0.299	0.567	0.222	0.147
30days major AE	0/58 *0%*	0/58 *0%*	1/58 *1.72%*	0.490	0.876	0.241	0.436

Table 4 illustrates performance assessments of the life cases by technical skill rating scales (LIVE), procedural parameters and complication rates. A mixed linear regression was performed to take into account both interventions. Statistical significant values are in bold. AE=Adverse Event.

In both intervention groups, trainees were highly satisfied with the e-learning modules according to a questionnaire on a Likert scale from 1 to 5 (Table 5). The modules have been rated as an interactive and pleasant way to study with interestingly presented content, resulting in more confidence to participate in endovascular procedures.

Similarly, simulation training was rated as a useful adjunct to clinical training by increasing understanding and confidence during endovascular procedures (Table 6). The trainees strongly agreed that simulation training should be completed by all surgical trainees prior to treating real patients.

TABLE 5: E-learning experience questionnaire

Statement	Score (mean, SD)
This e-learning has helped to develop my ability to work as a team member	3,33 (0,767)
After this e-learning i feel more confident approaching endovascular procedures	4,17 (0,924)
This e-learning has improved my communication skills	3,11 (0,676)
It seems to me that the e-learning content tries to cover too many topics	2,06 (0,539)
The e-learning has encouraged me to develop my endovascular interests	3,83 (0,618)
This e-learning is an interactive and pleasant way to study	4,11 (,676)
I can find the information in this e-learning by self-study	3,06 (1,056)
The MCQ assessment test is feasible if you have understood the content	4,17 (0,618)
It is hard to discover what is expected of you in this e-learning education	1,89 (0,323)
The subjects are presented interestingly	4,17 (0,618)
Overall, I'm satisfied with the quality of this e-learning tool	4,56 (0,511)

Table 5 illustrates trainees' experiences with e-learning rated on a Likert scale 1-5. The questionnaire was completed by all trainees receiving e-learning (N=19).

TABLE 6: Simulation training experience questionnaire

Statement	Score (mean, SD)
This simulation training has helped me to really understand the tools and steps of endovascular procedures	4,63 (0,518)
After this simulation training, I feel more confident to perform/assist endovascular procedures in the OR	4,50 (0,535)
This simulation training has increased my interest in endovascular surgery	3,75 (0,707)
Endovascular simulation training should be completed by all surgical trainees	4,75 (0,463)
This simulation training should be mandatory prior to treat real patients	4,38 (0,518)
Simulation sessions should be granted educational credits in surgical education e.g. simulated cases in Medbook	4,38 (0,744)
Overall, I think simulation training is useful for endovascular trainees in addition to traditional clinical training	4,63 (0,518)

Table 6 illustrates trainees' experiences with simulation training rated on a Likert scale 1-5.The questionnaire was completed by all trainees who completed simulation training (N=9)

Patient outcomes

No significant differences in patient outcomes were observed between the three groups (Table 4). Within 24 hours after endovascular treatment, three minor (pseudo-aneurysm N=1; wound infection N=1; temporarily decreased kidney function N=1) and three major (unstable angina N=1; amputation N=1; bypass surgery N=1) adverse events occurred.

At 30 days four minor adverse events occurred: hematoma (N=1), acute gout episode (N=1), recurrent epistaxis requiring reduction of anticoagulant therapy (N=1) and herpes zoster infection at the target leg (N=1). There was only one patient presenting with a de novo lesion at the treated leg within 30 days after surgery.

Skills retention

At 3 months follow-up the proficiency scores in the PROSPECT group for both cognitive and technical endovascular skills were maintained (Table 3). Similarly, the participants in the e-learning group retained the acquired knowledge skills 3 months post-training.

Discussion

This study is the first RCT that has evaluated operative performances of surgical trainees in the hybrid angiosuite after completion of a stepwise proficiency-based endovascular training program including virtual reality simulation (PROSPECT) versus solely multimedia-based learning versus no additional training complementary to clinical education.

The results of our study show that trainees who completed PROSPECT demonstrate superior technical skills during real life endovascular procedures compared to the other two groups and thereby suggest the transferability of the skills that were acquired during off-patient training. Furthermore, operating room performance after PROSPECT training was associated with fewer consultant takeovers. Training using e-learning without simulation sessions significantly improved cognitive skills; however, in terms of technical skills no proficiency levels were achieved.

Operative metrics and patient outcomes were similar across the three groups, which is in contrast to previous studies showing a decrease in operative time after simulation-based training.[34, 91] In our study, differences in operative metrics and complications were influenced by the increased number of consultant takeovers in the control group. Consultant takeovers took place due to ethical concerns, not differing from takeovers during conventional training to ensure patient safety. This consultant interference may mask differences in operative metrics and complications that would have occurred without any supervision. Therefore, performance-based assessment in clinical environment evaluating transfer of acquired competencies into job behaviors (Kirkpatrick-level three evidence) could be provided, however changes in patient outcomes (Kirkpatrick-level four) could not be determined.[178] To obtain this highest level of evidence, a RCT should be conducted focusing primarily on patient outcomes. However, this would require assessment of more passively supervised interventions which was considered unethical in this trial.

A general improvement in scores was noticed between the first and second intervention probably due to familiarisation with the hybrid angiosuite and flow of the intervention.

Since the program offers basic endovascular skills' training that significantly improves trainees' performance, the PROSPECT program should be integrated preferentially predominantly in the early phase of the learning process.[179] Similarly to the FLS, completion of PROSPECT should not be optional but it should become a prerequisite prior to treating real patients.[180, 181] After completing this program, the acquired endovascular skills can be fully mastered, improved and maintained by performing real-life interventions in clinical practice. In our study, the acquired cognitive and technical endovascular proficiency levels by PROSPECT were retained at 3 months after completing the program. Further skills retention will depend on clinical practice opportunities; however, refresher courses may be needed to retain expert proficiency.[182]

Although the results of this study demonstrate superior surgical skills acquisition and skills transfer to the hybrid angiosuite by PROSPECT training, the challenge will be the implementation of this program in surgical education. In simulation-based endovascular training tutors are still needed to provide structured feedback, which might pose a problem given the already limited staffing in surgical departments. Furthermore, these supervisors should be trained in providing constructive feedback and criticism to enrich the learning experience of surgical trainees.

Another barrier to implement this curriculum in surgical education is the limited time of the trainees who are already challenged by having to learn more surgical skills in less time[183]; however this study has shown that it is feasible to implement PROSPECT into busy clinical activities. If necessary, these training sessions can be flexibly organised during off-clinical time and after night shift work[156, 184]

Moreover, since the curriculum improves OR performance and probably shortens the learning curve, fewer real life interventions may be needed to achieve endovascular proficiency.

Finally, integration of PROSPECT in surgical curricula will require resources and funding for logistics and supervision.[62, 185] A cost-effectiveness analyses should be carried out to weigh the educational costs and health care system benefits of this training curriculum. Other studies have shown a significant medical care cost saving after simulation training, mainly due to a decrease in complication rate.[67]

Limitations

There are several limitations to this study. The results of this trial may not be applicable to other countries. Trainees were explicitly told not to disclose the randomisation group to the supervising consultant but this may have occurred unintentionally and this may have influenced the scores of the supervising consultant. Therefore, an independent blinded consultant vascular surgeon carried out post-hoc video ratings, showing strong agreement with the life ratings.

Non-technical skills assessment during the life interventions was not carried out, this evaluation might have been useful since failure in team interactions leads to high rate of errors occurring during endovascular procedures.[37]

In this study there was a drop-out rate of 9%, which is within the expected range and is acceptable according to sample size calculations.

Long-term skills retention was not assessed beyond three months post-training, which would provide more specific valuable information about the timing of refresher courses.

This RCT suggests that simulation-based training using a PROficiency-based StePwise Endovascular Curricular Training is superior to traditional training or solely multimedia-based training in terms of real life technical endovascular performance. These results should stimulate educational leaders to incorporate PROSPECT or similar structured, stepwise, proficiency based training programs including theoretical as well as practical training in postgraduate training to improve trainees' technical operating room performance and to ensure that patients are only cared for by doctors who have achieved proficiency levels of endovascular training prior to performing real-life procedures.[186]

6

Economic analysis of a Proficiency-based StePwise Endovascular Curricular Training program

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Ready for submission.

Abstract

Objective

Classically, training in endovascular procedures, like any surgical training, is performed on real patients, in a real world situation, without curricular support and dependent on a highly variable caseload. This study aimed to determine the costs associated with a PROficiency-based StePwise Endovascular Curricular Training (PROSPECT) program including e-learning and hands-on Virtual Reality (VR) simulation.

Methods

A Randomised Controlled Trial (RCT) was performed to assess endovascular performance of surgical trainees after structured training (PROSPECT; N=11)) compared with solely e-learning (N=10) or conventional training (N=11). Costs for the development of e-learning and VR simulation sessions were determined. Time spent studying and practicing within the curriculum was converted to indirect saving of operating time. Costs of logistics, faculty time supervising simulation sessions and 30-day complication rates were registered. Based on these results an analysis was performed of the costs related to the implementation of this program to learn endovascular procedures.

Results

Fifty-eight peripheral endovascular interventions, performed by 29 surgical trainees were included in this RCT from October 2014 to February 2016. Yearly costs include 6,588.50€ for curriculum design, 31,483.53€ for implementation and 1,143.20€ operational costs. Per trainee at our university, simulation-based training until proficiency would require a total amount of 3,805.86€.

Conclusion

Simulation-based training in endovascular procedures is financially feasible. Structured proficiency-based, simulation-based training curricula should be included into surgical education.

Introduction

Surgical training is depending on trainee's exposure to a large volume and variety of surgical experiences, learning in authentic surgical setting and the provision of a supportive environment.[187, 188] Traditional basic surgical skills training during real-life interventions in the operating room (OR) is inefficient, expensive and prolongs procedure time[189] resulting in higher OR expenses.[64, 190] For example, each tympanoplasty intervention requires an incremental cost of 35.53€[66] and 1,322.53€ is added for each laparoscopic anastomosis performed by supervised trainees.[65] Incremental costs associated with laparoscopic cholecystectomy and inguinal hernia repair were rated at 8,370€ for residents and 22,922€ for junior consultants per year.[191] Therefore, additional surgical education outside of the OR, may reduce costs within the health care system.

Moreover, a surgical training program may lead to a decrease in complication rate and reduction in costs associated to these complications and increases patient safety.[192] Cohen et al. concluded that simulation-based education in central venous catheter insertion declines infection rates in the Medical Intensive Care Unit at an urban teaching hospital. The incremental cost related to treatment of a central venous catheter infection was determined 72,176.75€, resulting in an annual saving of 616,142.95€.[67]

Structuring surgical education in predefined proficiency-based programs has proven to be cost-effective in several fields.[193] Virtual Reality (VR) simulation-based education requires a significant financial investment and therefore a health economic evaluation to assess its economic value.

Cost-effectiveness of VR simulation-based training programs has been examined in several surgical disciplines. Simulation-based robot-assisted surgical training has shown to save up to 528,122.53€ over 1 year at Roswell Park Center for Robotic Sugery, taking into account investment, utilisation of equipment and costs of operating room training.[194] Similarly, simulation training in ophthalmologic interventions reduces costs by increasing operative efficiency.[195]

In the field of endovascular surgery, a PROficiency-based StePwise Endovascular Curricular Training program (PROSPECT)[177] using virtual reality simulation to acquire the endovascular skills has shown to improve surgical performance in the operating room.[196] However, in order to justify implementation of this simulation-based curriculum in surgical education the costs of this program on the health care system should be critically assessed.[192, 197] The objective of this study is to perform an economic evaluation of the PROSPECT program.

Methods

Data were obtained in a prospective Randomised Controlled Trial (RCT) including 58 endovascular interventions in 56 patients.[196] Thirty-two general surgery trainees at an academic institution were randomised in three groups using closed-envelope technique. The first group received standard practice training combined with a simulation-based proficiency-based endovascular curriculum PROSPECT (N=11) including multimedia-based training and simulation sessions. The second group had standard practice combined with multimedia-based training modules (N=10) and the third group only received standard practice (N=11).

Standard practice refers to conventional training based upon intraoperative learning and self-study. Within 6 weeks of completing the training program, each trainee performed two endovascular interventions in the angiosuite under supervision. Patients were eligible if they suffered from symptomatic atherosclerotic stenotic disease in the lower limbs (Rutherford classification 2-5; stenosis TASC type A or B of iliac and/or femoral arteries). The supervising consultant consented the patient and an Informed Consent form was also signed by the surgical trainees. Detailed study methods are described in our previous work.[196]

During the course of the RCT, curriculum development costs, faculty and administrators' salary (man-hours), space rental, administrative costs, operating times and material costs were prospectively registered.[198, 199]

Four principal factors were implemented in the analysis: training time cost, developmental cost, implementation cost and operational cost. A hospital perspective was taken.

Training time cost included the time spent by trainees to study the multi-media modules (logbook) and to learn and practice during endovascular simulation sessions as registered by the supervisor (salary trainee 18.67€ per hour). Developmental cost was calculated by analysing time spent by all team members to design, review and validate the e-learning and simulation modules (Table 1).

Table 1: Overview of curricular developmental costs

Item	Time (hours)	Unit cost	Expense
Design e-learning modules	384	Salary faculty surgeon (71,45€ per hour)	27,436.80€
Review e-learning modules	12	Salary faculty surgeon (71,45€ per hour)	857.40€
Validate knowledge questionnaires	22	Salary faculty surgeon (5 hours; 71,45€ per hour)	357.25€
		Salary medical student (17 hours; 10€ per hour)	170.00€
Develop and validate simulation-based training	57	Salary faculty surgeon (17 hours: 2 hours' case selection, 15 hours performing simulation cases; 71,45€ per hour)	1,214.65€
		Salary medical student (40 hours)	400.00€
Feasibility assessment	47.5	Salary faculty surgeon (12 hours :6 hours supervising simulation sessions, 4 hours of pre-post testing and 2 hours supervising MCQ tests; (71,45€ per hour)	857.40€
		Salary medical student (35,5 hours of medical student time (23,5 hours: 6 hours performing simulation cases and 6 hours taking tests; 10€ per hour)	355.00€
Purchase materials		Cost desk and computer	1,294.00€
Cost over 5 years			32,942.50€
Yearly cost			**6,588.50€**

Table 1 illustrates the cost included for development of the curriculum. Medical student time has been considered 10€ per hour. Salaries were based upon average gross salaries at our operating theatre.

Implementation costs included the maintenance, staffing, logistics and consumable costs associated with the usage of the VR simulator (Table 2). The maintenance and material costs for the VR simulator were obtained from the manufacturer (Simbionix USA Corp., Cleveland, Ohio, USA). Operational cost was determined as time that faculty had spent to update the modules (salary team members 71.45€ per hour).[200]

Table 2: Overview of curricular implementation costs

Item	Unit cost	Expense
Adjustable simulation table	Purchase cost	1,840.17€
Simulator, incl. software	Purchase cost	57,500.00€
Maintenance simulator	Yearly maintenance cost	(5x) 7,900.00€
Rent room, incl. electricity and maintenance	Yearly rental costs	(5x) 846.00€
Skills lab coordinator	Part-time year salary	(5x) 10,869.50€
Cost over 5 years		157,417.67€
Yearly cost		**31,483.53€**

Table 2 illustrates the cost included for implementation of the curriculum

The study protocol was approved by all the appropriate institutional review boards. The trial was registered at clinical trials.gov (NCT01965860).

Statistical analysis

Statistical analysis was performed using SPSS 22.0 (SPSS Inc, Chicago, IL). The incremental curriculum costs per trainee were determined: training time cost, developmental cost, implementation cost and operational cost.

Results

Training time cost

Trainees spent 517 min (mean, range 280-830, SD 156) studying the e-learning modules and 256 min (mean, range 118-900, SD 252) performing hands-on endovascular simulation exercises. The total training time was 773 min or 12.9 hours per trainee. This translates into a cost of 240.84€ per trainee (salary trainee 18.67€ per hour).

Developmental cost

Development of the program is thoroughly described in our previous work.[196] Time spent designing and reviewing the e-learning modules took respectively 384 hours and 12 hours. Completing the knowledge questionnaires during the validation process took 5 hours of faculty time and 17 hours of medical student time.

Seventeen hours of faculty time (2 hours' case selection, 15 hours performing simulation cases to validate the exercises and define proficiency scores) was needed to develop and validate simulation-based training modules and 40 hours of medical student time was needed to treat the simulated cases included within the curriculum.

The feasibility study took 12 hours of faculty time (6 hours supervising simulation sessions, 4 hours of pre-post testing and 2 hours supervising MCQ tests) and 35.5 hours of medical student time (23.5 hours of study time, 6 hours performing simulation cases and 6 hours taking tests).

The cost associated with assessment of the performances in real life, was not reported because it was the same in the three groups of the RCT. Curriculum development required 522.5 hours. In total, development time and purchase of materials, as described in table 1, translated to a total yearly cost of 6,588.5€ over five years, assuming that a new curriculum is to be developed every five years.

Implementation cost

Implementation costs include 1,840.17€ to purchase an adjustable simulation desk, 57,500€ for the simulator including software components with 7,900€ yearly maintenance costs, 846€ yearly rental costs of the simulation room with electricity and maintenance, and 10,869.5€ yearly cost for a part-time skills lab coordinator. The total implementation cost was estimated at 31,483.53€ per year (table 2).

Operational cost

Total time spent updating the modules took 16 hours a year (salary team members 71.45€ per hour), translating in 1,143.2€ operational costs per year.

General cost

Yearly, 11 surgical trainees are trained at Ghent University Hospital, translating into a yearly PROSPECT curricular cost of 3,805.86€ per trainee, including training time, curriculum development, implementation and operational costs.

Discussion

Over the past decade education based on structured, stepwise and competency-based surgical training curricula has gained popularity, supported by growing evidence of clinical effectiveness and the increasing emphasis on patient safety.[197, 201] In order to receive financial support for development and implementation of these educational programs, an economic analysis is required to weigh the educational costs and health care system benefits of such a curriculum.

This analysis has provided an overview of all curricular costs associated with the PROSPECT program, including 6,588.50€ for development, 31,483.53€ for implementation and 1,143.20€ operational costs per year. In the literature, curricular design costs differ significantly dependent on the educational tools used, ranging between 2,402.08€ for Mashaud et al.'s knot tying curriculum[198] to 151,040.40€ for Webb et al.'s general surgery curriculum.[199]

Endovascular training requires high-tech materials and resources within an expensive training environment and may be more expensive than basic surgical training programs. For example, the basic surgical skills training of Jiang DJ et al, costs between 19.23€ and 30.00€ per trainee.[202] Other more specialised courses such as a cardiology residency program and an introduction to clinical medicine course are more expensive, costing respectively 65,081.42€ per fellow[203] and 1,479.62€ per student.[204] It must be noted that these training programs do not include VR simulation-based training, which is an expensive tool in surgical education. In 2007 Berry et al. estimated that an endovascular training course with VR simulation costs 3,022.62€ per trainee. This cost calculation is similar but slightly lower to ours possibly because teacher's salaries were not included in the study of Berry et al.[63]

The cost per trainee can be reduced by including a larger number of trainees in the program, since costs hardly increase if more participants are added by spreading administrative costs.[205] Therefore the curriculum may be more cost-effective if more trainees participate. Yearly 32 trainees begin surgical training in Flanders, Belgium. If all 32 novice trainees would participate in the program instead of 11 trainees, the yearly cost would drop from 3,805.86€ to 1,466.32€ per trainee. Costs could also be diminished by sharing the same VR simulator with other departments using endovascular techniques (neurosurgery, vascular surgery, interventional radiology, and interventional cardiology).

Who will pay for surgical training?

Implementing an endovascular training curriculum requires resources and a considerable initial investment. Although this investment will pay off, the initial cost must be disbursed. Since this simulation-based curriculum (PROSPECT) has been shown to be effective in improving OR performances of surgical trainees[196], the implementation should be mandatory into every surgical training program, and be funded by the government. Instead of financing random educational courses without showing return on investment, government resources could be spent more efficiently. Improving surgical performance and reducing errors while training on real patients should be an investment highly prioritised by society.

Additional support by other stakeholders, for example industry support, may also be considered but one should be aware that these industries may have an underlying agenda promoting specific products and procedures. This bias should be recognised, declared and appropriately managed.

Limitations

There are several limitations to this study. The cost savings related to complications, operating room time and materials couldn't be accurately defined, since an endovascular consultant supervised all endovascular interventions and intervened in endangering situations. Furthermore, the costs represented are averages inherent to our hospital. The results of this study at Ghent University Hospital cannot be expanded to surgical training in other countries subjected to other healthcare system organisation.

Conclusion

Although the costs associated with VR surgical training are quite significant, the results of this economic analysis suggest that endovascular training by the PROSPECT program is feasible, suppressing any financial concerns as a barrier to implement this stepwise, structured, proficiency and simulation-based training program into daily surgical training programs. The provision of more effective surgical training may not only increase patient safety but may also reduce the financial burden on our healthcare system by increasing operative efficiency.

7

Discussion and future perspectives

Discussion

Surgical evolution towards minimally invasive procedures poses challenges to training of future surgeons since these advanced technologies are more complex to master. It has been shown that adverse healthcare events mostly occur as a result of medical errors.[8, 206-208] These errors can take place due to a defect in the chain of the health care system. Common examples are anaphylactic shock in consequence of failure to communicate patient allergy and operation performed on the wrong limb. Making mistakes is part of any learning process; however surgical errors may have important, even lethal, consequences. To prevent errors and improve patient safety the WHO developed a Surgical Safety Checklist (SSC) to stimulate an effective functioning of the healthcare chain, resulting in reduced morbidity and mortality.[209] However, individual technical ability, knowledge and human factor skills also play an important role in the prevalence of medical errors.[210] Taking into account this growing concern for patient safety, reduction in training time and pressure to limit operating room costs, additional educational tools are increasingly studied to develop surgical curricula outside of the operating room to complement the traditional clinical training programs. Standardised training of these key skills in a proficiency-based curriculum may shorten the learning curve in the operating room, resulting in safer and high quality surgical care for patients.[7, 14]

Although previous research has shown that endovascular skills acquired during a single session of simulation training to treat femoral artery disease translates to the operating room[57, 175], this small study did not implement the simulation-based training within a stepwise proficiency-based endovascular curriculum using evidence-based learning objectives.[176]

Furthermore, the biggest barrier to routinely integrate simulation-based training into endovascular education was the lack of an approved curriculum.[20] This thesis has developed and critically appraised a Proficiency-based StePwise Endovascular Curricular Training (PROSPECT) program consisting of e-learning modules and simulation-based hands-on training sessions allowing skills acquisition in a stepwise manner until endovascular proficiency-levels are achieved.

The characteristics of an effective endovascular training curriculum were determined in **Chapter 1**. A surgical curriculum should be based upon specific learning goals[49] using a stepwise approach[52] with standardised and objective assessment methods and structured formative expert feedback, allowing gradual training until proficiency is achieved.[43] Several types of training tools have been developed to improve endovascular skill acquisition. High fidelity Virtual Reality (VR) simulation has shown to be an appropriate training tool for hands-on practice of endovascular procedures.[37] This type of simulator allows repetitive training of complex technical skills in a standardised life-like environment[32] resulting in highly effective skills transferability to real-life interventions.[32, 36, 37, 43, 49, 52]

The review described in **Chapter 2** was performed to critically evaluate the effectiveness of e-learning as a teaching tool for surgical skills. Eighty-seven Randomized Controlled Trials involving 7871 participants were included. This systematic review provides an overview of the impact of e-learning teaching tools on skills acquisition and retention, and attempts to elucidate features that are associated with improved outcomes. In general, there is strong evidence to suggest that e-learning is at least as effective as other training tools for teaching a broad range of surgical competencies. Nonetheless, the evidence is limited to short-term skill acquisition, with few studies demonstrating long-term retention or skill transfer to the clinical environment. Despite significant heterogeneity amongst platforms, the importance of designing e-learning curricula using a theory-driven approach and adhering to principles of educational psychology cannot be overstated. These include providing focused, immediate and formative feedback, learning in context and through high-level interaction and engagement, and providing opportunities for distributed and spaced education. Curricular content can be disseminated using Internet and computer-based platforms to optimise learning and ultimately contribute to better patient outcomes.

Based upon current evidence on creating efficacious surgical curricula[149], a structured endovascular training program was designed, integrating multimedia-based learning modules and high fidelity VR simulation training sessions in a stepwise manner. **Chapter 3** has sought to determine the learning goals that should be thought in this endovascular curriculum. Using a modified Delphi approach the key cognitive, technical and human factor skills necessary to fruitfully perform endovascular procedures have been successfully identified.

The top 5 most important Fundamental Endovascular Skills (FES) for knowledge are ‘Knowledge of the vascular anatomy’, ‘Benefits and limitations of endovascular procedures’, ‘Knowledge of indications for open and endovascular treatments’, ‘Risk associated with various procedural phases’ and ‘Interpretation of the imaging findings (normal and pathological)’.

The top 3 FES in terms of technical performance are ‘Select an appropriate access site and approach (i.e. retrograde, antegrade)’, ‘Insert selected guide wire correctly to appropriate level with proper care for obstruction, side branches and vessel trauma’ and ‘Evaluate the lesion and run-off (if unknown) prior to treat lesion’.

The top 3 FES for attitude are 'Know own limitations and call for help from his/her supervisor', 'Check patient records (blood results, medication…) prior to start the procedure', 'Check informed consent that has been obtained prior to start the procedure in the angiosuite'. Both European and American experts agreed that interventional radiology, interventional cardiology and vascular surgical trainees should acquire these FES prior to perform endovascular interventions in real patients.

Subsequently, a PROficiency-based StePwise Endovascular Curricular Training (PROSPECT) program including the key cognitive, technical and non-technical FES was designed and its construct validity was judicially evaluated in **Chapter 4**. Four endovascular training modules with adequate assessment methods were developed. Each module consists of both e-learning and simulation training, with increasing difficulty. Assessments were carried out using MCQ tests, automatically recorded simulation metrics and Objective Structured Assessment of Technical Skills (OSATS) derived rating scales.[57] Validity of the modules was confirmed by 49 participants (29 last-year medical students, 20 vascular surgeons) and proficiency-levels were determined based upon the mean expert scores. These are the scores that have to be achieved before advancing to the next module. The program was shown feasible to be carried out during clinical practice.

The focus of **Chapter 5** was to evaluate if successfully completing the PROSPECT program could indeed improve operative performance in the hybrid angiosuite. A Randomised Controlled Trial was carried out, in which 58 endovascular interventions were performed by 29 surgical trainees. The results from this study showed that trainees who completed PROSPECT performed superior during endovascular interventions in the angiosuite compared to trainees who only had access to e-learning or trainees who received no additional education. Trainees who completed PROSPECT showed superior performances under supervision during real life endovascular procedures, assessed by life ratings using OSATS derived ratings scales, compared to the other 2 groups. Cognitive skills were effectively taught by both training using the PROSPECT program and solely e-learning, however, achievement of technical proficiency levels required completion of simulation-based training.

Kirkpatrick's model for evaluating training programs provides 4 levels of evidence: self-reported opinions (level 1), assessment of the learning process (level 2), transfer of acquired competencies into clinical environment (level 3) and effect on patient outcomes (level 4). The most important limitation of this study is that the fourth Kirkpatrick-level was not shown. [178] Each trainee included in the RCT was closely supervised by a consultant due to ethical concerns. The supervisors were instructed to immediately take over if patient safety was endangered showing significantly more supervisor takeovers in the e-learning and control group in comparison with the group that received the full PROSPECT education program. Hence, more complications could have occurred in the control and e-learning groups and therefore, no definite conclusions about the incidence of complication rates and patient outcomes can be drawn based on this research.

Five different consultants supervised and assessed the life performances and it cannot be excluded that trainees unintentionally revealed their randomisation status, compromising blind assessment. To avoid bias, all cases were videotaped and one blinded independent rater evaluated all video's post-hoc, showing good inter-rater reliability with the life ratings.

Previous chapters have established the benefits of PROSPECT for endovascular training, patient safety and quality of surgical care. However, the question remains if these benefits outweigh the costs associated with this training model. In **Chapter 6** an economic evaluation has been performed, resuming the costs associated with development, implementation and maintenance of the PROSPECT program. Per trainee at Ghent University Hospital, it costs 3,805.86€ to achieve endovascular proficiency levels by completing the PROSPECT program.

It seems that improving surgical performance by implementing stepwise, proficiency-based simulation training programs is an investment, not an expense. Nevertheless, implementation of PROSPECT requires resources and a significant initial disbursement. There are several actions that can be undertaken to limit the initial costs of investment. First, a curriculum is more cost-effective if more trainees participate since incremental costs hardly change if more participants are recruited. If all 32 novice surgical trainees would be included in the program instead of 11 trainees working solely at Ghent University, this would reduce the yearly cost from 3,805.86€ to 1,466.32€ per trainee.

Furthermore, a single endovascular simulator can be used by various departments performing endovascular procedures i.e. interventional radiology, interventional cardiology and vascular surgery, cutting the costs associated with the purchase or rent of a medical simulator. These specialties can use the simulator not only to deliver basic training but also to organise advanced courses to learn how to use new devices, practice new techniques or complex interventions, set up pre-procedure rehearsal of patient-specific cases or organise in-situ training, using the same simulator. [211] If these proficiency-based training curricula would become mandatory and are integrated into surgical education, simulation training may be funded by the government.

Endovascular training according to a proficiency-based curriculum including simulation training and multimedia-based learning has shown to be more effective than endovascular training as we know it today, resulting in significantly superior performances in the OR. These findings have important consequences for training of future generations of surgeons. Every trainee should have the opportunity or must achieve proficiency levels in cognitive and technical endovascular skills prior to be involved in the treatment of real patients by implementing this curriculum into surgical education.

According to the Dreyfus model of skills acquisition there are five phases in the learning process: novice, advanced beginner, competent, proficient and expert.[212] The curriculum can train novices until proficiency levels are achieved (level 4 of the Dreyfus model), yet further real-life endovascular experience in the angiosuite will always be needed to obtain expert skills.

Indeed, simulation-training will not replace clinical practice but should be regarded as an adjunct to traditional training programs. Furthermore, by providing formative feedback, this educational tool may also stimulate deliberate practice.[37] Training according to PROSPECT should be applied predominantly in the early phase of the learning process, where after the achieved skills can be fully mastered and maintained by performing real-life interventions during clinical practice.

Implementation of this program into the daily clinical activities of surgical trainees and supervising surgeons will be challenging. The main issue is the need for a supervising consultant who provides structured expert feedback after each simulation session to organise and set-up proficiency-based training. Hence, surgeons should be granted dedicated time to train surgical trainees in order not to struggle with clinical duties. It has been suggested to train a simulation technician or nurse specialist to supervise the simulation sessions and provide standardised structured feedback. Overall, surgical trainees experience difficulties accepting feedback, since they assume this to be a test reflecting badly on their performance. Therefore, it is of great importance that educators learn how to provide constructive formative feedback and trainees should be open minded towards positive and negative comments. This problem has been identified at Ghent University Hospital and is managed by offering 'Train the trainer' programs, allowing surgeons who are willing to train young doctors to be trained themselves to become competent teachers.

Both providing dedicated teaching time for supervisors and obtaining protected training time for surgical trainees will be challenging. An easy accessible simulator location close to the workplace may help to implement this competency-based training, since unplanned training opportunities may arise between cases during operating lists.[197] During this study, the Angiomentor used in PROSPECT was located in the hospital nearby the OR. However, bringing the simulation close to clinical practice is not enough. The aim of surgical training is to deliver a competent surgeon within an acceptable time period. An efficient training program using a shorter training period allows surgeons to start contributing to the healthcare system and paying taxes at a younger age, resulting in a more cost-effective investment for society. The value of effective surgical education is not to be underestimated, both from clinical and financial perspectives, leading to critical appraisal of current surgical training worldwide. In order to improve surgical education, clinical practice in the OR and service on the ward should be thoroughly revised. Administrative support would ameliorate training since trainees are spending too much time on the computer instead of consulting, examining and operating on patients. Additionally, if proficiency levels were previously achieved by PROSPECT, trainees may be permitted to perform more substantial parts of endovascular interventions, leading to highly efficient training even in the operating room.

In the current surgical educational system in Belgium, trainees are paid because they are providing clinical service, not because they are in training. This concept is called the 'training versus service conflict' and seems to be the most challenging problem to train doctors in surgical disciplines. If the trainee would not perform these services because the focus shifts from clinical service to clinical training, additional personnel would be needed.[213] Although more efficient surgical education using stepwise curricula and optimised clinical practice is the way forward, the lack of financial support seems challenging in many countries. On the other hand, in other countries such as Ireland, Canada and Australia and the Netherlands, payment of trainees does no longer depend on the services they deliver and training has become highest priority, since they have found that shorter training periods are more cost-effective for society.

In Belgium the trainee contract can be considered hybrid for both training and service, since each workweek allows 4 hours of dedicated training time in the context of a Master degree in Surgery *'Master na Master in de Specialistische Geneeskunde - Afstudeerrichting Heelkunde'*. PROSPECT training might be implemented in this Masters' program, providing protected educational time during clinical service. Implementation of PROSPECT in surgical training might allow supervisors and program directors to ensure that all surgical trainees completed an endovascular training program achieving cognitive and technical endovascular proficiency prior to patient exposure.

Future prospects

The studies depicted in this thesis indicate that a Proficiency-based StePwise Endovascular Curricular Training (PROSPECT) program is a powerful, more effective tool for educating cognitive and technical endovascular skills compared to solely traditional clinical training. The current PROSPECT program addresses endovascular treatment of symptomatic iliac and femoral artery stenosis. There is room for expansion of the program by including additional modules addressing more complex endovascular interventions such as endovascular exclusion of aortic aneurysms, treatment of carotid artery stenosis and management of arterial lesions below the knee. Additionally, e-learning modules on radiation protection should be included, since X-ray radiation is a menace inherent to endovascular imaging techniques, associated with high risks for the surgeon, patient and entire endovascular team.[122, 124] Also training of open vascular procedures and crisis scenarios such as ruptured aortic aneurysm repair will have to be learned, practiced and maintained using modern training programs since the prevalence is decreasing and clinical training opportunities have become scarce.[214, 215]

Furthermore, non-technical skills' training has only been discussed briefly in PROSPECT using multimedia-based learning tools; nevertheless, failure in team interactions leads to a high rate of errors occurring during endovascular procedures. Training and assessment of these skills should be adequately taught by integrating multidisciplinary team training during endovascular procedures using fully immersive simulated hybrid angiosuites.[37]

Surgical training is responsive to national health care needs, forcing a global trend towards standardisation of curricula and competency-based training.[163] The Fundamentals of Laparoscopic Surgery (FLS) and Fundamentals of Endoscopic Surgery (FES) curricula have transformed the way surgeons acquire laparoscopic and endoscopic skills.[143, 144] Similarly, competency-based training programs to learn robotic skills are in progress, Fundamentals of Robotic Surgery.[216] PROSPECT is the first proficiency-based endovascular training curriculum worldwide. The research in this thesis confirms clinical effectiveness and financial feasibility of the PROSPECT program within the Belgian healthcare and surgical educational system. If future research would be able to show that the results of the PROSPECT program are transferable nationally and internationally in training endovascular skills, then official instances such as vascular societies or UEMS may be forced to organise these types of training curricula.

The workload in clinical surgical training is highly variable and may not provide the necessary opportunities to practice endovascular skills in order to maintain these. In our study adequate skills retention up to 3 months after completion of the curriculum has been demonstrated, however if trainees are not exposed to endovascular interventions, acquired skills may deteriorate and trainees may benefit from refresher training to optimally retain proficiency. For the FLS, a decrement in performance was detected after 6.5 months, but a minimal additional structured practice reinforced skill acquisition and minimised skill loss at 12.5 months.[217] Biannual refreshment courses consisting of two timed tasks can successfully maintain proficiency levels of laparoscopic skills.[182] Further studies should be undertaken to determine the frequency and content of continuous endovascular renewal courses required to maintain the acquired cognitive and technical endovascular skills.

To optimise surgical training programs, ideally only the most qualified medical students should be allowed to commence surgical education. The current surgical selection process, mainly assessing knowledge and personality shows poor predictive value[218, 219], failing to stratify candidates according to surgical qualities and future clinical performance.[220] Worldwide, there is an ongoing search for objective and predictive criteria to optimise surgical selection. Design of a prognostic selection method is important to identify surgical candidates with necessary qualities to become proficient surgeons, to eliminate future dropouts and reduce the number of underperforming residents causing organisational problems at a time where surgical education is already challenged. Future research should explore additional criteria including an evaluation of aptitude and innate technical skills in surgical selection and their predictive value towards future clinical performances.[221]

Research into surgical education has raised questions about surgical training, as we know it today. It is not acceptable to continue practicing complex procedures solely on patients if highly effective complementary surgical curricula outside of the operating room are available. Similar to other high-risk professions such as pilots, firefighters and astronauts, structured training until proficiency should become mandatory. Every surgical trainee should be certified before being allowed to continue clinical training on patients, providing proof that endovascular proficiency levels of cognitive and technical performance have been achieved to perform endovascular procedures. Furthermore, surgeons' competence and professionalism should be maintained to ensure continuous high quality surgical care. Certification and recertification of practicing endovascular interventionalists may be necessary to ensure skills' maintenance[180] with medico-legal consequences for physicians performing endovascular interventions on patients without prior endovascular certification, especially if adverse outcomes and complications did occur. In the light of current evidence, we should take our responsibility as physicians to protect patients from unnecessary and avoidable harm by setting clear values and conditions for surgical endovascular training.

8

Summary in English and Dutch

Summary

Many cardiovascular diseases can successfully be treated by minimally invasive endovascular procedures. Most require a specific set of technical skills. Training physicians to perform these interventions is challenging and has driven surgical education towards training tools outside the operating room. Focus on patient safety, decreased training times and growing attention to operating room costs are also drivers to optimise surgical training.

The main objective of this thesis was to design and implement an educational program for endovascular skills training to treat symptomatic atherosclerotic iliac and femoral artery disease. Secondly, we aimed to provide evidence that the acquired endovascular skills by this curriculum transfer to real-life interventions. Finally, we analysed if the benefits of this endovascular curriculum outweigh the costs.

The 21stcentury has brought an evolution of advanced computing, multimedia and Internet-based technologies that have huge potentials to modernise surgical education, make it more flexible to provide trainees, surgeons and other healthcare professionals the means to develop aptitudes that are fundamental to surgical competency and essential to ensure the safety of surgical patients. A systematic review of literature showed that multimedia-based learning has a place in surgical education if used within a curriculum with hands-on training opportunities and formative feedback.

A transatlantic Delphi questionnaire defined the learning objectives of an endovascular training program including cognitive, technical and non-technical endovascular skills. Based upon these learning goals, a PROficiency-based StePwise Endovascular Curricular Training (PROSPECT) was designed, consisting of four stepwise modules.

The first module starts with basic endovascular skills training, explaining the tools, imaging techniques and fundamental principles of endovascular procedures. The second and third modules focus on treatment of iliac artery and superficial femoral artery disease respectively, while the fourth module concentrates on postoperative complication management and attitude skills. These modules allow trainees to learn endovascular procedures at their own pace in a structured stepwise fashion and in a learner-centered environment away from clinical activities. Each module consists of an online e-learning part to acquire cognitive and non-technical skills and supervised hands-on simulation sessions to learn and practice technical endovascular skills. Knowledge is tested using multiple-choice questionnaires. Technical performance during simulation sessions is assessed using validated simulator metrics and rating scales. Every trainee is required to achieve cognitive (once) and technical competency (two separate occasions) at each step before advancing to the next module. Structured formative feedback is provided after each attempt.

The PROSPECT program is a valid educational program, leading to superior technical performances during real life endovascular procedures, assessed by the supervising consultant using OSATS derived ratings scales, compared with trainees who only had access to e-learning or in comparison to trainees who received no additional education besides their conventional training. Trainees who had solely access to e-learning and those with access to the entire PROSPECT program acquired the appropriate cognitive skills, but only trainees who completed PROSPECT achieved technical endovascular proficiency.

The implementation of PROSPECT into surgical training programs does not only improve the trainees' technical performance during endovascular interventions, it financially benefits society by reducing surgical costs for the health care system. Per trainee at Ghent

University Hospital, simulation-based training until proficiency requires a total amount of 3,805.86€.

In conclusion, endovascular training according to a proficiency-based curriculum including simulation training and multimedia-based learning has shown to be more effective than traditional clinical education only, resulting in significantly superior performances in the operating room. Given these advantages and favorable economic evaluation, surgical trainees should have the opportunity to complete the PROSPECT program and achieve endovascular proficiency prior to rotate at a vascular unit and perform endovascular procedures in real life.

Samenvatting

De meeste cardiovasculaire aandoeningen kunnen behandeld worden door middel van minimaal invasieve endovasculaire ingrepen. Het uitvoeren van dergelijke interventies vergt specifieke chirurgische vaardigheden. De uitdaging is om artsen op te leiden om deze ingrepen uit te voeren door bijkomende educatieve programma's te ontwikkelen buiten het operatiekwartier en op die manier de chirurgische opleiding te verbeteren. Daarnaast stimuleren ook groeiende bezorgdheden omtrent patiënt veiligheid, verminderde werkuren en de aandacht voor de kosten in het operatiekwartier deze evolutie in chirurgische training.

Het eerste doel van dit doctoraal proefschrift is het ontwikkelen en implementeren van een chirurgische opleiding of curriculum voor het trainen van endovasculaire vaardigheden ter behandeling van atherosclerotische aandoeningen van de bekken- en bovenbeenslagaders. Een tweede onderdeel van dit onderzoek tracht aan te tonen dat deze verworven chirurgische vaardigheden na voltooiing van de opleiding worden overgedragen naar de reële ingrepen in het operatiekwartier. En, tot slot, wordt ook een economische analyse uitgevoerd om na te gaan of de voordelen van deze endovasculaire opleiding opwegen tegen de financiële investering.

De 21ste eeuw brengt een evolutie van vooruitstrevende multimedia en internet technologieën met een groot potentieel voor de chirurgische opleidingen. Deze technologieën voorzien de nodige middelen aan assistenten, chirurgen en andere gezondheidsmedewerkers om de fundamentele vaardigheden te ontwikkelen voor chirurgische competentie en patiënt veiligheid. Een systematische review van de literatuur toonde aan dat e-learning een plaats heeft in de chirurgische educatie indien deze wordt gebruikt in een gestructureerd curriculum met praktische simulatie training' mogelijkheden en constructieve feedback sessies.

Door middel van een internationale enquête werden de leerdoelen gedefinieerd betreffende cognitieve, technische en niet-technische endovasculaire vaardigheden die zouden moeten behaald worden in een endovasculaire opleiding. Gebaseerd op deze leerdoelen werd het PROSPECT (PROficiency-based StePwise Endovascular Curricular Training) curriculum ontwikkeld, bestaande uit 4 modules. De eerste module start met training van fundamentele endovasculaire vaardigheden, waarbij de materialen, beeldvormingtechnieken en basisprincipes van endovasculaire interventies worden belicht. De tweede en derde module focussen op endovasculaire behandeling van vernauwde bekken- en bovenbeenslagaders. De vierde en laatste module leert het management van peri- en postoperatieve complicaties aan. Deze modules laten toe om de arts stapsgewijs en gestructureerd endovasculaire procedures aan te leren op eigen tempo, buiten de klinische activiteit. Elke module combineert een deel e-learning om cognitieve en niet-technische vaardigheden aan te leren, en gesuperviseerde praktische simulatie sessies om technische endovasculaire vaardigheden te oefenen. De kennis wordt getest door middel van MCQ tests (Multiple Choice Questions). De technische prestaties worden beoordeeld aan de hand van simulatie parameters en gevalideerde scorelijsten. Na elke oefensessie wordt een gestructureerde feedback gegeven. Bij elke stap moet een voldoende cognitieve en technische competentie bereikt worden voordat de arts mag overgaan naar de volgende module.

Er wordt aangetoond dat PROSPECT een haalbaar en valide opleidingsprogramma is dat leidt tot significant betere technische prestaties tijdens endovasculaire procedures, beoordeeld door middel van gevalideerde scorelijsten, in vergelijking met artsen die enkel toegang hadden tot e-learning of artsen die geen enkele bijkomende opleiding ontvingen naast hun klinische educatie. Zowel artsen die opgeleid werden volgens PROSPECT als artsen die enkel e-learning modules studeerden verworven de nodige cognitieve vaardigheden, echter, enkel artsen die het PROSPECT programma doorliepen bereikten competente technisch endovasculaire vaardigheden.

Een haalbare financiële investering maakt implementatie van PROSPECT in de chirurgische opleiding mogelijk ter verbetering van de chirurgische vaardigheden van de artsen tijdens endovasculaire interventies. Een bedrag van 3,805.86 euro is nodig per chirurg in opleiding in het UZ Gent die opgeleid wordt volgens deze stapsgewijze gestructureerde opleiding met e-learning en simulatie training.

In conclusie, deze endovasculaire opleiding met simulatie training en e-learning is efficiënter dan enkel de traditionele klinische opleiding en leidt tot significant betere chirurgische prestaties in het operatiekwartier. Gezien deze voordelen en de gunstige kosten analyse, dient ervoor geopteerd te worden om het PROSPECT programma te integreren in de opleiding heelkunde om de chirurgen in opleiding de kans te geven endovasculaire bekwaamheid te verwerven vooraleer endovasculaire ingrepen uit te voeren op patiënten.

9

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10

Appendices

APPENDIX I: Medline search strategy

1 Local Area Networks/

2 Computer-Assisted Instruction/

3 Computer Communication Networks/

4 Internet/

5 exp Video Recording/

6 Education, Distance/

7 ((computer* or electronic or online or on-line or web or virtual or internet or intranet or extranet or technolog* or software* or multimedia or multi-media or mobile or simulated or simulation* or video* or game* or gaming or distan* or correspond*) adj3 (train* or educat* or learn* or teach* or instruct* or curricul* or platform* or plat-form* or class* or course* or tutor*)).tw,kf.

8 (e-learn* or elearn* or e-educat* or e-instruct* or etrain* or e-train*).tw,kf.

9 (teleducat* or teleeducat* or telinstruct* or telelearn* or teletrain* or (tele adj2 (educat* or instruct* or learn* or train*))).tw,kf.

10 or/1-8

11 exp Specialties, Surgical/

12 exp Surgical Procedures, Operative/

13 exp Perioperative Care/

14 Surgical Equipment/

15 su.fs.

16 Bariatric Medicine/

17 or/11-15

18 ed.fs.

19 exp Education, Medical/

20 exp Education, Continuing/

21 exp Educational Measurement/

22 exp Curriculum/

23 or/18-22

24 17 and 23

25 ((surge* or surgic* or operativ* or operation* or neurosurg* or ophthalmolog* or trauma* or urolog* or gynecolog* or bariatr* or orthoped* or orthopaed* or transplant*) adj3 (skill* or train* or educat* or learn* or teach* or instruct* or curricul* or knowledge or competenc*)).tw,kf.

26 24 or 25

27 10 and 26

28 (randomized controlled trial or controlled clinical trial).pt. or random*.ab. or placebo.ab. or drug therapy.fs. ortrial.ab. orgroup.ab. orgroups.ab.

29 27 and 28

30 remove duplicates from 29

APPENDIX II: Summary of all included studies.

Study	No. Subjects	Control Group	E-Learning Tool Feature	Surgical Skill
Jamshidi et al. (2009)	15	*ϕ*	*MLT*	*PM*
Donnely et al. (2009)	89	*SIM*	*MLT, INT, VP*	*CO*
Kong et al. (2009)	90	*LEC, SGS*	*MLT, INT, VR, VP*	*CO*
Yeung et al. (2009)	80	*TX*	*MLT*	*PM*
Kulier et al. (2009)	61	*LEC*	*MLT, INT, ASS, FBK*	*CO*
Kerfoot et al. (2009)	206	*SUP*	*MLT, INT, SE, ASS, FBK*	*CO*
Kerfoot et al. (2009)	480	*SUP*	*MLT, INT, SE, ASS, FBK*	*CO*
Kandasamy et al. (2008)	55	*TX*	*MLT, INT, VP*	*CO*
Glicksman et al. (2009)	47	*TX*	*MLT*	*CO, PM*
Hull et al. (2009)	28	*CLN*	*MLT, INT*	*CO, PM, NT*
Nunnink et al. (2008)	51	*SIM*	*MLT, VP*	*CO, NT*
Kerfoot et al (2009)	115	*ϕ*	*MLT, INT, SE, ASS, FBK*	*CO*
Hisley et al (2007)	16	*SIM*	*MLT, INT, VP*	*CO*
Youngblood et al (2008)	30	*SIM*	*MLT, INT, VR, VP, GM, ASS, FBK*	*CO*
Chenkin et al (2008)	21	*LEC*	*MLT, INT, ASS, FBK*	*CO, PM*
Perfeito et al. (2007)	35	*LEC*	*MLT, INT*	*CO, PM*
Bott et al. (2008)	53	*ϕ*	*MLT, INT, VR, VP, ASS, FBK*	*CO*
Kerfoot et al. (2008)	237	*SUP*	*MLT, INT, SE, ASS, FBK*	*CO*
Bingener et al. (2008)	30	*ϕ*	*MLT*	*PM*
Xiao et al. (2007)	50	*TX*	*MLT*	*CO*
Xeroulis et al. (2006)	60	*ϕ,SIM*	*MLT, INT*	*PM*
Vash et al. (2006)	48	*ϕ*	*MLT, INT, VR, VP, ASS, FBK*	*CO*
Kerfoot et al. (2007)	156	*ϕ*	*MLT, INT, SE, ASS, FBK*	*CO*
Brandt et al. (2005)	60	*LEC*	*MLT*	*PM*
Nicholson et al. (2006)	61	*ϕ*	*MLT, INT, VP*	*CO*

Friedl et al. (2005)	126	*TX*	*MLT, INT*	*CO, PM*
Kerfoot et al. (2006)	351	*SUP*	*MLT, INT, VP, ASS, FBK*	*CO*
Takiguchi et al. (2004)	36	*ϕ,SIM*	*MLT*	*PM*
Prinz et al. (2005)	172	*VID*	*MLT, VP*	*CO, PM*
Macrae et al. (2004)	81	*TX*	*MLT, INT, FBK, CDG*	*CO*
Gold et al. (2004)	192	*TX*	*MLT, INT*	*CO, PM*
Seabra et al. (2003)	60	*LEC*	*MLT, INT*	*CO*
Carr et al. (2002)	70	*ϕ*	*MLT, INT, ASS, FBK*	*CO*
Carr et al. (1999)	58	*ϕ,SGS*	*MLT, INT, ASS, FBK*	*CO, PM*
Summers et al. (1999)	69	*LEC, VID*	*MLT, INT*	*PM*
Rogers et al. (1998)	82	*SGS*	*MLT*	*PM*
Devitt et al. (1997)	84	*ϕ*	*MLT, INT, VP, ASS, FBK*	*CO*
Elves et al. (1997)	26	*ϕ*	*MLT, INT, ASS, FBK*	*CO*
Stanford et al. (1993)	175	*ϕ,SIM*	*MLT, INT*	*CO*
Erkonen et al. (1992)	180	*ϕ,SIM*	*MLT, INT*	*CO*
Rayl et al. (1988)	65	*ϕ*	*MLT*	*CO*
Obdeijn et al. (2014)	28	*LEC*	*MLT, INT*	*PM*
Van Hove et al. (2014)	40	*ϕ*	*MLT, INT, VR, ASS, FBK*	*CO*
Nilsson et al. (2014)	25	*SIM*	*MLT*	*CO, PM*
Pape-Kohler et al.(2013)	101	*TX*	*MLT*	*CO, PM*
Succar et al. (2013)	188	*ϕ*	*MLT, INT, VR, VP, ASS, FBK*	*CO, NT*
Hearty et al. (2013)	28	*ϕ*	*MLT, INT, ASS, FBK*	*CO, PM*
De Sena et al. (2013)	50	*TX*	*MLT, INT*	*PM*
Flores et al. (2013)	32	*TX*	*MLT, INT*	*PM*
Pape-Koehler et al. (2013)	70	*ϕ,SIM*	*MLT, INT*	*CO, PM*
Mehrpour et al. (2012)	474	*ϕ*	*MLT, INT*	*PM*
Benharash et al. (2012)	37	*ϕ*	*MLT*	*CO*
Hards et al. (2012)	141	*SIM*	*MLT*	*CO*

Thompson et al. (2012)	35	*ϕ*	*MLT*	*CO*
Subramanian et al. (2012)	41	*ϕ*	*MLT*	*CO*
Durmaz et al. (2012)	48	*ϕ TX*	*MLT*	*NT*
Satterwhite et al. (2012)	93	*TX, SIM*	*MLT*	*PM*
Steedsman et al. (2012)	61	*TX*	*MLT, INT, VR, VP, ASS, FBK*	*CO*
Mata et al. (2012)	24	*LEC*	*MLT, INT, VP*	*CO*
Shippey et al. (2011)	20	*LEC*	?	*CO, NT*
Platz et al. (2011)	347	*ϕ*	*ASS, FBK*	*CO*
Bhatti et al. (2011)	33	*LEC*	*MLT, INT, VP*	*CO*
Ricciotti et al. (2010)	82	*SIM*	*MLT, INT*	*CO, NT*
McLeod et al. (2010)	17	*ϕ*	*MLT, INT*	*CO, PM*
Loveday et al. (2009)	25	*TX*	*MLT*	*CO*
Hu et al. (2010)	16	*LEC*	*MLT, INT*	*CO, PM*
Chao et al. (2010)	58	*ϕ,SGS*	*MLT*	*PM*
Patel et al. (2010)	44	*LEC*	*MLT*	*CO, PM*
Henderson et al. (2010)	148	*LEC*	*MLT, INT*	*CO*
Veredas et al. (2014)	23	*ϕ*	*MLT, INT, VP*	*CO, NT*
Aleman et al. (2011)	441	*SGS*	*SE, CDG*	*CO*
Corton et al. (2006)	53	*ϕ*	*MLT, INT, VR, ASS, FBK*	*CO, PM*
Platz et al. (2010)	100	*SUP*	*MLT, INT, VR*	*CO*
Davis et al. (2012)	67	*ϕ*	*MLT*	*CO, PM*
Shariff et al. (2014)	27	*SIM*	*MLT*	*CO, PM*
Khatib et al. (2014)	68	*TX*	*MLT, INT, VR, VP, ASS, FBK*	*CO, PM*
Boeker et al. (2013)	72	*LEC*	*MLT, INT, VP, ASS, FBK*	*CO*
Guerlain et al. (2004)	116	*LEC*	*MLT, INT, VP, ASS, FBK*	*CO*
Backstein et al. (2004)	39	*TX*	*MLT, INT*	*CO*
Curran et al. (2004)	48	*LEC*	*MLT*	*CO, PM*
Muffly et al. (2015)	128	*ϕ*	*MLT, INT*	*CO, PM*

Chung et al. (2013)	59	*LEC*	*MLT, INT*	*CO*
Collins et al. (2015)	59	*TX, SIM*	*MLT, INT, VR, VP, ASS, FBK*	*CO*
Ferguson et al. (2015)	145	*SGS*	*MLT, INT, VP, SE, GM, ASS, FBK*	*CO*
Kumar et al. (2007)	30	*VID*	*MLT, INT*	*CO*
Leopold et al. (2005)	29	ϕ*,SGS*	*MLT*	*PM*
Schneider et al. (2015)	60	*SIM*	*MLT*	*CO, NT*

ϕ: no intervention, SIM: simulation-based curriculum, SGS: small-group seminar with facilitator, LEC: didactic lecture, TX: textbook or article, VID: video, SUP: online supplement, CLN: clinical training, MLT: multimedia, INT: interactive, VP: virtual patients, VR: virtual reality, ASS: assessment, FBK: feedback, GM: gaming, SE: spaced education, CDG: community discussion groups, CO: cognitive skills, PM: psychomotor skills, NT: non-technical skills

APPENDIX III: Statements describing endovascular skills

Statement	Round 1 (N = 23)				Round 2 (N = 20)			
	Mean	**SD**	**Median**	**Consensus**	**Mean**	**SD**	**Median**	**Consensus**
KNOWLEDGE SKILLS								
Knowledge of the vascular anatomy	4,91	0,29	5	**100%**	4,75	0,91	5	**95%**
Benefits and limitations of endovascular procedures	4,74	0,45	5	**100%**	4,60	0,94	5	**95%**
Knowledge of indications for open and endovascular treatments	4,89	0,46	5	**96%**	4,60	0,94	5	**95%**
Risk associated with various procedural phases	4,70	0,47	5	**100%**	4,60	0,94	5	**95%**
Interpretation the imaging findings (normal and pathological)	4,87	0,34	5	**100%**	4,60	0,99	5	**90%**
Knowledge and choice of materials, devices and back-up tools	4,70	0,47	5	**100%**	4,55	0,99	5	**90%**
Content and use of the general endovascular tool kit	4,65	0,49	5	**100%**	4,50	0,96	5	**95%**
Risk associated with various anatomical zones during the procedure	4,52	0,59	5	**96%**	4,40	0,99	5	**90%**
Knowledge of optimal medical treatment of peripheral arterial disease	4,39	0,72	4	**96%**	4,25	0,97	4	**90%**
Principles of radiation safety and ALARA principles	4,48	0,59	5	**96%**	4,20	1,06	4,5	80%

TECHNICAL SKILLS								
Select an appropriate access site and approach (i.e. retrograde, antegrade)	4,52	0,59	5	**100%**	4,90	0,31	5	**100%**
Insert selected guide wire correctly to appropriate level with proper care for obstruction, side branches and vessel trauma	4,70	0,47	5	**100%**	4,85	0,37	5	**100%**
Evaluate the lesion and run-off (if unknown) prior to treat lesion	4,79	0,42	5	**100%**	4,85	0,37	5	**100%**
Insert stent if appropriate (type, length and size) across lesion, keeping wire steady	4,74	0,45	5	**100%**	4,70	0,47	5	**100%**
Feed the working catheter over the guide wire to the appropriate level i.e. catheter does not pass beyond the tip of the guide wire	4,48	0,74	5	**96%**	4,70	0,47	5	**100%**
Perform post dilation if appropriate	4,48	0,59	5	**96%**	4,70	0,47	5	**100%**
Remove the balloon over guide wire, leaving wire in place	4,74	0,45	5	**100%**	4,70	0,47	5	**100%**
Check intraluminal position of the catheter after crossing lesion with contrast	4,57	0,66	5	**91%**	4,70	0,47	5	**100%**
Withdraw working catheter, leaving the guide wire in place	4,52	0,66	5	**91%**	4,70	0,47	5	**100%**
Manipulate working catheter to position distal (antegrade puncture) or proximal (retrograde puncture) of the lesion	4,39	0,78	5	83%	4,65	0,49	5	**100%**
Choose appropriate balloon (type, length and size) for angioplasty	4,65	0,49	5	**100%**	4,65	0,59	5	**95%**
Insert balloon catheter across lesion while keeping guide wire steady	4,70	0,48	5	**100%**	4,65	0,59	5	**95%**
Remove stent delivery device over guide wire, leaving guide wire in place	4,57	0,51	5	**100%**	4,65	0,59	5	**95%**
Check run-off after angioplasty and/or stenting	4,78	0,42	5	**100%**	4,65	0,59	5	**95%**

Choose and prepare appropriate supportive (working) catheter	4,48	0,59	5	**96%**	4,65	0,59	5	**95%**
Choose and prepare an appropriate initial guide wire - type, diameter, length	4,61	0,58	5	**96%**	4,60	0,68	5	**90%**
Deploy stent according to IFU	4,39	0,72	5	87%	4,55	0,60	5	**95%**
Use fluoroscopy guidance during balloon angioplasty	4,48	0,59	5	**96%**	4,55	0,60	5	**95%**
Inflate balloon with the mechanical inflation device to appropriate pressure for appropriate duration	4,52	0,67	5	**91%**	4,50	0,69	5	**90%**
Decompress balloon fully before repositioning or removal	4,52	0,59	5	**96%**	4,45	0,51	4	**100%**
Use closure devices within IFU or perform manual compression	4,48	0,59	5	**96%**	4,45	0,69	5	**90%**
Navigate guide wire supported by working catheter using road map to cross the lesion	4,39	0,84	5	87%	4,35	0,59	4	**95%**
Administer the accurate dose of heparin	4,26	0,81	4	78%	4,25	0,72	4	85%
US guided puncture of the common femoral artery to obtain access	3,96	0,88	4	70%	4,15	0,50	4	**95%**
Perform angiogram in multiple projections to evaluate lesion after angioplasty	4,17	0,83	4	83%	4,10	0,55	4	**95%**
Perform an angiogram to check lesion after angioplasty in multiple projections	4,39	0,66	4	**91%**	4,10	0,64	4	85%

ATTITUDE SKILLS								
Know own limitations and call supervisor for help	4,87	0,34	5	**100%**	4,85	0,36	5	**100%**
Check patient records (blood results, medication,...) prior to start the procedure	4,53	0,47	5	**100%**	4,75	0,44	5	**100%**
Check informed consent that has been obtained prior to start the procedure in angiosuite	4,43	0,73	5	87%	4,75	0,44	5	**100%**
Communicate effectively with endovascular team members in the angiosuite	4,65	0,49	5	**100%**	4,70	0,47	5	**100%**
Communicate effectively with patient	4,87	0,34	5	**100%**	4,65	0,59	5	**95%**
Provide and record clear and appropriate post-intervention instructions	4,65	0,49	5	**100%**	4,65	0,59	5	**95%**
Check patient pulses, color and temperature of the foot at end of the procedure	4,52	0,73	5	**96%**	4,60	0,50	5	**100%**
Function as part of an endovascular team (decision making, coordination,...)	4,39	0,78	5	83%	4,50	0,51	4,5	**100%**
Give briefing to endovascular team (anaesthetist, nurses,...) prior to start the procedure	4,30	0,82	5	78%	4,35	0,67	4	**90%**
Ensure the endovascular team is wearing radio protective clothing	4,17	0,93	4	74%	4,30	0,73	4	85%
Check materials, equipment and devices with the endovascular team (e.g. US, aortic pump,...) prior to start the procedure	4,21	0,80	4	78%	4,25	0,55	4	**95%**
Proper and safe positioning of patient on table in angiosuite	4,21	0,79	4	78%	4,10	0,45	4	**95%**
Use assistant to the best advantage at all times	4,21	0,75	4	83%	4,05	0,40	4	**95%**
Ensure the side is marked prior to start the procedure	4,09	1,08	5	65%	4,05	0,83	4	80%

Statements considered to describe a Fundamental Endovascular Skill (FES) by consensus are in bold.

11

Acknowledgements and Curriculum Vitae

Acknowledgements

Throughout the research in this thesis I have been supported by numerous people. I would like to thank everyone who has contributed to the realisation of this work.

I would like to address a personal word to:

Prof. Dr. Isabelle Van Herzeele, my promoter, thank you for initiating this amazing project and introducing me to the world of educational research. Your ambition and passion for research has encouraged me throughout the entire process. Thank you for being there for me with valuable advice and guidance at every step of the way.

Prof. Dr. Frank Vermassen, my co-promotor, thank you for giving me the opportunity to become part of the academic world. Your engagement and calm attitude has supported me through stressful moments. I would like to thank you for the excellent education I received, both scientific and clinical.

Mr Rajesh Aggarwal, thank you for your dedication and guidance. You were involved in this research from the start, providing valuable advice and support. Thank you for believing in this project.

Prof. Dr. Yves Van Nieuwenhove, thank you for you willingness to participate on the guidance committee, for your interest and advice.

Dr. Amin Madani, thank you for your enthusiasm and the pleasant collaboration.

Prof. Dr. Piet Pattyn and members of the examination board, thank you for accepting the invitation to participate on the committee, for taking the time to read my thesis and for the valuable comments.

I would like to thank all consultants, residents, surgical trainees, medical students, nurses and secretaries at Ghent University Hospital for their valuable help and understanding. Without you this research would not have been possible. Thank you for your support throughout the years.

Vascular surgeons Cedrick Coucke, Bart Denys, Eva-Line Decoster, Liesbeth Desender, Frederic De Ryck, Michael Janssens, Philip Lerut, Nathalie Moreels, Caren Randon, Daphné Van den Bussche, Dries Vandeweyer and Willem Willaert, thank you for your expertise performing simulation cases and/or supervising real interventions.

My friends, in-laws and family, thank you for your encouraging words, sincere interest and understanding. A special thanks to Malik Fourir for always being there with IT advice and Stefanie De Buyser, Ina Sintobin, Delfien Bogaert, Elodie Melsen and Annouck Philippron for the supportive lunch dates discussing our research.

My parents, thank you for everything you have done for me. You offered me every opportunity to help me reach my goals. Thank you for listening and bringing distraction during numerous phone calls. Thank you for always being there.

My sisters, Vicky and Wendy, you inspire me to believe in myself and support me in everything I do. I could not have done this without you and I am so proud to be your sister.

Dear Bram, thank you for your unconditional support, trust and love. You strengthen me and I am very grateful for having you in my life.

Curriculum Vitae

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2013: Medical degree graduated Magna cum Laude.

Current position

Surgical trainee General Surgery, Ghent University Hospital, Belgium and research fellow Thoracic and vascular surgery, Ghent University Hospital, Belgium. (2013 – ongoing)

Representation surgical disciplines in supervisory council GVGA (Gentse Vereniging voor Geneeskunde Assistenten) Ghent University. Belgium. (2013 – ongoing)

Representation surgical disciplines in the Commission MSG (Committee Master in de Specialistische Geneeskunde) Ghent University. Belgium. (2013 – ongoing)

Junior member of the Belgian Society of Vascular Surgery. (2013 – ongoing)

Researcher in the Educational Research Network in Health Sciences (ERNHS), Ghent University Hospital, Belgium. (2014 - ongoing)

Active member of the scientific commission of the Dutch Society of Simulation and Healthcare (DSSH). (2015 – ongoing)

Guidance committee research project Dr. B. Doyen, Ghent University, Belgium. (2016)

Training Courses and workshops

Abdominal wall cadaver course BAST, Luik, May 12th 2016.

Organisatorische en chirurgische aspecten bij terreuraanslagen, Ghent, March 14th 1016.

Cardiovascular Suture Course Medtronic, Ghent, December 15th 2015.

Good Clinical Practice update at AnGes investigator meeting, Athens, May 7th 2015.

InForm 5.5 training AnGes trial, Athens, May 7th 2015.

Placement of PICC, Maastricht, The Netherlands, May 13 th 2014.

Vascular Access Ultrasound, Maastricht, The Netherlands, May 12 th 2014.

HD catheter placement, Maastricht, The Netherlands, May 12 th 2014.

OTAS training course, Emperial college London, UK, May 1-2 th 2014.

Educational research workshop, ICOSET Harrogate, UK, April 30th 2014.

Covidien RDC Study Coordinator Online Training, April 23 th 2014.

Advanced statistics training course, Ghent University, Ghent, Belgium, February 2014.

Profess Basic ICH GCP Qualification training course and examination, October 24th 2013.

Duplex Ultrasound Scanning (DUS) Hands-on workshop, Vienna, Austria, October 21th 2013.

INF 4.6 CRC - Modules class Phase Forward, E-learning Oracle, September 17th 2013.

Beginselen der electrocardiografie (ECG), Permanente vorming Ugent, Ghent University Hospital, Ghent, Belgium, June 14 th 2010.

Publications

A1 Publications in international journals included in the Science Citation index

Maertens H, Madani A, Landry T, Vermassen F, Van Herzeele I, Aggarwal R. E-Learning for Surgical Training: A Systematic Review. Br J Surg. In press. (IF 5.5, Q1 Surgery)

Maertens H, Aggarwal R, Macdonald S, Vermassen F, Van Herzeele I. Transatlantic Multispecialty Consensus on Fundamental Endovascular Skills: results of a Delphi consensus study. Eur J Vasc Endovasc Surg. 2016 Jan;51(1):141-9. (IF 3.1, Q1 Surgery)

Maertens H, Aggarwal R, Desender L, Vermassen F, Van Herzeele I. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. *J Surg Educ. 2016 Jan-Feb;73(1):51-60.* (IF 1,6, Q2 Education)

Maertens V, Maertens H, Kint M, Coucke C, Blomme Y. Complication rate after carotid endarterectomy comparing patch angioplasty and primary closure. Ann Vasc Surg. 2016 Jan;30:248-52. (IF 1.2; Q3 Surgery)

Cambron M, Maertens H, Paemeleire K, Crevits L. Autonomic Function in Migraine Patients: Ictal and Interictal Pupillometry. Headache. 2014 Apr;54(4):655-62. (IF 2.8).

Cambron M, Maertens H, Crevits L. Apraclonidine and my pupil. Clin Auton Res. 2011 Oct;21(5):347-51. (IF 1,3).

A3 Publications

Desender L, Aggarwal R, Maertens H, Vermassen F, Van Herzeele I. Case-Specific Rehearsal: the Patient-Tailored Approach for EVAR. Conference paper in the British Journal of Surgery. Brit J Surg, January 2015. (IF 5.5; Q1 Surgery)

Maertens H., Mets G., Van Herzeele I. PhD, Van Nieuwenhove Y., Pattyn P. Evaluation of an innovative initiative on the medical student career choices. Tijdschrift van Geneeskunde. July 2014.

C2 Abstracts

Maertens H, Aggarwal R., Moreels N, Vermassen F, Van Herzeele I. Does a proficiency-based endovascular training program enhance performance in real life: a randomized controlled trial. SVS Vascular annual meeting, Washington, USA, June 8-11th 2016.

Maertens H, Aggarwal R, Desender L, Vermassen F, Van Herzeele I. Design and construct validity of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. NextMed/MMVR22 conference, Downtown, LA, California, USA, April 7-9th 2016.

Maertens. H, Madani A, Landry T, Vermassen F, Van Herzeele I, Aggarwal R. E-Learning for Surgical Training: A Systematic Review. Dutch Society for Simulation and Healthcare (DSSH), Delft, The Netherlands, March 16th 2015.

Maertens H, Aggarwal R, Vermassen F, Van Herzeele I. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. Dutch Society for Simulation and Healthcare (DSSH), Alkmaar, The Netherlands, March 18th 2015.

Maertens H, Van Herzeele I, Aggarwal R, Vermassen F. Design and construct validity of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. Veith, New York, USA. November 18-22th 2014.

I. Van Herzeele, L. Desender, H. Maertens, F. Vermassen. Optimal preparation using simulation both in elective and ruptured case. IMAD 2014, Liège, Belgium, September 11th 2014.

L. Desender, R. Aggarwal, H. Maertens, F. Vermassen, I. Van Herzeele. Case-specific rehearsal: The patient tailored approach for EVAR. ICOSET 2014, Harrogate UK, April 29 th 2014.

Crevits L, Cambron M, Maertens H, Paemeleire K. The pupils in migraine. 11th European Neuro-Ophthalmology Society (EUNOS) Meeting in Oxford UK, April 12 th 2013.

Keereman V, Maertens H, Dewaele F, Van Eijkeren M, Camaert J. Interstitial radiotherapy for brain tumors at Ghent University Hospital: a retrospective study. Belgian Society of Neurosurgery (BSN), March 30th 2013.

Cambron M., Maertens H., Paemeleire. K., Crevits L. The pupils of migraine patients: Preliminary Results. 2nd European Headache and Migraine Trust International Congress in Nice, France October-28-31 th 2010.

Oral presentations

Vascular annual meeting of the Society for Vascular Surgery (SVS), Washington, USA, June 8th. Maertens H., Aggarwal R., Moreels N, Vermassen F, Van Herzeele I. Does a proficiency-based endovascular training program enhance performance in real life: a randomized controlled trial. Abstract presentation.

NextMed/MMVR22 conference, Downtown, LA, California, USA, April 7th. Maertens H, Aggarwal R, Desender L, Vermassen F, Van Herzeele. Design and construct validity of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. Abstract presentation.

Dutch Society for Simulation and Healthcare (DSSH), Delft, The Netherlands, March 16th 2015. Maertens. H, Madani A, Landry T, Vermassen F, Van Herzeele I, Aggarwal R. E-Learning for Surgical Training: A Systematic Review. Abstract presentation.

NASCE meeting, Ghent, Belgium, February 25th 2016. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, L Desender, F Vermassen, I Van Herzeele. Abstract presentation.

Cardiovascular and Interventional Radiological Society of Europe (CIRSE), Lisbon, Portugal, September 26-30th 2015. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, L Desender, F Vermassen, I Van Herzeele. Poster presentation.

European Society for Vascular Surgery (ESVS) annual meeting, Porto, Portugal, September 23-25th 2015. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, L Desender, F Vermassen, I Van Herzeele. Poster presentation.

SITE-CELA International symposium on endovascular therapeutics, Barcelona, Spain, June 24-27th 2015. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, L Desender, F Vermassen, I Van Herzeele. Poster presentation.

Dutch Society for Simulation and Healthcare (DSSH), Alkmaar, The Netherlands, March 18th 2015. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, F Vermassen, I Van Herzeele. Abstract presentation.

Sciency day, Ghent, Belgium, March 5th 2015. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, F Vermassen, I Van Herzeele. Abstract presentation.

Veith Symposium, New York, USA, November 21th 2014. Transatlantic Multispecialty Consensus on Basic Endovascular Skills: Results of a Delphi Consensus Study. H Maertens, R Aggarwal, F Vermassen, I Van Herzeele, on behalf of the FOundER group (Fundamentals Of Endovascular pRocedures). Poster presentation.

Veith Symposium, New York, USA, November 20th 2014. Design and construct validity of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, F Vermassen, I Van Herzeele. Abstract presentation.

ESVS, Stockholm, Sweden, September 26th 2014. Transatlantic Multispecialty Consensus on Basic Endovascular Skills: Results of a Delphi Consensus Study. H Maertens, R Aggarwal, F Vermassen, I Van Herzeele, on behalf of the FOundER group (Fundamentals Of Endovascular pRocedures). Poster presentation.

ICOSET, Harrogate ,UK April 30th 2014. L. Desender, R. Aggarwal, H. Maertens, F. Vermassen, I. Van Herzeele. Case-specific rehearsal: The patient)tailored approach for EVAR. Abstract presentation.

Sciency day 13 March 2014. Maertens H., Mets G., Van Herzeele I., Van Nieuwenhove Y., Pattyn P. Evaluation of an innovative initiative on the medical student career choices. Abstract presentation.

Awards

First prize best scientific abstract. Dutch Society for Simulation and Healthcare (DSSH), Alkmaar, The Netherlands, March 18th 2015. Development of a proficiency-based stepwise endovascular curricular training (PROSPECT) program. H Maertens, R Aggarwal, F Vermassen, I Van Herzeele. Abstract presentation.

Thanks to the Dutch Society for Simulation and Healthcare (DSSH)