Patient-specific Rehearsal Prior to EVAR: A Pilot Study

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WHAT THIS PAPER ADDS

Reduced training times, increased complexity of endovascular interventions, greater emphasis on operating room efficiency and concerns for patient safety have inspired the continuous evolution of virtual reality simulation, inducing patient-specific rehearsals in modern health care. This is the first scientific report on patient-specific rehearsal prior to endovascular abdominal aneurysm repair. It depicts that this technology is a practical tool that may influence technical factors and be useful for preoperative case evaluation and preparation of the interventional team. These features result in a powerful tool that may improve patient outcome and safety of both the patient and the team.

Objectives: This study aims to evaluate feasibility, face validity, influence on technical factors and subjective sense of utility of patient-specific rehearsal (PsR) prior to endovascular aortic aneurysm repair (EVAR). **Design:** A prospective, multicentre pilot study.

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

Results: Ten patients were enrolled. In one case, the treatment plan was altered based on PsR. In 7/9 patients, the rehearsal significantly altered the optimal C-arm position for the proximal landing zone and an identical fluoroscopy angle was chosen in the real procedure. All team members found the rehearsal useful for selecting the optimal fluoroscopy angle (median 4).

The realism of the EVAR procedure simulation was rated highly (median 4). All team members found the PsR useful to prepare the individual team members and the entire team (median 4).

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

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Various drivers are currently pushing the use of virtual reality (VR) simulation in health care, for example, growth in medical knowledge, changes in medical education, the European Working Time Directive, patient availability and

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patient safety. Much of the stimulus behind the focus on patient safety dates to the Institute of Medicine 2000 report 'To Err is Human: Building a Safer Health System'.¹ This report increased the level of public and institutional awareness of the high prevalence of medical errors in modern health care and proposed medical simulation as an efficient tool to enhance physician training, by allowing skills acquisition and training of procedures in a safe and controlled environment where patients cannot be harmed.

Subsequently, extensive research by EVEREST (European Virtual Reality Endovascular RESearch Team) and others was conducted to establish the role of VR simulation as

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a training and assessment tool for teaching and practicing endovascular techniques to physicians at various levels of experience.^{2–7}

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

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

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

MATERIALS AND METHODS

Patient inclusion

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

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

3D model reconstruction

The Simbionix PROcedure[™] rehearsal studio software (Simbionix USA Corp., Cleveland, OH, USA) was used to generate 3D reconstructions of the patient's relevant anatomy. They were created by the lead researcher (L.D.). CT data in Digital Imaging and Communications in Medicine (DICOM) format were uploaded by means of a CD-ROM, on

which the imaging from a local Picture Archiving and Communication System (PACS) client was saved.

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

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

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

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

Simulator device

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

Interventional team and simulation environment

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

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



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

Study design

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

Technical factors

Before and after the rehearsal, the lead interventionalist completed a questionnaire with his selection of C-arm angulation to adequately visualise the target landing zones based on dedicated 3D workstations and case-specific rehearsal. C-arm positioning was recorded during both the simulated and real EVAR procedure. A change of at least 10° in either cranio-caudal or oblique fluoroscopy angle was considered to be clinically significant. Similarly, an 'identical' C-arm positioning was defined as a change of $<10^{\circ}$ of fluoroscopy angulation for both cranio-caudal and oblique views between the simulated and real procedure.

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

Subjective questionnaire

After the real EVAR procedure, each team member completed a subjective questionnaire that addressed simulation realism (e.g., images and endovascular tool manipulation), effectiveness on technical issues, communication and teamwork. Responses were rated on a Likert scale from 1 (not at all) to 5 (very much). Participants also had the possibility to write down any suggestions or comments.

Data analysis

Data were entered in the Statistical Package for the Social Sciences version 20.0 (SPSS, Chicago, IL, USA). Nonparametric tests were applied for data analysis. The Mann—Whitney *U* test was used to compare groups (simulation vs. real operation) for continuous variables; the chisquared test was used for categorical variables. A level of p < 0.05 was considered to be statistically significant. All data are presented as median values unless otherwise indicated. Interquartile ranges (IQRs) are noted in parentheses.

RESULTS

Patient demographics

Between March and June 2012, 10 consecutive patients were enrolled. Nine had an infrarenal aortic aneurysm with a maximum outer diameter of at least 55 mm; one patient had a small aortic aneurysm (42 mm) and a left common iliac aneurysm of 50 mm.

One patient presented with a pseudo-aneurysm at the level of the proximal anastomosis after previous open AAA repair with an aortobifurcated graft. During the preoperative rehearsal of this case, a type 1a endoleak occurred (Fig. 3). Based on a case review instigated by this practice run, the physician altered his treatment plan. The intervention was postponed and the aneurysm was



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

successfully excluded using a stent graft with suprarenal fixation. This case was excluded from further analysis.

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

The nine PsRs and nine real EVARs were carried out successfully. No major adverse events occurred.

3D model reconstruction

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

Of the initial 10 CT angiographies, all could be reconstructed. Overall, a reconstruction took between 60 and 180 min, mainly influenced by the quality of the CT scan images.

Interventional team and simulation environment

One rehearsal was performed in the angiosuite, two in the OR and six in the laboratory environment. Seven different teams, consisting in total of 24 team members, performed the simulated and real EVAR procedures. Each team differed from another by at least one team member. A preceding training session accustomed all team members to the simulator set-up. The lead interventionalists were consultants and experienced practitioners who had performed more than 500 endovascular procedures and the majority (7/9) had performed at least 50 EVAR procedures



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

as the primary operator. Five of them were vascular surgeons, four were interventional radiologists. However, in three rehearsals the assistant (N = 3) and/or scrub nurse (N = 2) was inexperienced in EVAR (<10 EVARs). In three cases, the scrub nurse was not present during the case rehearsal.

Technical factors

PsRs were performed more rapidly than the corresponding live EVAR cases (total procedure time, median 32 (IQR 24– 41) vs. 43 (IQR 39–60) min, p = 0.015). By contrast, fluoroscopy time was higher, although not significantly, in the simulated case: 13 min (IQR 11–16) vs. 10 min (IQR 8–18), p = 0.354 (Fig. 4). The amount of contrast used (80 (IQR 75–97) vs. 80 ml (IQR 61–92), p = 0.424) and the number of angiographies taken to complete the endovascular exclusion of the aneurysm (5 (IQR 4–8.5) vs. 6 (IQR 4.5–7), p = 0.787) were similar between simulated and real cases.

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

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

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

Subjective questionnaire

Subjective questionnaires were completed by all team members (N = 24). Table 2 summarises the overall scores for the rating of the face validity and subjective evaluation of the procedure-rehearsal potential. The realism of the

Age (y)		74 (64—89)			
Gender M/F		9/0			
Maximal outer diameter AAA (mm)		58 (42—65)			
Aortic neck: length (mm)	21 (12-49)				
Aortic neck: diameter (mm)	21 (19–24)				
	Absent	Mild	Moderate	Severe	
Aortic neck: calcification/thrombus	(<25%)	(25—50%)	(>50%)	(—)	
	8/9	1/9	0/9	0/9	
Suprarenal angle	(>150°)	(150°—135°)	(135°—120°)	(<120°)	
	6/9	2/9	0/9	1/9	
Infrarenal angle	(160°—180°)	(140°—159°)	(120°—139°)	(<120°)	
	2/9	1/9	4/9	2/9	
lliac artery: calcification	(None)	(<25%)	(25—50%)	(>50%)	
	0/9	7/9	1/9	1/9	
lliac artery: angle	(160°—180°)	(121°—159°)	(90°—120°)	(<90°)	
	0/9	1/9	6/9	2/9	
lliac artery: tortuosity index (τ)	($ au <$ 1.25)	(1.25 $< au <$ 1.5)	(1.5 $< au <$ 1.6)	(τ > 1.6)	
	0/9	3/9	4/9	2/9	

M/F: male/female. Categorical scores (Absent, Mild, Moderate and Severe) according to the anatomic severity grading (ASG) scale.¹⁶. Number of patients with particular aneurysm characteristic/total number of patients (bold).

Та	ble	e 1.	. Patient	demographics	(medians	(range)).
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Figure 4. Total time and fluoroscopy time for the virtual and real cases.

simulated EVAR procedure, including the simulated angiographies of the aorta and iliac vessels, were rated highly by each team member. However, experienced team members rated the realism of the simulated angiographies significantly higher than the inexperienced team members (median 4 vs. 3, p = 0.032). All team members found the rehearsal especially useful for selecting the optimal C-arm angulation to adequately visualise the target landing zones. Furthermore, it was considered to be valuable to optimally prepare the entire team and to improve communication and teamwork. All team members thought case-specific rehearsal might lead to increased patient safety.

Compared to the lead interventionalist, both the assistant and the scrub nurse thought the rehearsal to be significantly more effective at increasing overall efficiency of tool use (median 4 (assistant) and 4.5 (scrub nurse) vs. 3, p = 0.001) and communication with the circulating nurse (median 4 vs. 3, p = 0.006).

The scrub nurse found the rehearsal significantly more effective than the lead interventionalist and assistant for understanding their role during the intervention (median 4.5 vs. 4, p = 0.004). Furthermore, scrub nurses indicated that their preconceived notion of how the procedure would

be performed was altered more frequently (median 4 vs. 3, p = 0.007).

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

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

DISCUSSION

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



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

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

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

PsR: patient-specific rehearsal.

In the majority of cases, PsR was able to predict and alter fluoroscopy preferences for optimal visualisation of the proximal and distal landing zones during the real intervention. Significantly longer fluoroscopy times during the simulated procedure may indicate that the rehearsal was used to identify the ideal C-arm angulation. Consequently, this technique may lead to a reduction of the radiation dose for the patient, physician and endovascular team.

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

The choice of tool kit, size of the device and the number of iliac extensions were not altered in this study, probably due to meticulous preoperative sizing on dedicated workstations by experienced teams. Besides its important role as a technical adjunct to the interventionalist, PsR may also be applied to enhance non-technical skills.^{14,15} This finding is supported by the results from this study, as team members regarded PsR as a valuable tool to increase coordination, communication and confidence during the real procedure.

Several limitations of the current generation of simulation-rehearsal capabilities have been described.⁹ Similar to this report, the 3D reconstruction of the relevant vasculature was identified as the most variable and time-consuming step in the whole process. Subsequently, the quality of the CT DICOM data is of major influence for both the set-up time and the quality of the simulated rehearsal.

Furthermore, biomechanical properties were often not accurately replicated in the preoperative simulation, for example, cannulation of the contralateral limb, absence of vessel straightening by insertion of guide wires and deployment of the stent graft. Several authors have noted this phenomenon for carotid artery stenting (CAS) rehearsals as well.^{11,15} The integration of additional biomechanical characteristics, using finite element analysis to evaluate the mechanical interaction between endovas-cular equipment and the vasculature, could lead to a significant improvement.²² However, increasing levels of simulator fidelity do not automatically translate into higher-quality performances and improved transfer of skills.^{23–25}

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

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

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

Further, only experienced interventionalists and team members were evaluated using this new technology. Although this allowed for an accurate comparison of the virtual and corresponding real operation, it presumably underestimated the inherent value of PsR. Less experienced operators and team members may benefit more from this technology as their tool choices, fluoroscopy preferences and team interactions are less automated, especially for complex procedures.²⁶

In conclusion, the results from this pilot study indicate that setting up a PsR prior to EVAR is feasible for various anatomies in different hospital settings. It permits creation of realistic simulated case studies, rated highly by endovascular experts. Although the impact on selecting endovascular tools seems limited, EVAR rehearsals may influence fluoroscopy preferences and alter the treatment plan. Furthermore, it may be useful to evaluate the real case, identify potential pitfalls and increase confidence within the team.

Further research will evaluate the potential of PsR prior to EVAR to increase patient safety by optimising patient and device selection, improving preoperative planning, preventing complications and reducing radiation dose and identifying for which patients (anatomy) and physicians (experience) preoperative rehearsal may be useful. A randomised controlled trial has been initiated to investigate if this new technology may enhance technical and nontechnical performance, clinical safety and efficiency, that is, if patients actually benefit from physicians and team members conducting PsRs of EVAR interventions.

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CONFLICT OF INTEREST STATEMENT

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