Patient-specific Rehearsal Before EVAR

Influence on Technical and Nontechnical Operative Performance. A Randomized Controlled Trial

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

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

Methods: A multicenter, prospective, randomized controlled trial recruited 100 patients with a nonruptured infrarenal aortic or iliac aneurysm between September 2012 and June 2014. Cases were randomized to preoperative PsR or standard care (no PsR). Primary outcome measures were errors during the real procedure and technical operative metrics (total endovascular and fluoroscopy time, contrast volume, number of angiograms, and radiation dose).

Results: There was a 26% [95% confidence interval (CI) 9%–40%, $P = 0.004$) reduction in minor errors, a 76% (95% CI 30%–92%, $P = 0.009$) reduction in major errors, and a 27% (95% CI 8.2%–42%, $P = 0.007$) reduction in errors causing procedural delay in the PsR group. The number of angiograms performed to visualize proximal and distal landing zones was 23% (95% CI 8%–36%, $P = 0.005$) and 21% (95% CI 7%–32%, $P = 0.004$) lower in the PsR group.

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

Keywords: endovascular team, error, EVAR, patient safety, patient-specific simulation

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

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

The 1999 Institute of Medicine report, ''To Err is Human,'' highlighted the incidence of medical errors in modern health care and their impact on patient safety, and recommended the use of medical simulation to enhance physician training.[8] It has inspired a continuous evolution of medical simulation, resulting in the development of patient-specific virtual reality rehearsal (PsR).[9] This technology enables the practitioner and team to practice ''real'' cases on a virtual patient before performing the procedure on the actual patient. Previous research by our group has established that PsR before carotid artery stenting (CAS) and EVAR is feasible, and that it may improve preoperative planning and preparation of the endovascular team.[10,11]

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

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METHODS

Trial Design and Participants

This study is a prospective, multicenter, parallel-group trial that randomized patients with an AAA or iliac aneurysm suitable for EVAR to either preoperative PsR (intervention group) or standard care (no PsR: the control group). The trial was conducted in 6 vascular centers, each of which performs at least 30 elective EVAR procedures per year: 2 centers in Belgium (1 academic, 1 district hospital), 2 in The Netherlands (district hospitals), 1 in Switzerland (academic), and 1 in the United Kingdom (academic). EVAR was carried out in a hybrid angiosuite with a fixed fluoroscopy unit or in an operating theatre with a mobile system.

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

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

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

Randomization, Blinding, and Sample Size

Patients were randomized to either the intervention or the control group in a 1:1 ratio using a computer-generated list. Randomization was by block permutations, with a block size of 4. The allocation sequence was concealed from the researcher (LD) enrolling and assessing patients by using sequentially numbered, opaque sealed envelopes. Randomization took place after obtaining informed consent and creating the 3D model. Outcome assessors and data analysts were blinded to the allocation. Since recent literature does not provide any data regarding the primary outcomes of this trial, a power analysis could not be performed. A number of 50 patients per group was chosen as a sufficient and achievable target.

Outcomes

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

Errors

For every EVAR procedure, the same observer noted in real-time from incision to skin closure any event that prevented the procedure progressing in an ideal manner. These events were recorded and categorized using the Imperial College Error CAPture (ICECAP) tool (Supplemental Digital Content 1, the ICECAP tool, http://links.lww.com/SLA/B47).[12] The determination of a ''true error'' and assessment of the severity (minor or major) and estimated delay of the error were independently performed by 2 investigators who were unaware whether the incident occurred in the intervention or the control group. Events classified as nonerrors were excluded from further analysis. The definitions used to classify incidents are provided in Table 1.

Technical Operative Metrics

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

In a separate analysis, the primary outcomes were corrected for difficulty of the aneurysm repair and experience of the endovascular team. The complexity of the aneurysm repair was evaluated using the Anatomic Severity Grading (ASG) score. This score was developed by the ad hoc Committee for Standardized Reporting Practices in Vascular Surgery/American Association for Vascular Surgery and has been validated.[13,14] An experienced endovascular team was defined as a team consisting of at least 2 (out of 3) team members who had performed (lead interventionalist) or assisted (assistant, scrub nurse) at least 50 EVAR cases.

Statistical Analysis

All analyses were performed using SAS 9.4 (SAS Institute Inc., NC) and using an intention-to-treat basis. The Kappa statistic was used to

TABLE 1. Definitions of Errors Used in the Study

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

investigate inter-rater reliability of error assessment. The number of errors was compared between the intervention and the control group using unadjusted and adjusted (covariates aneurysm difficulty and team experience) Poisson regression. Multiple Poisson regression was used to test the interaction between randomization group and team experience. A 2-sample *t* test and adjusted (covariates aneurysm difficulty and team experience) linear regression were applied to the log-transformed technical operative metrics. The interaction between randomization group and team experience was also tested using linear regression. All analyses were considered significant at the 5% level.

RESULTS

Study Population

Between September 2012 and June 2014, 100 patients (90% male) were enrolled at the 6 trial centers and randomized to the 2 study groups. Figure 1 shows the flow of patients through the trial. Baseline variables, including age, sex, maximal aneurysm diameter, ASG score, and treatment within or outside IFU, were balanced between the groups (Table 2). No patient was excluded from the analysis.

Outcomes

Errors

A total of 410 potential errors were identified, and 2 independent assessors rated 390/410 (95%) of these events as "true errors". Both raters assessed the severity (ie, minor or major error) similarly in 370/390 (95%) errors, with a good to excellent inter-rater reliability [kappa = 0.61, 95% confidence interval (CI) 0.46–0.76]. The majority of the errors (122/390) was related to technical issues (eg, unfamiliarity with the procedure, equipment, or techniques). The number of minor errors occurring during the entire procedure and the endovascular (rehearsed) part of the procedure was significantly lower (−26%; 95% CI −40 to −9%, $P = 0.004$; and −21%; 95% CI −36 to −2%, $P = 0.03$, respectively) in the intervention group compared with the control group. Similarly, the number of major errors arising during the complete procedure and the endovascular part was significantly lower (−76 %; 95% CI −92 to −30%, $P = 0.009$; and −82%; 95% CI −96 to −18%, $P = 0.03$, respectively) in the intervention group. Additionally, the number of errors causing delay was significantly lower in the intervention group (−27%; 95% CI −42 to −8.2%, $P = 0.007$), as was the number of errors occurring during the nonendovascular part of the procedure (−70%; 95% CI −86 to −35%, $P = 0.003$). After multiple Poisson regression with correction for complexity of the aneurysm repair and team experience, the positive effect of PsR on the reduction of minor and major errors remained significant. Additional data are provided in Tables 3 and 4.

Technical Operative Metrics

The number of angiograms performed until deployment of the main body of the stent graft and until deployment of all implanted stent grafts was significantly lower (−23 %; 95% CI −8 to −36%,

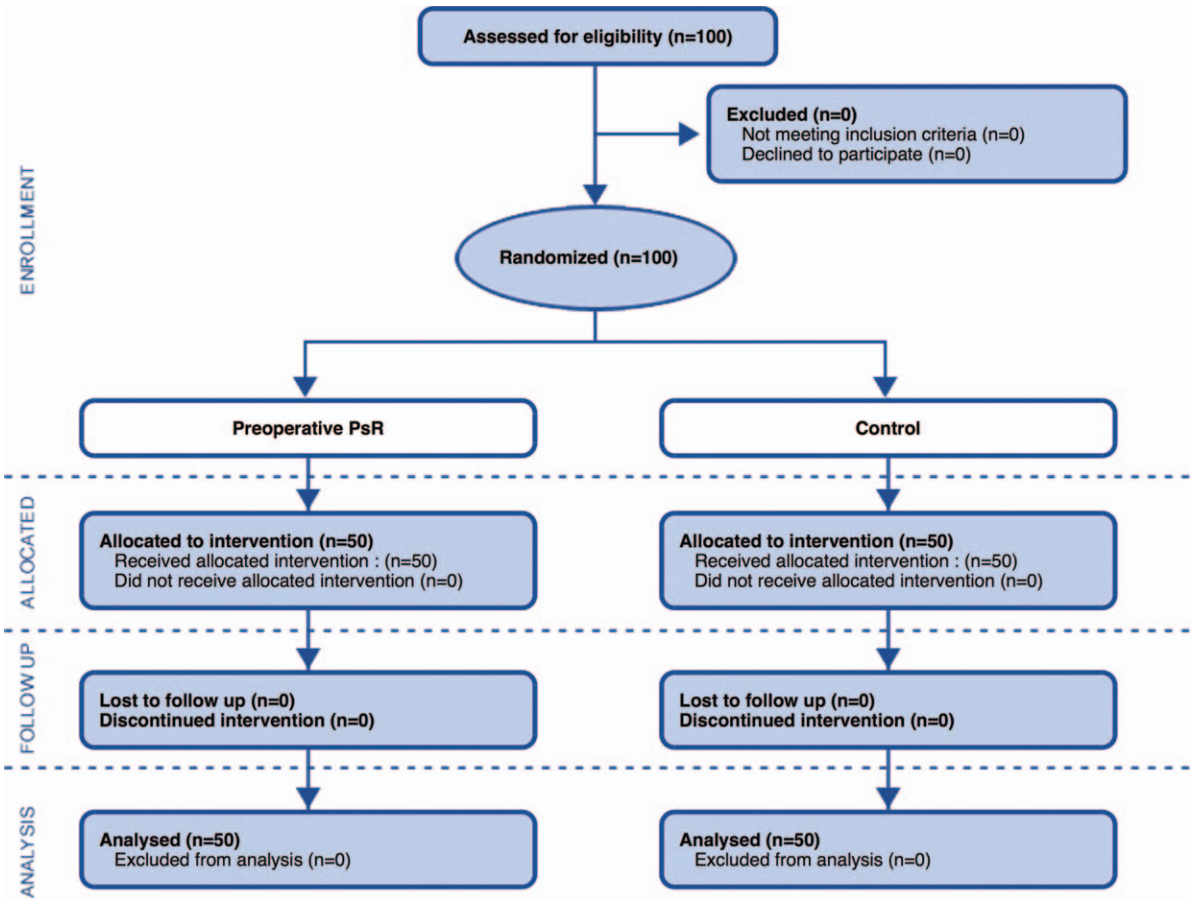

FIGURE 1. CONSORT 2010 diagram showing flow of patients through the trial. CONSORT indicates CONsolidated Standard of Reporting Trials.

TABLE 2. Baseline Characteristics Randomized by Group

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

Values are means (SD) or numbers (%).
ASA indicates American Society of Anesthesiologists.

$P = 0.005$; and −21%; 95% CI −7% to −32%, $P = 0.004$, respectively) in the preoperative PsR group compared with the control group. After multiple linear regression with correction for complexity of the aneurysm repair and team experience, the effect of PsR on both outcomes remained significant ($P = 0.007$ and $P = 0.005$, respectively). No statistically significant differences were noted between groups for other technical operative metrics (Table 5).

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

In-hospital mortality was 1/50 (2%) in the control group and 0/50 (0%) in the intervention group ($P = 1.000$). Thirty-day mortality was 1/50 (2%) in the control group and 2/50 (4%) in the intervention group, of which 1 was aneurysm-related.

DISCUSSION

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

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

TABLE 3. Errors Occurring During Procedure by Randomized Group

Variable	Errors, Intervention Group (95% CI)	Errors, Control Group (95% CI)	Difference, Intervention Vs Control Group	95% CI	P*	P Multivariate Analysis†
Minor errors Complete procedure	3.14 (2.67–3.67)	4.24 (3.71–4.85)	−25.9%	−39.8% to −9.0%	0.004	0.002
Minor errors Endovascular part	3.02 (2.58–3.54)	3.82 (3.32–4.40)	−20.9%	−36.1% to −2.1%	0.03	0.02
Major errors Complete procedure	0.08 (0.03–0.21)	0.34 (0.21–0.55)	−76.5%	−92.1% to −30.1%	0.009	0.009
Major errors Endovascular part	0.04 (0.01–0.16)	0.22 (0.12–0.40)	−81.8%	−96.0% to −18.0%	0.03	0.03
Total errors Endovascular part	3.06 (2.61–3.59)	4.04 (3.52–4.64)	−24.3%	−38.6% to −6.6%	0.01	0.006
Total errors Nonendovascular part	0.16 (0.08–0.32)	0.54 (0.37–0.79)	−70.4%	−86.5% to −34.8%	0.003	0.002
Errors without delay	0.78 (0.57–1.07)	1.20 (0.93–1.55)	−35.0%	−56.6% to −2.7%	0.04	0.04
Errors causing delay	2.46 (2.06–2.94)	3.38 (2.91–3.93)	−27.2%	−42.3% to −8.2%	0.007	0.003

*Univariate Poisson regression.
†Multiple Poisson regression with correction for aneurysm difficulty and team experience.

TABLE 4. Main Categories of Errors Occurring During Procedure by Randomized Group

Variables	Number of Errors (%)	Errors, Intervention Group (95% CI)	Errors, Control Group (95% CI)	Difference, Intervention Vs Control Group	95% CI	*P**
Technical issues	122/390 (31%)	0.78 (0.57–1.07)	1.64 (1.32–2.04)	−52.4%	−67.5% to −30.4%	<0.001
Minor errors	108/368 (29%)	0.70 (0.50–0.97)	1.46 (1.16–1.84)	−52.1%	−68.0% to −28.3%	<0.001
Major errors	14/22 (64%)	0.08 (0.03–0.21)	0.18 (0.10–0.35)	−55.6%	−86.4% to 44.3%	0.18
PIP	92/390 (23%)	0.86 (0.64–1.16)	0.98 (0.74–1.30)	−12.2%	−41.7% to 32.2%	0.53
Equipment	83/390 (21%)	0.84 (0.62–1.14)	0.84 (0.62–1.14)	0.0%	−34.8% to 53.4%	1.0
Communication	76/390 (19%)	0.60 (0.42–0.86)	0.92 (0.69–1.23)	−34.8%	−58.8% to 3.3%	0.07

*Univariate Poisson regression.
PIP indicates procedure-independent pressure.

depends on thickness of the imaged body part, field of view, pulse frequency, and dose level of fluoroscopy employed. Specifically, PsR seems to lead to the use of more oblique angles for optimal visualization of the landing zones, thereby increasing radiation dose.

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

The prospective, randomized nature of this study was designed to rigorously evaluate the effect of PsR before EVAR on patient safety. Although a formal power analysis to detect a difference in errors occurring during the procedure was not possible, the incidence of errors was significantly higher in the control group. Another limitation of this study was the inability to blind the observer of intraoperative events to the randomization group, which implies a possible bias. However, the construction of an event log was performed without judgment. The decision whether an intraoperative event constituted an error was taken by 2 blinded assessors, who had significant experience in EVAR procedures and error definition. Notwithstanding the limitations noted above, this study reflects real-life practice, performed in academic and district hospitals by experienced and inexperienced teams, cases were treated within and outside IFU, and patient demographics were in line with those previously reported in large randomized EVAR trials.[1,24] The results of this study indicate that PsR before EVAR can be used reliably and effectively in different hospital settings by teams with various experience for patients with diverse aneurysm characteristics. These

TABLE 5. Technical Operative Metrics by Randomized Group

Variables	Intervention Group (n = 50) Geometric Mean (95% CI)	Control Group (n = 50) Geometric Mean (95% CI)	Difference in Geometric Mean Intervention Vs Control Group	95% CI	*P**	*P* Multivariate Analysis†
Endovascular procedure time, min	52.1 (46.2–58.8)	54.6 (48.4–61.6)	−4.6%	−19.6% to 13.2%	0.59	0.48
Fluoroscopy time, s	916 (763–1099)	864 (720–1037)	6.0%	−18.1% to 37.3%	0.66	0.66
Contrast medium use, mL	81 (73–91)	93 (84–104)	−12.8%	−25.3% to 1.7%	0.08	0.10
No. of angiograms until deployment of main body	2.2 (1.9–2.4)	2.8 (2.5–3.2)	−23.1%	−35.8% to −7.8%	0.005	0.007
No. of angiograms until deployment of all stent grafts	4.3 (3.8–4.8)	5.4 (4.8–6.0)	−20.5%	−32.0% to −7.1%	0.004	0.005
Total number of angiograms	6.5 (5.9–7.2)	7.5 (6.7–8.2)	−12.6%	−24.1% to 0.7%	0.06	0.07
Radiation dose (DAP), mGycm^2	103,951 (79,657–135,653)	112,943 (86,548–147,387)	−8.0%	−36.8% to 34.1%	0.66	0.57

*Two-sample *t* test.
†Multiple linear regression with correction for aneurysm difficulty and team experience.
DAP indicates dose area product.

conclusions may not be applicable to other stent grafts as only Gore Excluder or Endurant stent grafts could be simulated during the rehearsal.

The current generation of commercially available endovascular PsR software has several limitations, including time, expertise, and costs to generate the 3D reconstructions, reliance on the quality of the preoperative imaging, and inadequate modeling of vessel biomechanical properties, for example, straightening of the iliac arteries by stiff wires and stent grafts.[11,23] Ongoing collaboration between clinicians and industry is paramount to address these concerns, by facilitating integration of the 3D models produced with dedicated sizing software, and by enabling part-task rehearsals to practice the more challenging steps of the procedure. Simulator costs (acquisition and maintenance) can be distributed, because these can be used not only for rehearsal but also to train individuals or whole endovascular teams, across a range of experience levels, in almost any endovascular procedure. Staffing costs may be addressed by performing rehearsals with the endovascular team during anesthetic preparation time. This technology may be used as a preoperative planning tool to adjust treatment plans and reconfirm stent graft measurements, a potentially cost-saving measure given the high costs of current stent graft devices. Further research is needed to evaluate how PsR before EVAR may be implemented in daily clinical practice, and if such rehearsals are cost-effective.

CONCLUSIONS

Patient-specific virtual reality rehearsal before EVAR can be used in different hospital settings by teams with various EVAR experience. It can reduce errors occurring during the procedure and the number of angiograms needed to deploy the stent graft, thereby reducing delays and improving procedure efficiency. Ultimately, this technology may improve patient safety.

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DISCUSSANTS

M.G. Wyatt (Newcastle upon Tyne, UK):

This is a well-presented study and certainly adds to the surgical literature on this subject. My comments to the authors are as follows. Who were the blinded observers and were they attached to the interventional team. Please explain how the blinding was ensured? Much of this is subjective interpretation and if the observers were not truly blinded, it adds a level of ''interpretation" to the data/analysis.

What was the nature of most of the minor errors? Could the authors group the nature of these errors in order for the reader to determine their significance?

Clearly, this trial involves team training. Were the teams identical for each of the cases in the trial? If not, how did this influence the results?

What is the distribution of the errors for individual patients? Did all cases record error or were the errors in the more challenging cases? In other words, do the data suggest that predeployment practice is of benefit in all cases of EVAR or just the more complex ones? Cost is clearly an issue here. Are the differences sufficient to recommend adding simulation to all cases of EVAR or should this new technique only be used for those more challenging cases?

Finally, this study assumes a definition for error, which is not presented to the reader. The results of the RCT depend on this definition, which requires clarification during publication.

Response From L. Desender (Ghent, Belgium)

The primary data collector, who recorded real-time all events that prevented the procedure progressing in an ideal manner, could not be blinded to the randomization group, but each suspected identified error was assessed by 2 blinded observers (a vascular surgeon and a registered nurse) who were previously trained in error assessment using the Imperial College Error CAPture (ICECAP) tool. This tool has been validated for capturing and categorizing errors occurring in (endo)vascular procedures. The blinded observers were not involved in the patient selection, randomization or EVAR procedures, nor were they part of any interventional team participating in the study. Assessment of potential errors was performed after completion of the data collection of all cases included in the trial.

Errors occurred in 98/100 cases. The majority of errors occurred during the procedure were related to technical problems (eg, unfamiliarity with the procedure, the equipment, or techniques used during the procedure). These accounted for 108/368 (29%) of minor errors and 14/22 (64%) of major errors. Procedure independent pressures (PIP), equipment related issues, communication issues, safety awareness, and patient-related issues accounted for 25%, 21%, 21%, 3%, and 1% of minor errors, respectively. For major errors, equipment-related issues and PIP accounted for 32% and 5 %, respectively. There were significantly less errors related to technical issues in the intervention group compared with the control group. As expected, there was no significant difference between both groups for the subcategory ''procedure independent pressures.''

The composition of the team, and hence also the experience of the team, varied from case to case and was based upon availability, according to daily practice. The proportion of experienced teams was similar in both randomization groups. Multivariate analysis with correction for team experience demonstrated that the positive effect of PsR on the reduction of minor and major errors and on the reduction of number of angiograms performed to visualize the landing zones remained significant. Multivariate analysis with correction for the complexity of the aneurysm repair also demonstrated that the effect of PsR remained significant.

N. Demartines (Lausanne, Switzerland):

A short question: Did you perform a cost-benefit analysis?

Response From L. Desender (Ghent, Belgium):

As this study was not designed to evaluate cost-effectiveness of patient-specific rehearsal before EVAR, we are not able to conclude if the reported effects translate in decreasing procedural costs. This may be an area for future research.

P. O'Dwyer (Glasgow, UK):

This method of simulation has implications for Laparoscopic Surgery; however, your study lacks hard data. How did you come up with 100 patients, what was your primary endpoint? Does simulation reduce procedure time and if so by how much. Was the difference statistically significant? Your study lacks the hard evidence required to convince me of its value.

Response From L. Desender (Ghent, Belgium):

The primary outcomes of this study were the number of errors occurring during the actual EVAR procedure and the technical performance measured by operative metrics. Recent literature does not provide any data regarding these primary outcomes. Consequently, a power analysis could not be performed and a number of 50 patients per group were arbitrarily chosen.

Although there was a slight decrease in the mean procedure time (4.6%), this did not reach statistical significance.