Title: The role of a simulator-based course in coronary angiography on performance in real life cath lab – A case control study

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ABSTRACT

Background

The aim of this study was to explore if a course involving lectures combined with simulator training in coronary angiography (CA) could reduce the early learning curve when performing CA on patients.

Knowledge in performing CA is included in the curriculum for the general cardiologist. The method, according to ACC and ESC guidelines, for this training is not well defined but simulator training is proposed to be an option. However, the transfer effect from a CA simulator to performance in real world cath lab is not validated.

Methods

Fifty-four residents without practical skills in CA completed the course and 12 continued to training in invasive cardiology. These residents were tracked in the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) and compared to a control group of 46 novel operators for evaluation of performance metrics. A total of 4472 CAs were analyzed.

Results

Course participants improved catheterization skills in the simulator but demonstrated no consistent reduction in the early learning curve in real world cath lab. They had longer fluoroscopy time compared to controls (median 360 seconds (IQR 245-557) vs. 289 seconds (IQR 179-468), p<0.001). Safety measures also indicated more complications appearing at the ward, in particular when using the femoral approach (6.25% vs. 2.53%, p<0.001).

Conclusions

Since the results of this retrospective non-randomized study were negative, the role of a structured course including simulator training for skills acquisition in CA is still uncertain. Randomized transfer studies are warranted to justify further use of simulators for training in CA.
<table>
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<tr>
<td>ACC</td>
<td>American College of Cardiology</td>
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<td>CA</td>
<td>Coronary Angiography</td>
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<td>ESC</td>
<td>European Society of Cardiology</td>
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<td>IQR</td>
<td>Inter Quartile Range</td>
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BACKGROUND

According to national and international guidelines for education and training of the general cardiologist, coronary angiography experience (CA) is of high priority. However, the rationale behind these curriculums is vague since training goals for cardiologist trainees often are built on recommendations without scientific support. A log book is a common way to register number and type of procedures performed but is limited by volume instead of quality. European Society of Cardiology (ESC) recommendations for the general cardiologist are to assist or perform 300 coronary angiographies CAs and to interpret 1000 investigations (1). There is also a statement that simulators might play an important role in training invasive procedures but recommendations for how to accomplish this is lacking. The recommendation from the American College of Cardiology (ACC) is to participate in CA of at least 100 patients and for the trainee who plans to perform independent diagnostic cardiac catheterizations a minimum of 200 procedures with primary hands-on responsibilities should be performed (2).

Simulator training in CA is not well validated and transfer studies are lacking. Experts usually demonstrate a higher proficiency level in different simulator tasks and procedures as reported in several construct validation studies and the same is true for endovascular procedures (3-7). Most randomized controlled trials (RCT) evaluating skills achieved in virtual reality (VR) transferred to the operating room (OR) have explored surgical procedures such as laparoscopy and flexible endoscopy (8-10). Three systematic reviews of the effectiveness of medical simulators have been published up-to-date. The findings in the review by Sutherland et al. showed that simulator training was superior to no training but not “convincingly” superior to standard training (11). Issenberg et al. identified 109 studies, whereof 35% were RCTs, with no study showing unequivocal proof of benefit or harm from simulated training (12). The most recent review by Lynagh et al. aimed for evaluating the effectiveness of medical skill
laboratories or simulators (13). Twelve of the included studies assessed the transfer of simulator performance to clinical skills performance on real patients but none on endovascular procedures. The conclusion drawn from this review was that medical skills laboratories do lead to improvement compared to standard training when transferred to real life but that there is a lack of well designed trials. A Cochrane review by Walsh et al. came basically to the same conclusion as Issenberg et al. that there is insufficient evidence to advise for or against the use of VR training, this time regarding gastrointestinal endoscopy (14). When exploring the transfer effect from endovascular simulators to real patients a review article by Tsang et al. included three studies on carotid stenting and four on peripheral vascular angioplasty (15). Only one of the RCT’s showed transferability from VR to OR and that was in peripheral vascular intervention (16). In a recently published review about the future of simulation technologies for complex cardiovascular procedures references were made to several VR validation studies in endovascular procedures to real world but few to real patients (17). To our knowledge, no study has evaluated the transfer effect from VR to OR on humans in CA.

The primary aim of this study was to evaluate if a structured training program including simulator training could improve the early learning curve for trainees in CA and thus make the learning process safer for the patient (transfer validity). A second aim was to evaluate the performance progress of the course participants in cognitive and practical skills (course validity).

METHODS

Course

The course was founded and initiated by the authors 2006 and only minor changes have been made over the years. The course is recommended by the Swedish Society of Cardiology and...
the Swedish Heart Association. At all course events residents had access to two simulators and three instructors. Each course was limited to six participants in order to keep a high exposure to the simulators. Three instructors, all experienced invasive cardiologists, were responsible for proctoring and lectures. A total of six hours of dyad proctored simulator training and six hours of theoretical lectures were completed during two days. Course participants voluntary aiming for certification in CA and in a geographical nearby occupancy enabling repeated solo VR training had an opportunity to extend the training in order to complete a practical exam in the simulator.

The VR training aimed for a safe behavior of the procedure completing CA with a small but sufficient amount of contrast used and accurate virtual C-arm angulations to project the coronary vessels in recommended views. Instructions of how to handle fluoroscopy, wires and catheters safely during CA were also given. In addition, femoral arterial puncture technique was practiced on a dummy constructed to give backflow of artificial blood when entering the vessel.

The theoretical part of the course included lectures about the CA procedure regarding anatomy, pharmacology, complications, puncture technique, radiation safety and materials, in total six hours. A web-based theoretical course was offered as a complement to live lectures during the two last years.

**Study subjects**

The course participants were all senior residents in cardiology and in their second half of their four years of training. They were recruited from all geographical areas of Sweden to attend the course by advertisement in the journal of Swedish Society of Cardiology and by direct mail to all cardiology units and invasive centers in Sweden. During six years, 54 residents participated and completed the course at two different sites in Sweden. **Twelve of the course**
participants progressed to become invasive cardiologists. Comparisons of these trainees were made to a similar group of 10 senior cardiology residents participating in a construct validation study of the VIST simulator in order to describe and compare the training effect in the simulator in two equal groups of CA beginners. Course training and assessment rational are illustrated in Figure 1.

**Simulator**

The two centers involved in the course had each access to one VR simulator (Mentice VIST™) on a dedicated center for simulation (Clinical training center, Karolinska University Hospital, Stockholm and Practicum, Skåne University Hospital, Lund). During the course an additional identical simulator was borrowed from one company involved in the device industry. Mentice VIST™, Gothenburg, Sweden is a VR simulator where you can practice coronary angiography in full scale, using real catheters and wires modified to fit the machine. The virtual femoral puncture of the vessel was preformed. Potentially harmful parts in the investigation such as radiation, fluoroscopy and filming were simulated as well as contrast injection. Skills metrics were extracted from the simulator computer such as total procedure time, fluoroscopy time and contrast use. Manually assessed metrics were time from catheter introduction in the femoral sheet to intubation of the coronary ostia.

**Study protocol**

The design of the study was a retrospective case-control study where the cases were residents exposed to the course progressing to invasive cardiologists and the controls novel operators found in the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). All hospitals in Sweden performing coronary angiographies (n=30) and interventions (n=29) register all their procedures. The definition of a beginner was set to be an invasive
A cardiologist who started to perform CA between 2005 and Q1 2012 and had performed at least 80 CAs and at least 40 CAs annually. A total of 58 novel operators were identified in Sweden during the observation period of seven years. Twenty percent attended the course. Cases (n=12) and controls (n=46) were tracked in the SCAAR registry and met the inclusion criteria for beginners. There were no gender differences between the two groups (16.6% vs. 17.3% females). Study metrics previously described representing proficiency in CA were compared between the groups and presented in learning curves and tables (18).

**Statistical analysis**

Data are presented as median and inter-quartile range (IQR), mean ± SD or median (range) and numbers (%). Descriptive summary statistics were used where appropriate. Differences were tested with Mann-Whitney U-test or Chi-Square test. Kruskal-Wallis was used where appropriate. Analyses were performed using Statistica version 10, (Statsoft, Inc, Tulsa, OK, USA)

**Ethics**

All participants received written information about the project declaring anonymity in the video recordings and evaluation. Only the monitors and the hands of the test objects were filmed and no sound was recorded. The protocols and procedures were approved by the local ethical committee for human research at Karolinska Institutet and at Uppsala University ref.nr. 04-202/1. The studies were performed according to the declaration of Helsinki and good clinical practice. Informed consent was provided to all participating residents, consultants and patients
RESULTS

Course assessment

Compared to a previously evaluated VIST simulator group of CA beginners performing five consecutive CA in the simulator (unpublished data), the course participants performed equally in the simulator after six hours of dyad VR training, hence representing a corresponding beginners group (Table 1a). When comparing the VIST group regarding baseline skills in their first VR CA to the course participants last VR CA, the course participants had a shorter total examination time and lower contrast use hence representing a learning curve in the simulator regarding these metrics during the course. The same result appeared in the course group progressing to invasive cardiology. No improvement was seen in fluoroscopy time or coronary ostia intubation time (Table 1b).

Eighteen participants aimed for certification and completed the course with additional solo VR training in CA for a median of 4.3 hours (range 2-7). These trainees tended to improve their fluoroscopy time in the simulator by in median of 24% (IQR 13%-38%), p=0.343. Improvement trend in total time was in median 24% (IQR 13%-34%), p=0.071. Contrast use was improved by in median 30% (IQR 20%-43%), p=0.007. Intubation time tended to improve for LCA in median by 34% (IQR 23%-43%), p=0.137 and improved for RCA in median by 25% (IQR -9%-65%), p=0.036. The median accurate score for the written exam was 80% (IQR 72%-86%).

Participant course evaluation

The course attendees rated the course according to a standardized form commonly used in national residents courses in Sweden. The course was highly appreciated and scored in average 5.3 of 6 in all 6 evaluation points (data not shown). All attendees would recommend the course to their colleagues according to the evaluation form.
Transfer assessment

A total of 4472 CAs were analyzed. In the metrics extracted from SCAAR and representing proficiency in cath lab, the trainees completing the course performed worse regarding fluoroscopy time compared to the controls which in turn demonstrated a typical learning curve, median 360 seconds (IQR 245-557) vs. 289 seconds (IQR 179-468), p<0.001 (Figure 2). Course participants demonstrated a less consistent improvement and the learning curves between the groups did not persistently cross during the observation time. The pattern was the same no matter of access site (Figure 3a-b), or the experience/time from taking the course to performing the first CA (Figure 4a-b), (Table 2). No learning curve was demonstrated in the use of contrast and the groups used the same amounts (Figure 5). There were no differences in the rate of complications at the cath lab, 0.92% vs. 0.57%, p= 0.421 but the course participants had more complications appearing at the ward, in particular, when using the femoral approach, 6.25% vs. 2.53%, p<0.001 (Table 3). The controls performed better through all the first 80 CAs without a benefit in the early learning curve in the course group (Table 4). The total time for the procedure and the time for intubation of the coronary ostia is not registered in SCAAR and could therefore not be evaluated.

DISCUSSION

In this study, course participants improved their skills in the simulator in general during the course event but this improvement was not statistically significant in all metrics measured and did not result in a reduced learning curve when performing CA on patients. Time from course event or previous CA experience did not affect the performance metrics and access site had no impact in favour for the course trainees. The number of complications in course participants
was elevated compared to control group suggesting that a structured course including simulator training might have a negative impact on the learning process of CA.

Simulation experience in medical procedures is regarded as the future for medical education and training. Many studies confirm what we all believe; simulators can improve our practical skills. However, convincing data of transferability from VR to OR have been shown only for a few procedures and most studies show conflicting data (11,13,14,19). Berry et al. showed a transferability from VR to a OR in a pig model of iliac vascular intervention and De Ponti et al. concluded that VR training in cardiac transseptal puncture (TSP) resulted in a shorter training time, a higher assessment score and fewer errors during TSP in patients (20,21).

Endovascular training in VR is unfortunately deficiently investigated and no data have been published regarding transfer effect to CA. In this study, our aim was to evaluate if a course in CA using simulators reduced the early learning curve in performing CA on real patients and if the patient benefited from this preparatory VR training. The results demonstrated that using simulators as a learning tool to increase clinical skills is not convincingly obvious and that the training actually can impair the early learning curve.

Several studies have reported limited or unimproved skills performance as mentioned in the review by Lynagh et al. (13) but only one study reported an impaired performance in the VR trained group in non-endovascular procedures (22). In our study, residents taking a course in CA, including theoretical and practical training, actually performed worse in parameters previously demonstrated representing proficiency (18). Course participants used longer fluoroscopy time no matter of puncture site and had more complications when using the femoral access. The initial learning curve was not altered whether they had a delay from the course or not to CA or had some CA experience when taking the course. Evaluation in the simulator of the participants progressing to invasive cardiology was compared to another group of beginners performing 5 CA in the same simulator. No differences were seen in
procedure metrics in the simulator indicating a representative group of novel operators. However, compared to this group’s first VR CA there was an improvement during the course in performance skills regarding total examination time and contrast use for the course attendees. Unfortunately, this study could not demonstrate a transfer effect from VR to OR in this setting. One possible reason for that is that despite proctored VR training the actual simulator training was not structured in that sense that no benchmarked proficiency level was reached before performing CA on patients. However by the time for these, simulator based, CA courses the expert proficiency level in the simulator was not known. Total time as a metric for proficiency demonstrated an improvement in the course attendees but unfortunately is not registered in SCAAR. Another explanation for the failure to show a transfer benefit from VR training to cath lab might be that the trainee becomes too self-confident after VR training thereby asking for less assistance with the actual CA procedure, previously described as simulator behavior. The course attendees had longer fluoroscopy time, perhaps dependent of time spent on unnecessary handling of catheters something not dangerous to the VR patient and thereby mixing VR and OR up. One might argue that a longer course or training period would have amplified the skills achieved in the simulator resulting in a higher proficiency level in cath lab but on the other hand this would have been time-consuming for the trainee as well as for the proctors. Supervised stepwise training in cath lab like the old master-apprentice model with graded increased responsibility is perhaps as safe as simulator training and more cost efficient. Zendejas et al. (23) made an attempt to systematic review cost as an outcome of simulation-based medical education (SBME). They could identify 15 studies comparing simulation training to other instructional modalities but none reported a formal cost-effectiveness analysis. Discussions promoting SMBE usually compare the cost of SBME to a hypothetical medical error thus saving money. However, in this study course participants actually had more complications than the control group using the femoral approach indicating
a higher cost. The types of complications were not classified but bleeding associated to the puncture site is likely to be the major part. Puncture of the access site is not achievable in the VIST simulator instead the course participants received arterial puncture training on a dummy. This training modality is not validated in a transfer setting and might therefore be of no use or even harmful.

A randomized single-blinded VR transfer study in CA is currently running in Stockholm and will be completed early 2013 and hopefully the future role for VR training in CA will be clearer.

Study Limitations

The limitations in this study were several. It was not randomized and thereby not adjusted for potential confounders such as poor performance of the course participants. However, the group was compared to another beginners group included in a construct validity study and no differences were found between the groups in simulator performance thereby being a representative beginners group. Course attendees progressing to invasive cardiology were few but corresponded to 20% of all novel operators in Sweden over the observation time of seven years. The course was short, only including 6 hours of training, but the trainees were practicing in pairs known to increase the learning process and the sessions were proctored by experienced invasive cardiologists ensuring appropriate catheter behavior. Simulator training sessions were not guided to reach an expert level since this level was not known at the time of the courses. All participants did not advance straight to the cath lab doing CAs after completion of the course. Five of the course participants had some experience of performing CA and they all continued with CAs in direct proximity to the course without delay (Table 2). However, delay or experience did not seem to affect the early learning curve (Figure 4a-b).
The study is based on a well-validated registry, tracking all coronary interventions in Sweden. However, this registry contains limited information regarding the operator. For example, we do not know how much help or supervision the trainees had during their initial procedures in cath lab. Total time for a CA is not recorded and the amount of radiation during a CA is not comparable between different sites because of different cath labs. These metrics is by all means important and might possibly represent proficiency level but could not be tested. However the strength of this study is that it is multicenter excluding site bias and representing the real world situation.

**CONCLUSIONS**

Since the results of this retrospective non-randomized study were negative, the use of simulators is not necessarily associated with improved learning of CA. In this study, the concept of cognitive and practical training with evaluation without a well-defined training goal resulted in an impaired learning curve and worse performance in cath lab. Randomized transfer validation studies with well defined expert training goals are warranted to justify further use of simulators for CA training.

**COMPETING INTERESTS**

The authors of this manuscript declare that no financial or non-financial competing interests exist related to the content of the manuscript. None of the authors have received reimbursements, fees, funding or salary from an organization that may gain or lose financially from the publication. None of the authors hold any stocks or shares or are involved in any patents relating to the content of the manuscript.
REFERENCES


FIGURE LEGENDS

Figure 1 Flowchart of training and assessment of the course participants. VR = virtual reality. CA = coronary angiography

Figure 2 Median fluoroscopy time for course participants and controls representing the early learning curve. CAs = coronary angiographies. Values in median (IQR)

Figure 3a Median fluoroscopy time course participants and controls representing the early learning curve for femoral approach. CAs = coronary angiographies. Values in median (IQR)

Figure 3b Median fluoroscopy time course participants and controls representing the early learning curve for radial approach. CAs = coronary angiographies. Values in median (IQR)

Figure 4a Median fluoroscopy time course participants and controls representing the early learning curve without delay from course to CA. CAs = coronary angiographies. Values in median (IQR)

Figure 4b Median fluoroscopy time course participants and controls representing the early learning curve with delay from course to first CA. CAs = coronary angiographies. Values in median (IQR)

Figure 5 Median contrast delivery course participants and controls. CAs = coronary angiographies. Values in median (IQR)
Figure 2

Median (IQR) fluoroscopy time

Time (sec)

Group by 10 CAs

Course
No course
Median (IQR) fluoroscopy time femoral

Figure 3
Figure 4: Median (IQR) fluoroscopy time for radial procedures, grouped by 10 CAs. The graph compares the time between "Course" and "No course" groups, showing a trend of lower times for the "Course" group across different groups.
Figure 5

Median (IQR) fluoroscopy time no delay

Time (sec)

Group by 10 CAs

Course
No course
Figure 7

Median (IQR) contrast delivered

Contrast (ml)

Group by 10 CAs

Course

No course
Additional files provided with this submission:

Additional file 1: Anonymised Manuscript Simulation Course BMC.doc, 145K
http://www.biomedcentral.com/imedia/1578906744911032/supp1.doc
Additional file 2: NewTable 1a.doc, 31K
http://www.biomedcentral.com/imedia/5349351879070789/supp2.doc
Additional file 3: NewTable 1b.doc, 45K
http://www.biomedcentral.com/imedia/1501644039907079/supp3.doc
Additional file 4: New Table 2.doc, 47K
http://www.biomedcentral.com/imedia/2340852349070791/supp4.doc
Additional file 5: NewTable 3.doc, 42K
http://www.biomedcentral.com/imedia/1647110427907079/supp5.doc
Additional file 6: NewTable 4.doc, 47K
http://www.biomedcentral.com/imedia/4881268429070794/supp6.doc