Author's response to reviews

Title: The role of a simulator-based course in coronary angiography on performance in real life cath lab

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Author's response to reviews: see over
Dear Editor,

Thank you for the thorough review of our manuscript MS: 1468732599905286 entitled “The role of a simulator-based course in coronary angiography on performance in real life cath lab – A case control study”.

We felt very encouraged by your decision to give us the opportunity to revise our manuscript according to the suggestions proposed by your reviewers and resubmit it. Since there is a paucity of studies in the field of validation of practical courses in invasive cardiology involving simulator training we hope that you after this revision will consider publishing our manuscript. We would hereby like to resubmit the revised manuscript. We feel that we have been able to respond to all the questions raised by the referees, please see the point-by-point response and we also think that the manuscript has improved a lot. We hope that the revised manuscript now can be considered for publication in BMC Medical Education

Sincerely Yours

Ulf Jensen, MD, PhD
Point-by-point response to Reviewer’s report by Kristin Fraser

Major Compulsory Revisions:

1. Comments

Title and elsewhere: This is not a case-control but rather a retrospective cohort with comparison.

Response

The statement “case-control” has been removed in the revised manuscript and replaced with “cohort” and “control” comparison

2. Comments

Background: Please define what you mean by simulation. Some of the “simulation” literature you quote is referring to a much larger literature than just procedural skills and not all of it includes VR. It would help to specify what each study meant by “simulation”. The readership of this journal might consider “simulation” to mean team-based training or “diagnosing” skills rather than specifically procedural skills.

Response

The background has been rewritten and so also the references to be defined in a more general simulator setting and specified in simulator training regarding procedural skills.

Reference #12 is incorrect citation

Response

Reference 12 has been replaced.

4. Comments

Methods: Course: Can you elaborate on how much time and how exactly the simulator was used to instruct in femoral catheterization. The increased complication rate is one of your main findings so any details about this training would be useful and could be discussed later in terms of how to optimize use of simulators for CA.

Response

A more thorough description of the use and training in femoral catheterization has been added in the revised manuscript in the Methods part and also more elaborated in the Discussion.

5. Comments

Study Subjects: Of the 12 course participants who formed this study intervention cohort, how many of those had the additional training mentioned?
Figure 1 is unclear on which of these course participants were the “cohort” of 12 that you ultimately studied for outcomes.

Response

Figure 1 has been removed to prevent confusion and the numbers of participants who had the opportunity to additional training has been clarified in Table 1.

6. Comments

Do you have any information about the 46 “controls”? For example, how were they trained in CA? Could they have been trained on a simulator at a different course at a different institution? (the reference provided does not give this information and it is important to see if these groups are similar in other ways apart from the intervention)

Response

We have knowledge about the 46 “controls” in that sense that we know that they were not simulator trained. This has been added to the revised manuscript. We only have 2 simulators for CA training in Sweden and the author has been responsible for the organization of simulator training for cardiologists both in CA and PCI on behalf of the Swedish Society of Cardiology.

7. Comments

Results: Course Assessment: Do you have any pre and post data on the actual course participants. Comparing one final test from your study group to a pre-and post of another unpublished group does not prove that your course resulted in learning. (IT does however show that the VIST group improved across 5 simulations suggesting that the simulator is usually effective for training on these parameters)

Response

The section of comparison to another simulator trained group “the VIST group” has been removed since it caused confusion regarding the purpose of the study. The paper of the VIST group has been published in another journal; Technical skills assessment in a coronary angiography simulator for construct validation; Jensen UJ, Jensen J, Olivecrona GK, Ahlberg G, Tornvall P. Simul Healthc. 2013 Oct;8(5):324-8.

8. Comments

Discussion; the negative results are interesting. I understand that fluoro time has been used to construct expert learning curves in past but it takes up to 150 caths to see leveling off of the curve to an “expert level”. Do you think it is a good surrogate measure for the first 80 caths in which your previous work has suggested supervision is still required? Interestingly, your participants did use more fluoros at baseline than the VIST participants (although not significant) Any ideas why some learners use more fluoros time; specifically, are there any good reasons to use more fluoros time that could have been instilled by the course (ie detail/completeness/ accuracy of assessment )? How could you test that in your next study?
Response

The reason for including only the 80 first CAs was that we wished to include as many as possible of the course participants advancing to CA operators. Not all of these 12 operators had performed 150 CA at the time for this analysis. In an analysis of CA learning curves (ref 20) we could describe the learning appearance illustrated in learning curves for 20 beginners reaching the IQR for experts after 150 CA. Our aim was to compare the early learning curves in CA of course participants to course naive operators and not to describe when course participants reached experts IQR for CA. The section of VIST comparison has been removed as mentioned in the previous paragraph.

9. Comments

The most compelling finding is the complication rate and your discussion around this is good. Again, some suggestions on how such a course might remedy this problem would be useful.

Response

Suggestions to improve the course have been added to the revised manuscript in the Discussion section.

Minor Essential Revisions:

1. Comments

Abstract Background and others: Consider using term “accelerate the learning curve” rather than “reduce” which is not as clear. Same applies to results and discussion sections.

Response

The term reduce has been replaced by accelerate as suggested in the revised manuscript.

2. Comments

Background para 2 2nd last sentence is confusing to me. Transfer to “real world but not patients”; if not patients then to what?

Response

By real life but not to patients means that this can include simulator training transferred on animals which not means that simulation training is subjected to a realistic environment doing such procedures on anesthetized animals. This has been clarified in the revised manuscript.

3. Comments

Methods para 1 last sentence: this description of the which participants got further training and why is not clear.
Response

In Sweden we only have two simulators for coronary angiography. The course participants had the opportunity to advance to become certified in CA simulation but this was not compulsory for course participation. Some participants had to travel up to 1000 kilometers to take this course and little ability to get the extra training needed to reach certification level. With the knowledge that interrupted practice is superior to massed practice we gave the participants the opportunity to come and practice at several occasions and then to have a practical exam in VR CA. Course participants exposed for this extra training are identified in Table 1.

4. Comments

Discussion: Please provide a reference for discussion re: “simulator effect” of over confidence

Response

Simulator behavior has been discussed in simulator networks in the Nordic countries especially in CRM simulator training but a good reference for this expression is lacking why this statement has been removed from the revised manuscript.

5. Comments

Discussion: Can you make recommendations for how to design the RCT to solve this issue? Ie mastery training, measure total cath time, appropriate training of femoral catheterization?

Response

Recommendations for future practice in CA simulators and for the CA procedure, including femoral catheterization have been added to the revised manuscript.

We have listen carefully to all your remarks and tried to meet all your suggestions for revision and hope that we now will have your approval for publication.

Best regards

The authors
Point-by-point response to Reviewer’s report by Lars Konge

1. Comments

Background: The lengthy description of existing studies concerning transfer of skills is unsystematic, missing important references, and should be rewritten. I believe reference number 12 is flawed - it is not a systematic review of 109 studies. Furthermore, to state that (only!) 3 reviews about 'the effectivenes of medical simulators have been published up-to-date', and to call Lynagh’s six years old review ‘the most recent’ shows a lack of careful review of the litterature. For instance, David Cook published a major review in JAMA a couple of years ago. A manuscript presenting national data covering 6 years deserves a (correct and) thorough description of existing litterature!

Response

The background section discussing previous studies has been elaborated and more organized, grouping reviews in general medical simulation and procedural skills separately. Ref nr 12 has been removed. Since our manuscript only includes a procedural skills simulator more effort has been made to refer to reviews and literature in procedural skills. The review by Cook is indeed a more recent review and has been added to the review list in the group of simulator training in general.

2. Comments

In my opinion the secondary aim does not add to the paper. That people training on a simulator improve their performance on the simulator has been shown (too!) many times and is merely quality control of only local interest.

Response

We agree that the secondary aim of the paper has been demonstrated many times before and we also agree that the comparison to the “VIST” group is somewhat confusing and has therefore been removed from the revised manuscript.

3. Comments

Ethics: Here it is stated that the procedures were video-recorded. It is not mentioned in the Methods section where (sim centre?, Cath lab?) and why this was done, and I am also not sure what Results have come from these recordings. This must be clarified. It is stated that all patients (4472 procedures) gave informed consent to participate in a training study comparing performance of trainees who had underwent simulation-based training with trainees without simulator training. If this is true it is an amazing effort - if it is not it should be removed from the paragraph.

Response

Since we decided to remove the parts in the manuscript comparing the course group to the VIST group we also removed the statement about video recordings. Video recordings were used in the sim centre for the group aiming for certification in VR CA. The participants that performed the extra training is marked in Table 1 in the revised manuscript. No further comparison to “VIST” group or
description of outcome of video recordings exists in the revised manuscript. All participants gave informed consent but not the patients why this has been removed from the revised manuscript. The SCAAR registry has a general ethics approval for retrospective analysis for procedural data excluding patient’s social security number. This opportunity was used in this analysis and it has been clarified in the revised manuscript.

4. Comments

Results: Course assessment compares some simulator metrics to some unpublished data. Participants course evaluation shows that participants like simulator training. I believe that it would add to the clarity of the manuscript to leave out these two redundant paragraphs.

Response

The results from simulator metrics is now published (Technical skills assessment in a coronary angiography simulator for construct validation; Jensen UJ, Jensen J, Olivecrona GK, Ahlberg G, Tornvall P; Simul Healthc. 2013 Oct;8(5):324-8.) but for the clarity of the manuscript we have removed these paragraphs as suggested.

5. Comments

Figures: I fail to see the relevance of Figures 3a and 3b. Please explain why it is necessary to divide results into femoral and radial access. The same is true for retention time: The relevance of this is not mentioned in the background or stated as a research question. Instead, it is suddenly treated in Figures 4a and 4b and 'introduced' in the discussion. Both issues are confusing and remove focus from the (important!) main finding of the paper.

Response

The time from taking a simulator-based course to actually performing the trained procedure in real life could have an impact of the freshness of the procedural knowledge practiced in the simulator. A general opinion is that a practical course should be attended in a near proximity to performing the actual procedure in real life but this did not seem to have any impact on the real life performance and therefore relevant to this study. Statements about this have been added to the revised manuscript. The statements about access site and fluoroscopy time have been removed since we agreed that it did not add to the study and original Figure 2a-b have been removed.

6. Comments

Discussion: A possible detrimental effect of training is a very important finding and should be discussed in more detail with more references and using a proper theoretical framework. The sentence: ‘... previously described as simulator behaviour’ must be properly referenced.

Response
The discussion about the “negative” effect of this course has been elaborated in more detail in the revised manuscript. However, there is limited literature in simulator-based training in procedural skills with neutral or negative results but more and relevant references have been added to the revised manuscript. Simulator behavior has been discussed in simulator networks in the Nordic countries especially in CRM simulator training but a good reference for this expression is lacking why this statement has been removed from the revised manuscript.

7. Comments

‘Future RCT’? I realize that the peer-review process can be long and sometimes exhausting. However it is necessary to carefully review the manuscript before each resubmission. Reading the manuscript for the first time in October 2013 it is annoying to hear about a RCT that will be completed in early 2013 - making the role for future VR training clearer. Makes me wonder why I am reading the current manuscript in stead of seeing the results of a study finished more than six months ago?

Response

We understand the reviewer’s frustration but there is a simple explanation for this statement. Yes, the submission procedure has been long and this manuscript was submitted to BMC in mid spring 2013 and after a long procedure trying to find reviewers (as explained to us by the journal editor) we got the answer that the paper was finally reviewed in late October. However, this “future RCT” is completed but still under statistical processing and not submitted.

8. Comments

Limitations: The important limitation of using fluoroscopy time as a parameter for competency should be mentioned and discussed in further detail.

Response

One limitation is using only one parameter for competency. However, we have demonstrated in a previous study (ref 20) that this was the only solid parameter to describe the learning curve in CA based on metrics and parameters extractable from the SCAAR registry. This parameter was also associated to patient outcome and we still think that this is a good and trackable parameter to follow the learning process in novel CA operators. This discussion has been added to the revised manuscript.

We have listened carefully to all your remarks and tried to meet all your suggestions for revision and hope that we now will have your approval for publication.

Best regards

The authors