Prospective, randomised and blinded comparison of proficiency-based progression full-physics virtual reality simulator training versus invasive vascular experience for learning carotid artery angiography by very experienced operators

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ABSTRACT

Introduction We assessed the transfer of training (ToT) of virtual reality simulation training compared to invasive vascular experience training for carotid artery angiography (CA) for highly experienced interventionalists but new to carotid procedures.

Methods Prospective, randomised and blinded.

Setting Catheterisation and skills laboratories in the USA.

Participants Experienced (mean volume=15 000 cases) interventional cardiologists (n=12) were randomised to train on virtual reality (VR) simulation to a quantitatively defined level of proficiency or to a traditional supervised in vivo patient case training.

Outcome measures The observed performance differences in performing a CA between two matched groups were then blindly assessed using predefined metrics of performance.

Results Experienced interventional cardiologists trained on the VR simulator performed significantly better than their equally experienced controls showing a significantly lower rate of objectively assessed intraoperative errors in CA. Performance showed 17–49% ToT from the VR to the in vivo index case.

Discussion This is the first prospective, randomised and blinded clinical study to report that VR simulation training transfers improved procedural skills to clinical performance on live patients for experienced interventionalists. This study, for the first time, demonstrates that VR simulation offers a powerful, safe and effective platform for training interventional skills for highly experienced interventionalists with the greatest impact on procedural error reduction.

INTRODUCTION

Training in medicine is currently going through a paradigm shift. The provision of one-on-one apprenticeship learning of doctors is abrogated by high-profile error cases and radical reductions in acceptable duty hours and therefore training experience. The settled solution appears to be the harnessing of technology-enhanced learning, particularly simulation-based training. Also recently, the Department of Health in the UK has directed that a procedure should not be performed on a patient, the first time that it is performed.

Virtual reality (VR) simulation as an approach to training skills was first validated in 2002 for a surgical procedure and was subsequently adopted and championed by American Surgery in 2006. This method has also been enthusiastically embraced by interventional cardiologists (IC) with the adoption of VR simulation training for the training of new interventional devices. This is not surprising given the rate of change and evolution of cardiovascular devices and the morbidity associated with some new procedures (eg, transcatheter aortic-valve implantation (TAVI), carotid stenting, stroke intervention), even by experienced operators. Furthermore, vascular medicine has access to the most sophisticated VR simulators currently available in healthcare.

There is a relative lack of published studies evaluating the impact of VR simulation training on actual individual operator clinical performance on patients. In a review of simulation studies on intra-vascular procedures, Desender et al reported only two transfer of training (ToT) studies of VR simulation training on in vivo performance. De Ponti et al reported the beneficial effects of VR simulation training in comparison to conventional training on transseptal catheterisation performance. Indeed, none of the prospective, randomised clinical validation studies that have evaluated simulation training have determined its utility for training highly experienced operators learning a new technique or new procedural skill, even in surgery.

The aim of this study is to evaluate the utility of VR simulation training in comparison to one-to-one procotored/mentored in vivo training for highly experienced IC attempting to learn a new procedure, that is, carotid angiography (CA).
basic didactic training on CA technique. All 12 of the participants underwent the Carotid Artery Stenting Education System (or CASES education system, eTrinsic, Inc (Denver, Colorado, USA) and purchased by Simbionix, Cleveland, Ohio, USA) before their first case. CASES is a comprehensive online education solution providing ‘hands-on’ training. The online training includes instruction on the carotid anatomy and aortic arch types and their relevance to procedure performance and the devices to be used for performance of the procedure. It also includes instruction on the steps of the procedure including a simulation of a physical object (catheters, wires, stents (of different lengths) and embolic protection device that can be manipulated by a user (with a computer mouse) and the executable program having a monitoring capability. Independently, we utilised standardised video and knowledge assessments of basic technique for which participants demonstrated excellent didactic performance with passing scores (100%). Participant operators were assigned in matched pairs (based on age and experience) and then one of the pair was randomly allocated to the VR training versus conventional training. Participants were trained by independent researchers on the basis of information retrieved from the sealed envelope. Outcomes assessments and analysis were conducted by individuals blinded as to subject identity and their training group status.

**Apparatus**

The Vascular Interventional Simulation Trainer (VIST; figure 2A—D), described elsewhere, was used for the study. The system uses a geometrical vessel representation together with physics-based calculations to determine the behaviour of the interventional devices. The simulation uses programmed properties of the devices (stiffness, friction, etc) to calculate the forces. The haptic feedback to the user’s actions are calculated in real time and depend on the interaction between the virtual devices and the virtual anatomy (vessel geometry and vessel properties) and give realistic tactile feedback to the operator during the training procedure.

**Proficiency definition**

Proficiency levels were established on experts’ mean performance on a specific CA VR case (case 2) on the VIST simulator, V.6.0. This methodology was first reported by Seymour et al and is described in detail elsewhere. Intraoperative defined errors included tool vessel errors such as severe dragging of the tip of the catheter along the wall of a vessel for a distance >3 mm. A catheter movement error was defined and recorded when the catheter was advanced into the carotid artery without the guide-wire tip inside the catheter or if the catheter was too close to the lesion. These metrics had been previously validated using a large number of trainees learning carotid angiography. The mean score used to define proficiency levels for the experts was fluoroscopy time ≤6.2 min and total technical error score ≤4.

**Procedure**

The study was approved by the Institutional Review Board (Emory University, Georgia, USA). Simulation subjects were trained to reach a metric-based level of proficiency before completing their first procedure. Proficiency levels were defined on the objectively assessed performance of five US-based intravascular faculty experts (ie, had performed >1000 carotid angiograms) using the VIST case 2, V.6.0 and with the same metrics.

On the basis of prospective randomisation group A were trained on the VIST until they reached the quantitatively defined level of proficiency (figure 1). The other half (group B) completed a supervised and mentored training during an elective in vivo case according to the traditional mentor-apprenticeship learning model. Group B standard trained subjects were mentored for one complete CA case by a cardiologist very experienced in CA and stenting procedures. Both groups then completed a separate supervised but unmentored complete CA case functioning as the primary operator, proctored by an experienced interventional cardiologist who was also an expert on CA, but who was blinded as to the training status of the subject. The proctor was instructed to behave the same towards the subject as they would during a normal case.

The operative performance was video-recorded for subsequent analysis by experienced operators described above, who were blinded as to the operator’s identity and training status. Video assessment was scored and analysed for unambiguously defined metric errors (box 1), attending takeovers, procedure time and fluoroscopy time for both groups. The mean interrater reliability (IRR) for metric assessment was 0.98 (range = 0.88–1.0).

**Statistical power calculations**

Power calculations were based on a previous VR to OR study using an almost identical experimental design. Previous studies...
found that the mean number of errors enacted by the VR trained group was 1.9 (SD=0.5) and by the Standard trained group was 7.38 (SD=2) with eight subjects in each group, that is, a 74.3% difference. Thus the statistical power of a 40% difference between the groups was calculated for N=6 in each group (ie, VR trained group hypothesised mean=4.428 (SD=2.0) vs Standard trained group mean=7.38 (SD=2), an α of 5%, a β of 50%) was found to be 95.1% for a two-tailed test.

This study was an investigation of a training technique, and thus there was no deviation in patient care from the normal standard of care in a teaching hospital. The patients were selected for CA. Anatomic exclusions criteria from the training process were patients who exhibited complex anatomic subsets deemed too difficult by the trainer for the primary operator.

**RESULTS**

The mean amount of time to perform the carotid artery angiography (CA), fluoroscopy time and operator intraoperative errors are shown in [figure 3](#). Differences between the groups were compared with one-factor analysis of variance (ANOVA). Cardiologists trained to proficiency on the simulator (group A) performed the procedure faster (CI 18.13 to 35.67 vs 24.47 to 40.21) and used less fluoroscopy time (CI 10.82 to 16.48 (CI vs 12.58 to 22.13) than colleagues who were not trained on the simulator (group B) but not statistically significant better (procedure time F (df=1, 10)=1.41, p=0.262; fluoroscopy time F...
This means that the trainees are given proximate formative as well as summative performance feedback which enhances and speeds the learning process. Gallagher has proposed that simulation should be defined as (1) an artificially created or configured ‘learning’ situation that allows for the practice or rehearsal of all or salient aspects of a procedure. Crucially, the artificial learning situation should (2) provide the span of appropriate sensory responses to learner physical actions that are behaviourally consistent with what would be experienced in real life (including the opportunity to enact both appropriate and inappropriate learner actions (ie, errors)). The simulation should also afford the opportunity to (3) perform the procedure (4) in the same order and (5) with the same devices with which the procedure would normally be performed. Thus, the fidelity of the VR simulation and correct simulation curriculum are critical for appropriate skills transfer to the trainee. That said, simulation-based training will never completely replace the in vivo clinical training experience. Rather, the function of simulation-based training (with the highest fidelity that is reasonably achievable) is to supplant the early part of the learning curve.

ighthall et al reported operator outcomes in 24 701 procedures by 2339 operators for carotid artery stenting with embolic protection and showed a clear operator annual volume/outcomes relationship. Evidence now shows that procedural skills can be maintained with intermittent VR simulation training. VR simulation models for skills training work because they provide a context, organisational structure and focus so as to allow for information to be easily retrieved from long-term memory. Interventionists can also practise/rehearse the sequencing of psychomotor skills to complete the task effectively, efficiently and safely with a highly structured, proximate, formative performance feedback, thus reducing the rate of skills loss that would naturally occur with non-use.

The implications of the study reported here are considerable for new procedural skill acquisition as well as for maintenance of skills and competency assessment in procedure-based medicine disciplines. There is a growing body of evidence suggesting that the relationship between outcomes and procedure volume may not be as straightforward as previously thought and may in fact be better correlated to skill levels as well as other factors related to hospital quality controls and the support systems available for the delivery of care. One of the limitations of this study is that we relied on the volume of procedure experience as a surrogate for skills. The clinicians who participated were, however, so experienced with angiographic and interventional procedures that excellent ‘procedure’ skills were a reasonable inference. In addition, our study suggests that the additional use of high fidelity VR simulation can afford very experienced practising physician operators with the opportunity to acquire and maintain new procedural skills.

One of the limitations of this study was the small subject numbers, though even with small subject numbers the results demonstrated a large effect size which replicates the findings of previous studies but in different contexts. Additionally, although there was widespread enthusiasm expressed for the study by many colleagues, they were less forthcoming about enrolling and engaging in a randomised training study which objectively measured operator performance. This fact has implications and insight into an important issue, explaining why there might be resistance by very experienced physicians in learning new procedural skills in a more formal, quality-assured setting where actual operator skill and measured performance are assessed.
CONCLUSIONS
This report is the first study in medicine to demonstrate in a prospective, blinded and randomised way that experienced physician operators can be trained in a new procedure on a VR simulator and that the VR training improves the operator’s procedural skills and transfers those improved skills to performance of that new procedure on actual patients. The results from this study have implications for new procedural skill acquisition. They suggest that full physics VR simulation may be a more effective way of very experienced physicians acquiring the skills for performance of a procedure novel to them. To date, simulation training has primarily been aimed at skill acquisition for less experienced operators. The data from this study suggest that this technology may have wider applications.

Contributors
CUC and AGG were responsible for study design and data collection. CUC, LL and AGG were responsible for data analysis, writing the manuscript, results interpretation, paper critical revisions and agreed on final draft.

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REFERENCES