Efficient Implementation of Patient-specific Simulated Rehearsal for the Carotid Artery Stenting Procedure: Part-task Rehearsal

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Abstract Objective(s): Patient-specific simulated rehearsal (PsR) is a technological advance within the domain of endovascular virtual reality (VR) simulation. It allows incorporation of patient-specific computed tomography Digital Imaging and Communications in Medicine (CT DI-COM) data into the simulation and subsequent rehearsal of real patient cases. This study aimed to evaluate whether a part-task rehearsal (PTr) of a carotid artery stenting procedure (CAS) on a VR simulator is as effective as a full-task (FTr) preoperative run through.

Methods: Medical trainees were trained in the CAS procedure and randomised to a PTr or FTr of a challenging CAS case (Type-II arch). PTr consisted of 30 min of repeated catheterisations of the common carotid artery (CCA). Thereafter, both groups performed the CAS procedure in a fully functional simulated operating suite (SOS) with an interventional team. Technical performances were assessed using simulator-based metrics and expert ratings. Other aspects of performance were assessed using the Non-Technical Skills for Surgeons (NOTSS) scoring.

Results: Twenty trainees were evenly randomised to either PTr or FTr. No differences in performance were seen except for the total time the embolic protection device (EPD) was deployed (9.4 min for the PT vs. 8.1 min for the FT, p = 0.02). Total time (26.3 vs. 25.5 min, p = 0.94), fluoroscopy time (15.8 vs. 14.4 min, p = 0.68), number of roadmaps (10.5 vs. 11.0, p = 0.54), amount of contrast (53.5 vs. 58.0 ml, p = 0.33), time to deploy the EPD (0.9 vs. 0.8 min, p = 0.31) and time to catheterise the CCA (9.2 vs. 8.9 min, p = 0.94) were

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similar. Qualitative performances as measured by expert ratings (score 24 vs. 24, \( p = 0.49 \)) and NOTSS (\( p > 0.05 \) for all categories) were also comparable.

Conclusions: Part- and full-task rehearsals are equally effective with respect to the operative performance of a simulated CAS intervention. This finding makes a patient-specific rehearsal more efficient and may increase the feasibility of implementation of this technology into medical practice.

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Introduction

Virtual reality (VR), patient-specific rehearsal of endovascular procedures is a recent technological advancement in the field of medical simulation. By incorporation of patient-specific computed tomography (CT) or magnetic resonance imaging (MRI) data, it allows interventionalists to rehearse, plan and address problems related to their own specific patients in a preoperative simulated and risk-free environment.\(^1\)

In the endovascular domain, this new technology has initially been developed for the carotid artery stenting (CAS) procedure. This seems logical as CAS represents a high-risk procedure, which, in itself, carries the risk of causing a stroke. It is well established that the outcome after CAS is dependent on multiple factors, none the least on the expertise and preparation of the operator performing the procedure.\(^2,3\) Therefore, a tool, such as procedure rehearsal, may enhance individual operator experience, aid the planning of these complex procedures and ultimately prove beneficial for patients undergoing CAS procedures.

Research into patient-specific or procedure rehearsal for CAS has already shown that it is feasible to set up and conduct these kinds of rehearsals in the clinical setting and that these simulations resemble the real operation.\(^4-7\) Furthermore, full-task, patient-specific rehearsal has shown to be more effective than no preparation at all for novice interventionalists performing the CAS procedure in a simulated environment.\(^8\) However, as with the introduction of any new technique or technology, the challenge with procedure rehearsal is how to successfully incorporate it into daily medical practice. Several factors can impede this incorporation, of which time constraints on the part of the interventionalist and his or her team might be the most significant.

The purpose of the current study is to determine whether part-task patient-specific VR rehearsal is as effective as a full-task patient-specific VR rehearsal with regard to technical outcome and other elements of performance of interventionalists carrying out the CAS procedure. If so, focussing this technology on specific parts of the operation could make the process of patient-specific VR rehearsal less time-consuming and more efficient. This may increase the likelihood of successful incorporation of the technology into a real-life setting as a preoperative, preparatory tool.

Materials and Methods

Subjects

A total of 20 junior medical residents (surgery, radiology and cardiology) were recruited. All had prior experience in an interventional or surgical setting as an operator or assistant. After an extensive training programme in CAS (see below), all were included into the trial. All participants gave prior informed consent.

Simulator device

The AngioMentor\textsuperscript{TM} Express (Simbionix USA Corp., Cleveland, OH, USA) simulator was used to conduct both the preoperative part-task and full-task simulated patient-specific simulation (Fig. 1). The actual ‘real’ case was also performed on the same simulator, set up in the simulated operating suite (SOS). The Simbionix PROcedure\textsuperscript{TM} rehearsal studio software was used to create the three-dimensional (3D) reconstruction of the patient-specific case.

CAS training

All participants underwent standardised training in CAS prior to the inclusion into the trial and data collection. Participants were trained with both a cognitive and technical module. Each participant attended a 25-min video lecture on carotid artery disease and stenting. The content was based on the training requirements identified by expert consensus,\(^9\) and the video was approved by two independent experts in the field of CAS for content and quality. Simulator training consisted of 10 generic CAS simulations under supervision. Feedback was provided based on the objective simulator metrics, procedure steps, advice on technique and observed procedural errors using documented techniques.\(^10\) Ten repetitions were chosen for the
technical training programme, as pilot participants in a previous study reached a training plateau in less than seven interventions during their learning curve for CAS. As strict proficiency measures for the CAS procedure are not available in the literature at present, a potentially superior training programme based on these proficiency measures was not possible.

Study design

A randomised study design was used (Fig. 2). After completion of training, each participant was randomised using the closed-envelope technique to either a part-task or full-task rehearsal. Thus, after randomisation, each group consisted of 10 participants.

Both the part-task and full-task rehearsal took place in a VR simulation skills laboratory (Fig. 1). The part-task consisted of 30 min of catheterising the common carotid artery (CCA) of the specific patient case on the simulator, with an assistant present (WW). The participants were allowed to catheterise the CCA as many times as they wished, with different endovascular material, if requested. A time period of 30 min was chosen, as this corresponded with the average time three pilot participants had taken to complete the whole procedure. The full-task rehearsal consisted of one start-to-finish run through of the patient-specific case on the simulator in the skills laboratory. This rehearsal was only conducted once, as it would seem unlikely that, in a real-life setting (with time constraints), an interventionalist would perform multiple full-length rehearsals.

Immediately following the part- or full-task rehearsal in the laboratory, each participant was transferred to the SOS where, in full scrubs, they performed the ‘real’ procedure (using the patient-specific case) with an interventional team present consisting of a scrub nurse, circulating nurse and radiographer.

Simulated case

The real patient case was a 72-year-old male with a type II arch and asymptomatic 90% stenosis of the right internal carotid artery (ICA). The clinically relevant anatomy was obtained from the patient’s CT angiogram and a 3D model was created using PROcedure Rehearsal Studio software’s (Simbionix, Cleveland, OH, USA) volume-rendering technique described extensively in a previous report. The type II arch made this case more difficult than a standard type I arch with regard to access and cannulation of the CCA (Fig. 3).

Simulated interventional team and SOS

All ‘real’ patient-specific CAS cases were performed in the SOS with an interventional team present (Fig. 4). The interventional team consisted of a scrub nurse (WW), a radiographer and a circulating nurse. All team members were medical trainees, familiar with endovascular simulation and real CAS procedures in the clinical setting (procedure steps, endovascular material and use of fluoroscopy), as they had been involved in the set-up of two previous simulation studies in the field of CAS.

At the Department of Biosurgery and Surgical Technology, Imperial College London, the SOS is available for training, assessment and research purposes. The facility integrates the state-of-the-art operating theatre with the latest technologies and is fully equipped, including an operating table and mobile C-arm. A moderate fidelity anaesthetic mannequin simulator (SimMan, Laerdal, UK) allows, amongst others, modification of cardiac rhythm and blood pressure. The level of immersion was further increased by adding audiovisual cues, such as background music from a radio and sounds related to the opening and closing of doors.

Video and audio recordings of team interactions and interventionalists’ performance are accomplished by four ceiling-mounted cameras. The multiple streams of audio and video data are recorded and enable those present in the control room to view the data in real time or to conduct post hoc video analysis.

Assessment

Technical

Simulator-derived dexterity metrics were recorded. These included total procedure time, fluoroscopy time, contrast
volume and number of roadmaps. Video recordings were made of the fluoroscopy screen and hand movements of all the simulated CAS procedures. As videos only showed the hands of the interventionalists, the identity of the participants was not revealed during playback. These videos were reviewed blindly in a random order (WW and FC) and rated with the Objective Structured Assessment of Technical Skills (OSATS)-derived generic endovascular (Global Rating Scale, GRS) and procedure-specific rating scales (PSRS) for CAS to assess the quality of the interventionalists’ performance. The specifics and content of these two rating scales are discussed in detail in previous reports.12 The Imperial College Complex Cannulation Scoring Tool (IC3ST) scale was used to rate the quality of the cannulation of the arch vessels. The construct validity of the IC3ST scale has also been previously tested in a carotid artery cannulation model, demonstrating significant differences in IC3ST scores between operator groups of varying endovascular experience (i.e. construct validity) (unpublished data). The videos were also used to track the time taken to catheterise the CCA and the ICA and the total time the embolic protection device was deployed in the ICA.

Non-technical skills for surgeons (NOTSS) ratings
Video recordings were made from four angles using the SOS-installed video cameras. Two concentrated on the operating suite and team interactions, and two concentrated on the performance of the interventionalist alone. These video

Figure 3  Screenshots of the (simulated) patient-specific CAS case.

Figure 4  ‘Real’ case in the simulated operating suite at The Department of Biosurgery and Surgical Technology, Imperial College London.
feeds were used for post hoc analysis of the non-technical skills of the participants using the NOTSS (Non-Technical Skills for Surgeons) rating scale, reviewed blindly by two independent raters (DN and TM) trained in using the scale. NOTSS is a validated behaviour-rating system for interventionalists/surgeons and allows for structured observations of non-technical aspects of performance in four categories: Situation Awareness, Decision Making, Communication/Teamwork and Leadership. For each category, points are given on a 4-point rating scale: 4 good, 3 acceptable, 2 marginal, 1 poor and N/A not applicable.13

Face validity and self-assessment
After completion of the ‘real’ case, the participants completed a questionnaire evaluating their subjective assessment on the face validity of both the SOS and simulated procedure, and usefulness of the rehearsal activities. Questions were answered on a 5-point Likert scale, with 1 representing a negative response and 5 a positive response. With the validated short version of the State Trait Anxiety Inventory (STAI) questionnaire, the emotional, cognitive and physical stress was recorded by participants’ self-report.14 The STAI questionnaire consists of six items on a 4-point scale, which participants use to self-report how stressed they feel before, during and after the endovascular task. Total STAI scores range between 6 (minimum) and 24 (maximum), with higher scores indicating increased psychological stress.

Data analysis
Data were analysed with the Statistical Package for the Social Sciences version 17.0 (SPSS, Chicago, IL, USA) using non-parametric tests. Learning curves were analysed with the Friedman test. The effects of the two types of preoperative rehearsal were compared using the Mann–Whitney U test. Inter-rater reliability between the two video assessors was calculated with the Cronbach’s alpha (cr α) statistic. A p < 0.05 is considered statistically significant for the metrics and a Cronbach’s alpha of >0.700 as reliable for the video assessment. All data are presented as medians, unless otherwise indicated.

Results

Participant demographics
The characteristics of the recruited medical trainees are summarised in Table 1. Both groups of 10 participants (part- and full-task rehearsal) did not differ in baseline characteristics.

Training
Significant learning curves were demonstrated between the first and 10th CAS training sessions for total procedure time (median of 31.9 vs. 14.9 min, p < 0.0001), fluoroscopy time (13.8 vs. 7.7 min, p < 0.0001) and contrast volume (75.0 vs. 48.5 ml, p < 0.0001) but not for the number of roadmaps (10 vs. 9, p = 0.1220), which was relatively consistent. Plateau levels were reached for fluoroscopy time after seven sessions and after four sessions for contrast volume. No statistically significant plateau was reached for the total procedure time.

Performance metrics

Technical
There was no statistical difference in the performance between the part- and full-task rehearsal group with regard to the dexterity or qualitative metrics (Figs. 5 and 6). The part- and full-task rehearsal group performed the procedure in the same total time (median of 26.3 vs. 25.5 min, p = 0.940, respectively), using the same amount of fluoroscopy (15.8 vs. 14.4 min, p = 0.677), contrast (53.5 vs. 58.0 ml, p = 0.325) and number of angiographies (10.5 vs. 11.0, p = 0.535). There was no significant difference in time to deploy the embolic protection device (EPD) (0.9 vs.

<table>
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<tr>
<th>Table 1</th>
<th>Demographics of all study participants. Where applicable numbers are average ± standard deviation.</th>
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<td>Cardiology</td>
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<tr>
<td>Radiology</td>
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<tr>
<td>Endovascular procedures performed independently</td>
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<tr>
<td>Total</td>
<td>15 ± 31</td>
</tr>
<tr>
<td>Prior Endovasc. Sim. experience (# of participants/10)</td>
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0.8 min, \( p = 0.307 \) and time to catheterise the CCA (9.2 vs. 8.9 min, \( p = 0.940 \)) between the two preoperative strategies. However, the full-task rehearsal group did have a shorter time period in which the EPD was present in the ICA (9.4 vs. 8.1 min, \( p = 0.019 \)).

Furthermore, there was no difference in the quality of performance with regard to generic endovascular skills (GRS score 25 vs. 28, \( p = 0.495 \)), CAS procedure-specific skills (PSRS score 24 vs. 24, \( p = 0.569 \)) or quality of the carotid cannulation (IC3ST score 27 vs. 27, \( p = 0.596 \)). Much like in other reports on endovascular simulation, the sample size of 20 participants did not rule out a potential type II error. The inter-rater reliability was high for the GRS (cr \( \alpha = 0.72 \)) and IC3ST scale (cr \( \alpha = 0.82 \)) and moderately so for the PSRS scale (cr \( \alpha = 0.66 \)).

**NOTSS scores**
Both the part- and full-task rehearsal group scored acceptable scores in all categories of NOTSS (Fig. 6). There was no statistical difference between part-task and full-task for situation awareness (median of 3.0 vs. 3.2, \( p = 0.392 \)), decision-making (3.0 vs. 3.0, \( p = 0.379 \)), communication/teamwork (3.0 vs. 3.5, \( p = 0.379 \)) and leadership (2.3 vs. 3.8, \( p = 0.201 \)).
The inter-rater reliability was high for all categories: situation awareness (cr α 0.860), decision-making (cr α 0.930), communication/teamwork (cr α 0.936) and leadership (cr α 0.936).

Face validity and self-assessment
Overall, all participants found the simulated procedure, environment, team and patient case highly realistic (average score 4/5).

There was no difference between the two groups in how effective they considered their preoperative rehearsal strategy to be (p < 0.05 for all categories): both groups scored high (5/5) on how effective they considered the rehearsal at preparing them for the case, how it effective it is in increasing the operative flow (4/5), how it enhanced their decision-making process and their confidence and reducing their anxiety (5/5). All participants agreed that the preoperative rehearsal had aided them in their choice of selective catheter, sheath and fluoroscopy angle (score 5/5 for all). Other endovascular material was not evaluated, as the part-task group had not rehearsed with these tools. Both groups scored similarly in how effective they judged the rehearsal to enhance the communication with the assistant (4/5), radiographer (4/5) and circulating nurse (3/5).

The STAI results for both groups can be seen in Table 2. As can be appreciated, there is no difference in the subjective sense of pre-, intra- or postoperative stress levels between the part- or full-task rehearsals. Thus, one of both preoperative strategies did not appear to be more effective than the other in influencing stress levels.

Discussion

In the present study, for novice interventionalists performing a moderately difficult CAS case in a high-fidelity simulated environment, part-task patient-specific rehearsal proved to be as effective as a full-task run through with respect to both the technical and other elements of operative performance. Therefore, some elements of the rehearsal can be considered redundant and discarded without affecting the overall effectiveness of the rehearsal activity. For both strategies, the dexterity metrics, such as the total procedure time and fluoroscopy time, and the qualitative standard to which the procedure was performed, was equivalent. Furthermore, scores reflecting performance in situation awareness, decision-making, communication/teamwork and leadership were also equal. The catheterisation of the CCA was chosen as the part-task, as this arguably constitutes one of the most important steps of the CAS procedure. This step was practiced preoperatively for the same duration as the full-task preoperative run through, to allow for a reliable comparison of both preoperative strategies. Further research could reveal whether the number of times the part-task needs to be repeated can be reduced without detrimental effects on procedural outcome. This would increase the efficiency of procedure rehearsal by minimising the time necessary to both create and execute a worthwhile preoperative rehearsal.

The only metric that did show a significant difference was the total time the EPD was deployed in the ICA. This was shorter in the full-task rehearsal group as they required less time to choose the correct stent and balloon, as they had evaluated that step in the preoperative setting. The time saved by this step was, however, offset by the faster catheterisation of the CCA by the part-task group. Furthermore, the part-task group recorded a narrower interquartile range for this metric, signifying they performed the catheterisation of the CCA more consistently as a group (Fig. 5). One can speculate that in cases with more difficult access to the ICA, such as with a type III aortic arch or tortuous carotid vessels, part-task rehearsal might lead to an improved performance as it concentrates on the step most difficult and prone to causing perioperative embolic events.

Procedure rehearsal has been shown to be feasible to set up in the clinical setting,1 to influence interventionalists in their tool choice for complex procedures and to resemble real procedures to a high degree.4–9 More importantly, there is data to suggest that a full-task CAS procedure rehearsal can increase the performance of novice interventionalists performing patient-specific cases in a simulated environment.8 However, to ensure a successful uptake of procedure rehearsal in the endovascular domain, one must also prove that it can be effectively integrated into existing healthcare workflow processes. Part-task rehearsal can provide part of this solution, as it can minimise both the time it takes to construct a patient-specific simulation and also reduce the time to perform a worthwhile rehearsal by concentrating on key elements of a procedure. As in other high-performance industries (the military, sports and aviation), the successful incorporation of this kind of preprocedural technology can eventually play a role in enhancing procedural performance and increasing safety for those involved.15,16 Procedure rehearsal seems particularly appropriate for the CAS procedure, as CAS constitutes a high-risk and technically demanding endovascular procedure for which the outcome is, amongst others, dependant on the experience and expertise of the operator.2,3,17–21

Improving operator experience in CAS is an area where endovascular VR simulation and patient-specific VR rehearsal can play an important role. Previous studies have

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<th>STAI</th>
<th>Part-task</th>
<th>Full-task</th>
<th>p-Value</th>
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<td>11.80 ± 0.39</td>
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<td>STAI intra</td>
<td>13.60 ± 0.37</td>
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<td>STAI post</td>
<td>14.00 ± 0.33</td>
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shown that generic endovascular simulation can improve the performance of interventionalists performing virtual CAS procedures and shorten their learning curves. Patient-specific rehearsal is an excellent adjunct to generic VR training and can tailor the training to specific patients who will undergo an intervention. It has already been suggested that the success of any carotid revascularisation strategy will lie in a tailored approach to each specific patient as opposed to a one-operation-fits-all strategy. This tailored approach entails the use of stents, EPDs and selective or guiding catheters individually selected for patients based on specific device characteristics and vascular anatomy presentations. Procedure rehearsal may aid the inexperienced interventionalists and their team in this patient-tailored approach and minimise the peri-procedural embolic risk and optimise CAS for the patient. Much like a recent expert-derived anatomic scoring system for CAS, procedure rehearsal could also guide interventionalists in choosing appropriate cases for the CAS procedure, with the additional benefit of being able to practice real patient cases until proficiency is reached.

In conclusion, the results from the present study indicate that for a moderately difficult CAS case, performed by inexperienced interventionalists, a part-task patient-specific VR rehearsal is as effective as a full-task run with regard to the operative performance. This finding potentially makes a patient-specific rehearsal less time-consuming and increases the feasibility of implementing this technology in daily medical practice. Successful incorporation of this kind of technology in multiple domains, such as for carotid, aortic and coronary interventions, could eventually increase safety and minimise complications for patients undergoing standard and more complex procedures.

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