From the Society for Vascular Surgery

Computer simulation as a component of catheter-based training

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Introduction: **Computer simulation has been used in a variety of training programs, ranging from airline piloting to general surgery. In this study we evaluate the use of simulation to train novice and advanced interventionalists in catheter-based techniques.**

Methods: **Twenty-one physicians underwent evaluation in a simulator training program that involved placement of a carotid stent. Five participants were highly experienced in catheter-based techniques (>300 percutaneous cases), including carotid angioplasty and stenting (CAS); the remaining 16 participants were interventional novices (<5 percutaneous cases). The Procedicus VIST simulator, composed of real-time vascular imaging simulation software and a tactile interface coupled to angiographic catheters and guide wires, was used. After didactic instruction regarding CAS and use of the simulator, each participant performed a simulated CAS procedure. The participant's performance was supervised and evaluated by an expert interventionalist on the basis of 50 specific procedural steps with a maximal score of 100. Specific techniques of guide wire and catheter manipulation were subjectively assessed on a scale of 0 to 5 points based on ability. After evaluation of the initial simulated CAS procedure, each participant received a minimum of 2 hours of individualized training by the expert interventionalist, with the VIST simulator. Each participant then performed a second simulated CAS procedure, which was graded with the same scale. After completion, participants assessed the training program and its utility via survey questionnaire.**

Results: **The average simulated score for novice participants after the training program improved significantly from 17.8 ± 15.6 to 69.8 ± 9.8 ($P < .01$), time to complete simulation decreased from 44 ± 10 minutes to 30 ± 8 minutes ($P < .01$), and fluoroscopy time decreased from 31 ± 7 minutes to 23 ± 7 minutes ($P < .01$). No statistically significant difference in score, total time, or fluoroscopy time was noted for experienced interventionalists. Improvement was noted in guide wire and catheter manipulation skills in novices.. Analysis of survey data from experienced interventionalists indicated that the simulated clinical scenarios were realistic and that the simulator could be a valuable tool if clinical and tactile feedback were improved. Novices also thought the simulated training was a valuable experience, and desired further training time.**

Conclusions: **An endovascular training program using the Procedicus VIST haptic simulator resulted in significant improvement in trainee facility with catheter-based techniques in a simulated clinical setting. Novice participants derived the greatest benefit from simulator training in a mentored program, whereas experienced interventionalists did not seem to derive significant benefit. (J Vasc Surg 2004;40:1112-7.)**

The use of simulation technology is well established in many industries outside of medicine as part of training programs for high-risk situations. In the fields of aviation and aeronautics[1,2] simulators have been demonstrated to improve pilot skills[3,4]; similarly, simulation exercises are used to train personnel in nuclear plant[5] and military operations.[6] The major advantage to this approach is the ability to place a trainee in a graphic scenario and provide real-time feedback and discussion of actions and consequences without risk for harm.

Simulators were first used to train medical personnel in the field of anesthesiology with the SIM I system[7] and have evolved to encompass a variety of fields including laparoscopy[8], endoscopy[9], and trauma.[10] The field of laparoscopic surgery quickly embraced the use of simulation technology to train both residents and practicing surgeons, and recent studies have documented that training surgical residents to do a laparoscopic cholecystectomy with a virtual reality laparoscopic simulator led to improved operative performance.[11] This successful model emphasizes the idea that the traditional apprenticeship model of training is not the only way to teach procedural skills. The extension of this technology to teaching endovascular techniques has now been proposed.[12]

The effectiveness of an endovascular simulator for instruction of novice and experienced interventionalists was evaluated in this study. The simulator was also assessed for realistic performance commensurate with actual clinical practice.

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MATERIALS AND METHODS

Simulation device. The Procedicus VIST system (Mentice AB) is a multimedia device designed to simulate endovascular techniques in a variety of clinical scenarios, including carotid stenting. The system consists of a standard desktop personal computer (Intel Xeon, 2.66 GHz, 1 Gb RAM, nVIDIA GeForce4, Ti 4200, with AGP 8X) with software that contains a 3-dimensional representation of the human arterial system. This is coupled to a haptic module that uses a force feedback system that provides tactile sensory information when the user inserts and manipulates standard angiographic catheters and guide wires. The term haptic, defined as pertaining to the sense of touch, or tactile, refers to the simulator module ability to provide tactile feedback to the participant, which is an essential component of performing an endovascular procedure. For example, if too much forward force, or torque, is applied to a guide wire, the haptic module will make further manipulation increasingly difficult. Separate devices are attached that simulate the injection of contrast dye, performance of angioplasty, deployment of stents, and performance of fluoroscopy with digital subtraction angiography. The instructional system is displayed on a touch screen monitor that also allows for selection of devices and catheters for the simulation. A simulated fluoroscopic image is displayed on a second monitor (Fig 1).

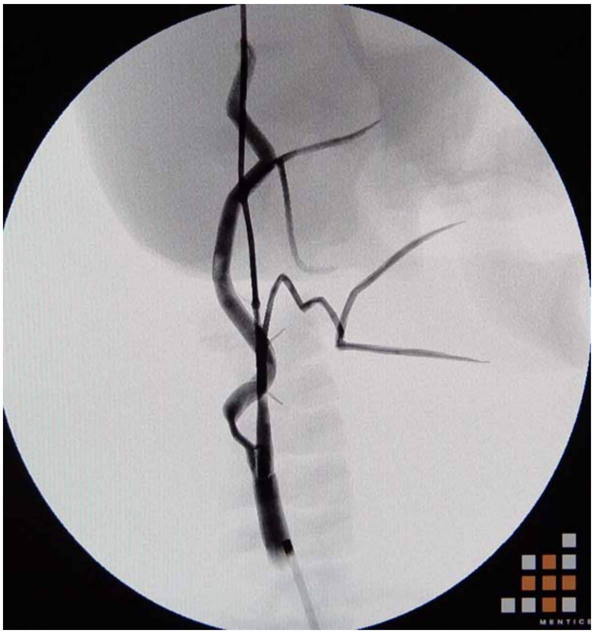

Fig 1. Simulated digital subtraction angiogram of common carotid artery shows lesion in internal carotid artery.

Study design. The study was designed to assess the utility of simulation for participants with various degrees of proficiency in endovascular techniques. Twenty-one physicians were enrolled, consisting of 16 general surgery residents who had performed fewer than 5 percutaneous angiographic procedures and 5 vascular surgeons, each with experience in greater than 300 peripheral interventions, including carotid angioplasty and stenting (CAS). No interventional radiologists or interventional cardiologists were enrolled in the study. Each participant was evaluated in 3 ways. First, the participant's performance of a simulated CAS was graded by a single experienced interventionalist using a checklist of 50 steps required for completion of the procedure (Table I). The maximum attainable score derived from the checklist was 100. Maneuvers that could cause an adverse event such as dissection or perforation, and failure to perform a procedural step resulted in loss of up to 2 points. Second, time to complete the CAS, fluoroscopy time, and amount of dye used was tabulated by the simulator and recorded for each participant. The participants were given a maximum of 45 minutes to complete the scenario. Third, the instructor subjectively evaluated the participant's technical ability in 4 areas, on a scale of 0 to 5: guide wire manipulation, catheter manipulation, catheter exchanges, and monorail balloon technique.

All participants received introductory didactic instruction on the use of the simulator and the techniques for carotid stenting. Each participant was then evaluated as described, during performance of the initial simulated CAS procedure, followed by a minimum of 2 hours of training on the simulator with the expert interventionalist. The overall instruction time was 142 ± 26 minutes (range, 120-169 minutes). Training, by necessity, was individualized, and the object of training was acquisition of catheter-based skills, not time spent on the simulator. Specific instruction on guide wire manipulation, arteriography, selection of vessels, methods of catheter exchange, and angioplasty and stent deployment were given. The instructor did not include training on operating the simulator that was not clinically relevant to CAS. Each participant then performed a second graded CAS simulation. All participants were evaluated and instructed by the same interventional vascular surgeon in all aspects of the study, and all participants completed an exit questionnaire (Table II, online only). Questions specifically addressed to the advanced interventionalists were designed to determine whether advanced participants considered the simulator realistic and useful for teaching beginner and advanced catheter interventions. Participants rated their opinions with a Likert scale from 1 to 5 (1, strongly disagree; 2, disagree, 3, neutral; 4, agree; 5, strongly agree).

Statistical methods. Data obtained before and after training, and questionnaire data from all participants were entered into a database and subsequently analyzed. The paired 2-tailed Student *t* test was used to analyze each participant's change in score, time, and amount of contrast dye used, before and after instruction. Analysis of variance (ANOVA) was performed to assess statistically significant differences in scores obtained between the novice and expert groups. All values are represented as mean ± SD, and mean differences and correlations were considered significant at $P < .05$.

Table I. Checklist of precedural steps*

1. Select 0.035-inch guide wire.
2. Advance into aortic arch.
3. Advance into ascending aorta with directional catheter.
4. Advance flush catheter into ascending aorta.
5. Remove guide wire.
6. Change orientation to 24-45 degrees left anterior oblique.
7. Inject contrast dye with patient breathhold (25 mL/s for 25-mL volume).
8. Exchange for selective catheter (eg, V-Tek, Vert).
9. Select appropriate carotid artery with 0.035-inch guide wire and selective catheter.
10. Obtain selective views.
11. Obtain views in 2 planes.
12. (Lose point for crossing lesion with 0.035-inch guide wire.)
13. Advance guide wire into external carotid artery.
14. Advance catheter over guide wire to external carotid artery.
15. Maintain access to external carotid artery during insertion of guide wire and catheter.
16. Exchange catheter without losing guide wire access.
17. Advance interventional sheath into common carotid artery over guide wire.
18. Follow progress of sheath from aorta to common carotid artery.
19. Stop advancing sheath proximal to carotid bifurcation.
20. Obtain selective views.
21. Obtain intracranial views.†
22. Advance embolic protection device.
23. Cross lesion safely.
24. (Lose point for excessive manipulation.)
25. Deploy embolic protection device.
26. Deployed embolic protection device in straight segment of internal carotid artery.
27. (Lose point for deploying prematurely.)
28. Obtain angiogram to confirm apposition to vessel wall.
29. Obtain angiogram in 2 planes.
30. (Lose point for excessive filter manipulation.)
31. Advance pre-dilation balloon.
32. Center balloon over lesion.
33. Choose correct size balloon.
34. Inflate and deflate balloon correctly, without abrupt or sudden changes.
35. Insert stent.
36. Choose correct size stent.
37. Center stent over lesion.
38. Deploy stent without excessive manipulation.
39. Maintain stent position during deployment.
40. Remove stent under fluoroscopic guidance.
41. Insert post-dilation balloon.
42. Center balloon over lesion.
43. Choose correct size balloon.
44. Inflate and deflate balloon correctly, without abrupt or sudden changes.
45. Remove balloon under fluoroscopic guidance.
46. Obtain completion angiogram.
47. Insert embolic protection device recovery sheath.
48. Recapture embolic protection device.
49. Remove embolic protection device and recovery sheath under fluoroscopic guidance.
50. Obtain completion angiograms in 2 views.
51. Assess for spasm.
52. Assess for dissection.
53. Assess for residual stenosis.
54. Obtain intracranial views.†

*Positive steps worth 2 points; deduct 2 points for negative steps.

†Indication by participant that intracranial views were necessary counts as completion of this step.

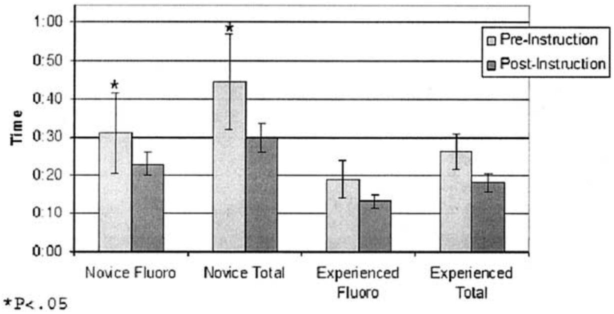

Fig 2. Improvement in total time and fluoroscopy *(fluoro)* time used to complete simulation for novice and experienced interventionalists before and after instruction. Note significant improvement only in novice group.

RESULTS

Comparison of recorded simulator data obtained from novice and experienced interventionalists before receiving instruction revealed that novices required more time to complete the simulation (44 ± 10 minutes vs 26 ± 12 minutes; $P < .05$) and greater fluoroscopic time (31 ± 7 minutes vs 19 ± 10 minutes; $P < .05$; Fig 2). After instruction, novices required less total time to complete the scenario (30 ± 8 minutes), but this was still greater than that of the experienced surgeons (18 ± 4 minutes; $P < .05$). Novices also were able to reduce fluoroscopy time (23 ± 7 minutes) after instruction, though experienced interventionalists required even less time (13 ± 5 minutes $P < .05$; Fig 3). No difference was noted in amount of contrast dye used before instruction ($P = .29$) or after instruction ($P = .07$) between novice and experienced groups.

Novice interventionalists. Before instruction, 10 of 16 participants (62.5%) could not complete the simulation within the 45-minute time allotment, and 4 of 16 (25%) completed the scenario, but with manipulations that would have caused significant morbidity. Only 2 of 16 participants (12.5%) completed the simulation without major adverse event. For novice participants the procedure score improved from 17.8 ± 15.6 to 69.8 ± 9.8 ($P < .01$), time to complete simulation improved from 44 ± 10 minutes to 30 ± 8 minutes ($P < .01$), fluoroscope time decreased from 31 ± 7 minutes to 23 ± 7 minutes ($P < .01$), and amount of contrast dye used decreased from 64 ± 8 mL to 51 ± 6 mL ($P < .01$; Fig 4). All participants completed the simulation within the allotted time.

Statistically significant improvements were noted in the subjective scoring of catheter and guide wire manipulation techniques. Catheter manipulation techniques were improved from 1.33 to 3.5 ($P < .01$), guide wire manipulation from 1.11 to 3.39 ($P < .01$), catheter exchanges from 1.06 to 3.61 ($P < .01$), and monorail technique from 0.83 to 3.28 ($P < .01$).

Experienced interventionalists. After receiving instruction, experienced interventionalists did not demonstrate statistically significant improvement in procedure

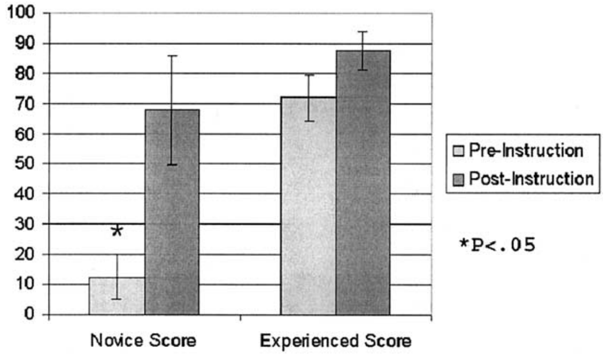

Fig 3. Change in simulator score for novice and experienced interventionalists after instruction. Note significant improvement only in novice group.

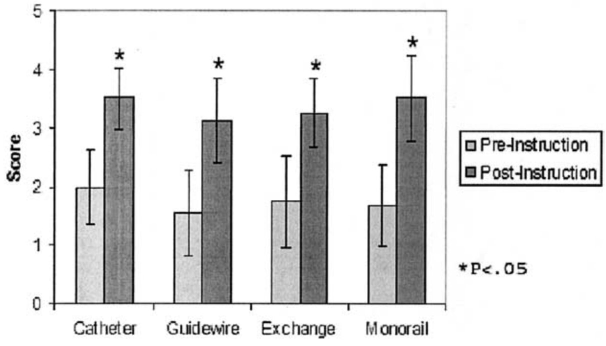

Fig 4. Improvement in subjective areas of catheter manipulation, guide wire manipulation, catheter exchange, and monorail technique in novice group.

score, time to complete the simulation, fluoroscopy time, or amount of contrast dye used (Figs 2 and 3). All participants completed the simulation without major adverse event. No statistically significant improvement was found in the subjective scores for catheter and guide wire manipulation.

Questionnaire data. A questionnaire was administered to all participants after completion of the simulation. In the group of experienced interventionalists, 4 of 5 indicated that clinical and tactile feedback were inadequate (mean score, 1.75), and 3 of 5 indicated that the devices did not respond in a predictable and realistic manner (mean score, 2.0). All 5 experienced interventionalists indicated that the simulated clinical scenarios were realistic, and thought the simulator could be a valuable tool if clinical and tactile feedback were improved (mean score, 4.0). Four of 5 participants indicated that the simulator increased their willingness to teach catheter-based techniques with the simulator, but 4 of 5 stated that the simulator could not replace performance in a live patient. Most novice participants (14 of 16) indicated that they thought time spent on the simulator was worthwhile, and desired additional instruction.

DISCUSSION

Novice interventionalists benefit from a mentored training program using the Procedicus VIST simulator to teach catheter techniques. Improvement was seen in completion of specific steps to perform a complex percutaneous intervention, and reduction in both time to complete the procedure and fluoroscopy time. Improvement was also noted in specific techniques of catheter and guide wire manipulation, catheter exchange, and monorail technique. No statistically significant improvement in performance was noted in experienced interventionalists using the same instructional paradigm. A limitation of this study is the low number of experienced interventional vascular surgeons enrolled, which may have limited our ability to detect improvement in performance of experienced interventionalists.

A major aspect in deciding whether simulation is an adequate teaching tool is determining whether the simulator has achieved "construct validity," defined as the ability of the simulator to award performance scores that correlate with the level of technical proficiency of the practitioner.[13] In comparing procedure scores, total time, fluoroscopy time, and amount of dye used before and after instruction between the novice and expert groups, the simulator consistently reported numbers that were statistically significantly better for the experts than for the novices. This indicates that the simulator is able to accurately reflect the skill of an individual participant, and may be viewed as a valid teaching and assessment tool.

However, a major limitation of the current iteration of the endovascular simulator is that available machine-generated measures of performance are relatively limited. While it may seem that a purely objective machine analysis would be more reproducible, there is evidence that objective evaluation of technical ability, coupled with subjective grading, offers a more useful analysis.[14] Grading of performance by an instructor using checklists has proved both valid and reliable,[15] whereas subjective analysis with self-assessment is fraught with error, because participants tend to overemphasize their own abilities.[16,17] Of interest, the more sophisticated, newer generation of virtual reality laparoscopic simulators can assess both damage to surrounding tissues and economy of motion.[18] Lack of these features on the endovascular simulator mandates that a mentor or instructor be present throughout the training and assessment, to reinforce proper technique. Limitations of this study include the low number of advanced interventionalists enrolled, which may account for the lack of significant improvement with instruction noted in this group. Improvement in total time to complete the scenario and in fluoroscopy time used was noted for experienced interventionalists, but this did not achieve statistical significance. While these time measures are objective measures of performance, they alone do not indicate endovascular proficiency, and are secondary indicators of performance. An area in which the simulator was valuable was the learning of proper sequencing of endovascular procedures. This is an essential component of training, and virtual reality simulators may provide this key component of teaching.

For the Procedicus VIST simulator, immediate improvement and greater utility for participants at all skill levels could be obtained by having the simulator independently grade performance, assess whether maneuvers are overtly harmful, and provide clinical feedback. Most experienced interventionalists thought that clinical and tactile feedback provided by the simulator was inadequate, and was the greatest impediment to achieving realistic simulation. Improvement in both clinical feedback and the haptic force feedback module would enable the simulator to become a valuable teaching tool and enhance the experience for all participants. However, the ultimate goal of completely substituting training performed on the simulator for training in patients may be difficult because of the myriad anatomic and physiologic variables encountered in real life as opposed to the limited scenarios of a simulation. This remains an unsolved problem for laparoscopic simulators, which have been available and in use for several years.[19]

Preparation using simulation may enhance training within established surgical, vascular, and interventional programs, and may enable practicing physicians to rehearse new techniques in settings that do not rely on the traditional apprentice model. This has become increasingly important with the rapid and requisite incorporation of endovascular approaches by practitioners who have completed their formal training programs. Of particular significance, the initial introduction of new technology may be associated with an increase in the number of adverse events, as was seen with the rate of common bile duct injuries in early laparoscopic cholecystectomy.[20,21] Our data show that the endovascular simulator has construct validity and therefore can be an important and timely tool for instruction after formal residency training.

CONCLUSION

The Procedicus VIST endovascular simulator resulted in significant improvement in performance of catheter-based techniques for novice participants using CAS as the teaching scenario. Physicians with extensive endovascular experience did not derive significant benefit from simulator training, which was attributed to lack of clinical and tactile feedback. Enrollment of more experienced physicians may have reversed this finding; however, the simulator was still judged to be a valuable educational tool. Future studies, such as use of an inanimate or animal model, will need to be performed to determine whether techniques learned on the simulator translate to skills that are of use in the clinical setting.

DISCUSSION

Dr Sean P. Lyden (Cleveland, Ohio). Dr Faries and his colleagues have addressed a critical issue in vascular surgery that we now face, that is, dissemination of new technology, training physicians without compromising patient outcomes, and minimizing or eliminating individual learning curves. They used Procedicus VIST or Mentis simulator and accessibility of the simulator to train novice interventionalists in performing carotid stenting. The authors certainly demonstrated improved procedural scores, decreased fluoroscopy time, decreased contrast load, and subjective scorings in both catheter and wire manipulation skills. I have several questions.

Do the authors have any data that show that the improved skill of the novice with the simulator will translate to the ability to clinically perform these interventions, or have we simply proved that increased time on the simulators, or video games, improves proficiency with the simulator and doesn't translate to real clinical use? A vital function of a simulator is not only to train how to perform functions, but also the ability to troubleshoot when things go wrong. What ability to perform these functions can be built into or has been built into these devices? And is there a way to define, or have you defined, a minimum time or optimal time on a simulator to achieve these proficiencies?

Dr Peter L. Faries. With regard to translating the effects of the simulator to the clinical scenario, we have not established that with the current study. Future studies would need to be designed to enable that to be accomplished. Studies of that type have been done in certain areas. In aviation, simulators have been demonstrated to be a potentially successful tool in training, and are widely utilized. Similarly, in surgical laparoscopy, training has been shown to reduce the learning curve. So I think the potential is there for the tool to be utilized in that fashion, but that its utility remains to be demonstrated.

The use of the simulator for troubleshooting is also an excellent potential application. There are clinical scenarios now being constructed for the Mentis simulator that incorporate the development of technical complications and challenging anatomic configurations. Approaching these in a simulated scenario may facilitate the subsequent actual procedure. Finally, a minimum time for training cannot be determined based on the current analysis.

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Table II, online only. Questionnaire administered to participants*

Advanced participants

Unity/realism of specific components/elements:

1. Scenario of carotid stenting was realistic.
2. Appropriate catheters and equipment were available.
3. Was clinical feedback adequate?
4. Devices were realistic in use.
5. Tactile feedback was realistic.
6. Devices behaved in predictable manner.

Value for novice/resident/fellow in training:

1. Did you feel that working on the simulator was a worthwhile experience?
2. Did you want to spend more time on the simulator?
3. The simulator could be a valuable tool to teach carotid stenting.
4. If the requirement for carotid stenting was 15 cases, how many could be replaced with the simulator?
5. The simulator could be a valuable tool to teach a beginner catheter interventions.
6. Does increased familiarity with the simulator increase your interest in teaching catheter techniques?

Novice participants

1. Did you think that working on the simulator was a worthwhile experience?
2. Did you want to spend more time on the simulator?

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*Responses were graded with a Likert scale: 1 = strongly disagree, to 5 = strongly agree.