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RANDOMIZED TRIAL

Does Simulation-Based Training Improve Procedural Skills of Beginners in Interventional Cardiology?—A Stratified Randomized Study

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Objective: *To assess whether mentored simulation-based-training can improve the procedural skills of beginners in coronary interventional procedures.*
Background: *Simulation based-catheter training is a valuable tool to practice interventional procedures. Whether this type of training enhances the procedural skills of fellows learning percutaneous coronary interventions has never been studied.*
Methods: *Eighteen cardiology fellows were randomized either into the simulation-based training ($n = 9$) or the control group ($n = 9$). The simulation group received 7.5 hours of virtual reality (VR) simulation training, whereas the control group attended 4.5 hours of lectures. Each participant had to perform a simple (pre-evaluation) and a more complex (post-evaluation) catheter intervention on a pulsatile coronary flow model in a catheterization laboratory. All procedures were videotaped, analyzed, and rated by 3 expert interventionalists, who were blinded to the randomization. To assess the individual performance level, a "skills score" was determined, comprising 14 performance characteristics (5-level Likert scale, maximum score of 70 points).*
Results: *The "skills score" increased by 5.8 ± 6.1 points in the VR simulation group and decreased by 6.7 ± 8.4 in the control group ($P = 0.003$) from the simple stenosis at pre- to the more complex lesion at post-evaluation demonstrating the effectiveness of simulation-based training.*
Conclusion: *This pilot study suggests that curriculum-based mentored VR simulation training improves the performance level of cardiology fellows in coronary interventions. Further investigation to evaluate the effect on clinical outcomes is warranted.* (J Interven Cardiol 2015;9999:1–8)

Introduction

Simulation-based training offers a safe and mentor assisted environment for trainees to practice interventional procedures. Advances in computer technology have fostered introduction of virtual-reality (VR) simulators into multiple medical specialties[1–5] including catheter based interventions.[6–12] It has previously been demonstrated that skills required to adequately perform diagnostic cardiac catheterization can be learned employing mentored simulation training.[13] However, whether this type of training also enhances the procedural skills required for the performance of percutaneous coronary interventions (PCI) has not yet been reported. We sought to evaluate if mentored simulation-based catheter training can improve the performance level of novices in interventional coronary procedures by means of a randomized pilot study.

Methods

Recruitment of Participants. To recruit appropriate participants invitation letters were sent to directors

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Wolfram Voelker and Nils Petri contributed equally to this work.

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of 540 catheterization laboratories in Germany. The candidates had to fulfill the following criteria:

1) Performance of at least 50 diagnostic catheterizations, but no interventional procedure as a primary operator.
2) No training experience with VR-simulators.

All participants gave their written informed consent.

Evaluation Model. For pre- and post-evaluation the participants performed a coronary intervention on a commercially available pulsatile coronary artery model (CoroSim^R, Mecora, Aachen, Germany). This mechanical flow model (Fig. 1) provides realistic conditions for PCI (http://www.mecora.com). The CoroSim^R consists of an inlay manufactured from silicone, duplicating the iliac vessels, the aorta, and the left heart with coronary arteries taking off the sinus of Valsalva. This closed circulatory model is powered by a pulsatile roller pump. Three narrowings representing stenotic lesions are implemented within the coronary artery tree of this model. The left coronary artery system contains 2 narrowings, which served as target lesions for this study. “Stenosis” No. 1 is a simple type A lesion in the mid portion of the left anterior descending (LAD) (corresponding to AHA Segment 7), “stenosis” No. 2 represents a bifurcation stenosis Medina classification 0,1,0 of the left circumflex artery (LCx) (corresponding to AHA Segment 13) (Fig. 2). Stenosis length and the reference diameter of the non-stenosed vessel had been quantified by QCA.

Study Protocol. The study was performed in the catheterization laboratory of the University Hospital of Würzburg. The CoroSim^R was placed on the catheter table and covered with drapes sparing of the simulated femoral artery with the introducer sheath already in place. The heart was not visible for the trainee, allowing catheterization under fluoroscopic guidance only while preventing direct visual guidance. An experienced interventional cardiologist supported the participants in C-arm handling. Commercially available guiding catheters, balloons, and wires were used. Due to the commonly cumbersome removal of implanted stents from the model of the coronary tree stent implantation was simulated by balloon inflation only. Continuous video-documentation together with capturing of x-ray fluoroscopy and cine-x-ray coronary angiography was performed throughout the procedure in order to document all handling maneuvers of the participants (Fig. 3).

Figure 1. CoroSim®, the pulsatile coronary artery model for pre- and post-evaluation of the participants.

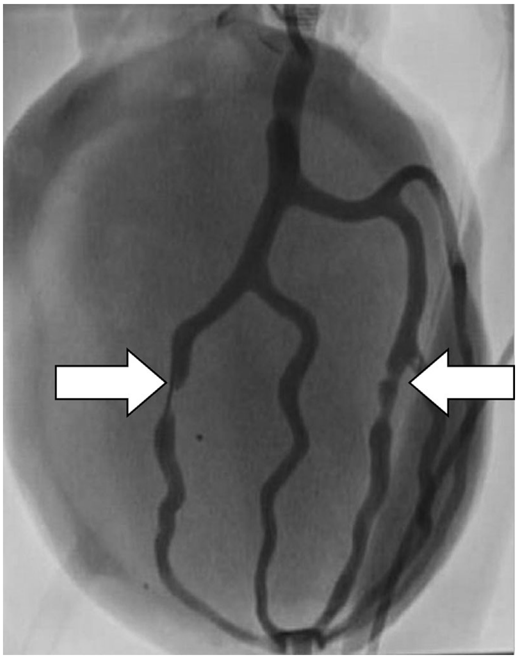

Figure 2. Angiographic image of the target lesions at the CoroSim. (Left: Stenosis No. 1 for pre-evaluation. Right: Stenosis No. 2 for post-evaluation).

Evaluation Process. To assess performance, the participants performed the following steps:

(1) Introduction of a 6F guiding catheter using a 0.065″ guidewire through the femoral sheath.
(2) Retrograde advancement of the catheter into the aortic root.
(3) Withdrawal of the guidewire.

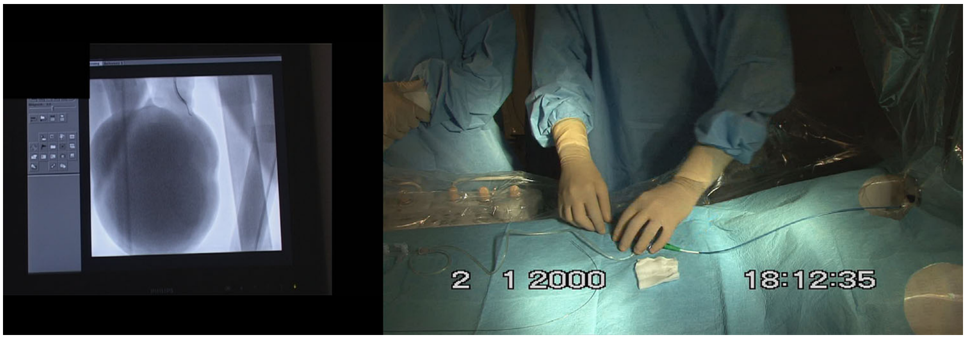

Figure 3. Set-up for video-documentation during pre and post-evaluation.

(4) Careful co-axial catheter-engagement of the left ostium under fluoroscopic guidance.
(5) Contrast injections in different projections to visualize the target "stenosis" under x-ray fluoroscopy/cine-angiography guidance.
(6) Tip-shaping of a 0.014″ guide wire and retrograde introduction into the guiding catheter through a Y-connector.
(7) Maneuvering of the guide wire into to the target vessel and across the stenotic lesion.
(8) Selection of a balloon catheter (length and diameter).
(9) Retrograde advancement of the balloon catheter and exact positioning of the balloon.
(10) Balloon inflation.
(11) Angiographic control.
(12) Withdrawal of the balloon catheter leaving the guide wire in place.
(13) Selection of a stent (length and diameter).
(14) Retrograde advancement of a balloon catheter of the selected size and exact positioning.
(15) Balloon inflation.
(16) Final x-ray angiographic control.
(17) Withdrawal of the guiding catheter.

During pre-evaluation all participants performed the intervention on stenosis No.1, for post-evaluation stenosis No. 2 served as the target lesion. The maximum allotted time was 25 minutes, thereafter, the procedure was terminated.

Stratified Randomization. 18 cardiology fellows were randomized either into the simulation-based training (n = 9) or the control group (n = 9). To prevent imbalance between the simulation and the control group a stratified randomization was performed. Therefore, the results of the pre-evaluation were used to establish a ranking of the participants. From this ranking nine pairs were formed. The 2 individuals of each pair were randomized either to the simulation group or the control group.

Simulation Based-Training Group. Training was performed according to a standardized curriculum for VR simulation in interventional cardiology (see: http://www.agikintervention.org/fileadmin/templates/agik/agikpool/agik-2015/Quality_criteria_and_list_of_contents_for_GCS_simulation_courses.pdf). Prior to the training period all mentors received a detailed introduction to simulator training according to the above mentioned curriculum. The participants of the simulation group (n = 9) received a short instruction in handling of the VR-simulators. Then, every participant of this group underwent 2.5 hours of mentored-training on each simulator resulting in a total of 7.5 hours of simulation training, a setting typically employed in training courses[14]. The ratio of mentor to trainee was 1:3, which enabled the mentor to keep the trainees fully engaged throughout the entire VR training. Three different simulators were employed to evaluate the effect of simulation training: Vist-C (Mentice, Gothenburg, Sweden), CathLabVR (CAE Healthcare, Guenette, Canada), and AngioMentor Express (Simbionix, Cleveland, Ohio). Each simulator has its specific advantages and disadvantages.[15] Using of three different simulators allows for a broader scale of training and limits burnout of the participants on one machine.

Control Group. The participants of the control group (C, n = 9) attended a 4.5 hours lecture emphasizing coronary intervention step-by-step, covering the selection of appropriate catheters, balloons, wires, and stents, complication prevention, case presentations by 2 expert interventionists. As a bonus each participant of the control group also received simulation-based training after completion of the study.

Construct Validity. In order to define the construct validity of the pulsatile model CoroSim^{R}, 5 experts (E) in interventional cardiology (with individual experience of >1,000 PCIs) performed an intervention on stenosis No 2.

Data Analysis. Three independent and blinded experienced interventional cardiologists, who were unaware about the training mode of the participants (simulation vs control), reviewed the videos to assess the participant's performance quality for 14 predefined items (according to a 5-point Likert scale) (Table 1). For each of these items 5 performance levels were possible. The sum of these 14 items was defined as "Skills score" and was used to express the procedural skills of the participants (maximum "Skills score": $14 \times 5 = 70$ points). In the case of disagreement among the three observers, defined as deviation by 2 or more points, a consensus among the raters for this item was reached. In addition, the amount of contrast dye, fluoroscopy time, and procedural time were measured (see Table 2).

Statistics. The effects of the simulation training vs. control on the overall performance score was evaluated using ANCOVA (dependent variable = change in overall score; group as factor; baseline score as covariate). The reported P-values refer to the between-group differences. The specified errors apply a twofold standard deviation. The "skills score" between experts and study participants was compared using the Kruskal–Wallis test for overall testing. For the consecutive between-group comparison the Mann–Whitey U-test applying a simple Bonferroni-correction for multiple testing was used.

Results

Skills Score. The "skills score" increased in the simulation group (47.2 ± 8.5 ⇨ 53.0 ± 5.6), but decreased in the control group (50.3 ± 4.5 ⇨ 43.6 ± 7.0). The change in both groups differed significantly (simulation group: +5.8 ± 6.1; control group: −6.7 ± 8.4; $P = 0.003$) (Fig. 4). Four of the 14 single items demonstrated a statistical significant change from pre- to post-evaluation: (1) position of the coronary wire after insertion of the balloon, 2) technique of balloon-stent exchange, 3) position of the wire tip after exchanging balloon and stent, 4) stent positioning (see Table 1).

Individual Improvement of "Skills Score" Depending on the Initial Performance Level. The 5 low performers at baseline ("skills score" ≤50) revealed a more pronounced increase than the 4 initial high-performers (>50): (10.0 ± 4.4 vs 0.6 ± 3.0) (Fig. 5).

Validity of the Evaluation Process. The overall test comparing the "skills score" of the 5 experts with the post-evaluation "skills score" of the study participants yielded significant differences (Kruskal–Wallis test $P < 0.001$). Experts (59.9 ± 5.4) outperformed participants of the simulation group (53.0 ± 5.6; $P = 0.004$) and the control group (43.6 ± 7.0).

Additional Parameters. The amount of contrast dye remained constant from pre- to post-evaluation in the simulation group (178 ± 45 ml vs 178 ± 48 ml) but increased in the control group (146 ± 27 ml vs 165 ± 33 ml). Fluoroscopy time increased in the simulation group from 4.5 ± 2.3 minutes (pre) to 6.1 ± 1.9 minutes (post) and in the control group from 2.8 ± 1.0 minutes (pre) to 6.1 ± 2.1 minutes (post). The mean procedural time at baseline was 21.1 ± 3.6 minutes in the simulation group and 17.6 ± 2.9 minutes in the control group. During post-evaluation mean procedural time was 19.4 ± 2.4 minutes (simulation group) and 20.9 ± 3.7 minutes (control group), respectively. Two participants (both from the control group) exceeded the time limit of 25 minutes.

For each of these additional parameters no significant differences between the simulation and control group were found.

Discussion

We assessed the hypothesis that simulation based training may improve the hand-eye coordination and procedural skills of novices in interventional cardiology. Mentored simulation training has the advantage that it does not only train the manual component of PCI, but also the analytical and interpretational part and the fellow's three-dimensional perceptivity.

In our study, pre- and post-evaluation of the individual catheterization skills was performed on a commercially available pulsatile coronary heart model. Whereas the assessment on real patients is limited due

Table 1. Results (“Skills Score”)

	Simulation Group		Control Group	Expert Group
1. Careful catheter movements				
Pre-evaluation	2.9 (1.4)		3.2 (1.7)	
Post-evaluation	2.5 (1.0)		2.8 (1.4)	4.5 (0.6)
P-value		0.749		
2. Atraumatic catheter engagement of the coronary artery				
Pre-evaluation	3.9 (0.7)		3.7 (1.2)	
Post-evaluation	3.7 (1.1)		3.7 (1.3)	4.5 (0.8)
P-value		0.856		
3. Shaping/preparation of the tip of the wire				
Pre-evaluation	2.8 (1.4)		3.3 (1.4)	
Post-evaluation	3.5 (0.9)		3.4 (0.7)	5.0 (0.0)
P-value		0.936		
4. Wire-advancement				
Pre-evaluation	3.0 (1.5)		3.2 (1.0)	
Post-evaluation	3.0 (1.4)		2.7 (1.6)	4.8 (0.4)
P-value		0.475		
5. Positioning of the wire-tip in the distal vessel prior to balloon insertion				
Pre-evaluation	4.0 (1.4)		4.4 (0.6)	
Post-evaluation	4.8 (0.3)		4.3 (0.7)	4.9 (0.3)
P-value		0.105		
6. Position of the wire after the insertion of the balloon				
Pre-evaluation	4.0 (1.1)		3.0 (1.3)	
Post-evaluation	4.4 (0.7)		2.7 (1.5)	3.8 (1.2)
P-value		0.008		
7. Balloon diameter				
Pre-evaluation	4.8 (0.7)		4.8 (0.7)	
Post-evaluation	5.0 (0.0)		4.5 (0.9)	4.6 (0.8)
P-value		0.239		
8. Balloon length				
Pre-evaluation	3.9 (1.8)		4.3 (1.0)	
Post-evaluation	3.6 (1.6)		4.0 (1.4)	3.0 (1.3)
P-value		0.105		
9. Balloon positioning				
Pre-evaluation	4.4 (0.8)		4.6 (0.5)	
Post-evaluation	4.6 (0.5)		4.0 (0.8)	4.5 (0.7)
P-value		0.144		
10. Technique of balloon/stent exchange				
Pre-evaluation	2.1 (1.1)		2.4 (1.0)	
Post-evaluation	3.4 (0.5)		2.3 (1.2)	4.3 (0.9)
P-value		0.044		
11. Position of the wire tip after exchanging balloon and stent				
Pre-evaluation	1.7 (0.9)		3.0 (1.6)	
Post-evaluation	2.2 (1.3)		1.5 (0.9)	3.5 (1.6)
P-value		0.046		
12. Stent diameter				
Pre-evaluation	2.3 (1.4)		3.9 (1.1)	
Post-evaluation	3.2 (1.6)		3.0 (1.5)	3.4 (0.8)
P-value		0.969		
13. Stent length				
Pre-evaluation	3.2 (1.6)		3.9 (1.5)	
Post-evaluation	3.8 (1.0)		3.4 (0.7)	4.2 (0.8)
P-value		0.224		
14. Stent positioning				
Pre-evaluation	4.5 (0.6)		4.3 (1.0)	
Post-evaluation	4.5 (0.7)		3.8 (0.7)	4.7 (0.6)
P-value		0.023		
“Skills score”				
Pre-evaluation	47.2 (8.5)		50.3 (4.5)	
Post-evaluation	53.0 (5.6)		43.6 (7.0)	59.9 (5.4)
P-value		0.003		

Mean value (±standard deviation). P-values refer to the between-group differences.

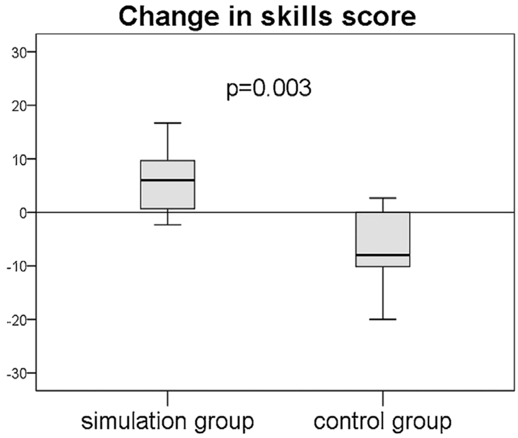

Figure 4. Change of "skills score" in both groups from pre- to post-evaluation.

to ethical reasons and varying anatomical constellations, our experimental set-up allowed for a true comparison of skills by providing equal and life-like conditions for all participants. Evaluation was deliberately not performed on VR-simulators but on this pulsatile flow model avoiding interference between training and evaluation. Procedural skills were assessed using a "skills score," which consists of 14 single items. These items refer to the selection and handling of the guiding catheter, the wire, the balloon, and the stent, all of which are important steps for a successful and safe coronary intervention. Experienced interventional cardiologists provided immediate and delayed feedback (debriefing) and used the simulators to transfer their knowledge and skills. The importance of feedback in simulator training has been demonstrated in other simulation studies.[7,13,16]

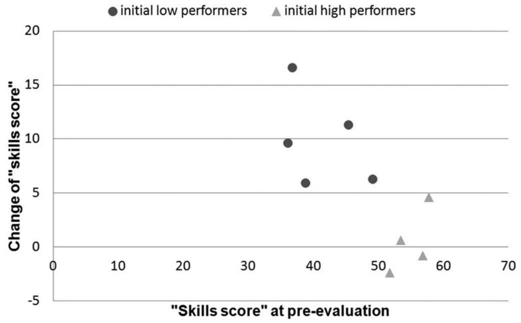

Figure 5. Comparison of the initial low ("skills score"$\leq$50) and high performers ("skills score">50).

The main result of our study was a significant increase of the mean "skills score" in the simulation group from pre- to post-evaluation despite the increase in complexity of the treated lesion. In contrast, mean "skills score" in the control group decreased. Thus, our pilot study demonstrates for the first time that mentored simulation-based training may significantly improve the performance level of novices in interventional cardiology. However, no significant improvement in procedure time, contrast volume, and fluoroscopy time was found. This might be due to an increased risk-awareness, which may have triggered the simulation group participants to a more cautious and careful approach. Medical Education has been traditionally performed based on the apprenticeship model. According to this model the trainee acquires knowledge and skills through studying, observing and assisting a senior operator, and then ultimately performing the procedures independently. However, this approach has several limitations including the random admission of patients.[9] Simulation-based training can provide a solution for the drawbacks of classical teaching methods. It has been speculated that simulation-based training has the potential to reduce the early and risk-prone part of the learning curve, while allowing faster learning and increasing patients' safety.[17] Progress in computer technology has promoted the development of computer-based simulators in healthcare. Computer-based training on simulators has some general advantages, they provide:

- Life-like scenarios for unlimited repeated training.
- Safe learning environment, where learning from mistakes is allowed.
- Systematic training of hand-eye-coordination.
- Repeated training even of rare procedures and complications.

These advantages of simulation in healthcare have been supported by several trials. In the VR-to-OR study it could be demonstrated that residents who were trained on VR simulators made significantly fewer objectively assessed intra-operative errors compared with the standard-trained group when performing laparoscopic cholecystectomy.[18] Since this landmark trial several studies have reported that simulation-based training improves medical procedural knowledge, skills and behavior in several disciplines in medicine.[5] However, studies to evaluate the impact of

Table 2. Results (Additional Parameters)

	Simulation Group		Control Group	Expert Group
Used amount of contrast dye (ml)				
Pre-evaluation	178 (45)		146 (27)	
Post-evaluation	178 (48)		165 (33)	98.8 (46)
P-value		0.891		
Fluoroscopy time (min)				
Pre-evaluation	4.5 (2.3)		2.8 (1.0)	
Post-evaluation	6.1 (1.9)		6.1 (2.1)	4.8 (1.4)
P-value		0.744		
Procedure time (min)				
Pre-evaluation	21.1 (3.6)		17.6 (2.9)	
Post-evaluation	19.4 (2.4)		20.9 (3.7)	17.0 (5.8)
P-value		0.216		

Mean value (±standard deviation). P-values refer to the between-group differences.

simulation in training of percutaneous coronary interventions are lacking.[19,20]

How Do the Results of Our Study Fit in the Present Data About Catheter Based Simulation in Interventional Cardiology? To evaluate the effect of simulation based training on the procedural skills of coronary arteriography Bagai et al.[13] studied 27 cardiology trainees, who were either randomized to mentored training on a virtual reality simulator (n = 12) or no training (control, n = 15). It was demonstrated that skills required to perform diagnostic coronary angiography can be learned via mentored simulation training and are transferable to actual procedures in the catheterization laboratory. Furthermore, they demonstrated that the effect of simulator training is a function of baseline performance. Participants with lower performance scores at baseline were associated with greater improvement. These findings compare favorably with our results. We found that initial low performers benefited more than the participants with higher score at baseline. Thus, simulation-based training may be most effective in the early learning phase.

In the study of De Ponti et al.[21] the effect of simulation based training on transseptal puncturing was studied. In this study no significant effect was found for fluoroscopy time, contrast volume, and procedure time. Measurable effects were found for handling of catheters and devices. Whereas De Ponti et al. aimed for a pre-specified level of procedural skills, we offered a fixed amount of training time. Although the authors' goal oriented approach of individualized simulation based training might be more adequate to reach the highest training effect, our approach (fixed amount of simulation-based training time) is more compatible with schedules of current simulation courses.

Limitations of This Study.

- Only 18 participants took part in this study, however, this number is comparable to other validation studies on VR simulation.[6,8,12,13,17,21]
- The novices were not evaluated on real patients, which would have caused ethical concerns. Furthermore, in real patients anatomical conditions vary and would require a high case number for a valid comparison of the participants. In contrast, the chosen pulsatile model provided identical and life-like conditions for each participant. Construct validity of this unique evaluation method has been demonstrated; experts significantly outperformed the participants of the control and the simulation group.
- The assessment of the trainees according to a Likert-score is subjective. However, this score is a commonly used evaluation method in simulation studies. Additionally, every effort was made to provide a valid assessment: clear-cut and concise definition of each of the 14 parameters, video-taping of the whole procedure and analysis by 3 independent observers.

Conclusion

The results of this randomized and controlled trial demonstrate that simulation-based catheter training using current simulation technology can improve operator performance in beginners of interventional coronary procedures. Further investigation to evaluate the effect on clinical outcomes is warranted.

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