Author’s response to reviews

Title: Incidence and Predictors of Groin Complications Early after Coronary Artery Intervention: A prospective Observational Study

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Author’s response to reviews:

Response to reviewer comments

• First we would like to thank the editors and the reviewers for their time, effort and the valuable comments.
• Below is a point by point response/explanation to the comments with actions taken in the manuscript.

Reviewer comment   Action/response   Location in manuscript

Geraldine Lee, PhD, BSc (Reviewer 1)
In the abstract: 'Females and participants aged more than 65 years were approximately double the time more likely to develop groin complications' - reword as this doesn't read well.

   Fixed accordingly   Abstract

Methods: These are fellows NOT follows. (p. 8, line 12)

   Fixed accordingly   Methods

P. 10, line 54- 'Data were verified by the cardiologist in the unit who is available' change to 'who was available'

   Fixed accordingly   Data collection procedure
p. 19, line 41. Change 'Newer studies' to 'New studies'

Fixed accordingly  Recommendation for future studies

Table 2, numbers are on wrong line: 234 should be beside the 78%

Fixed accordingly  Table 2

Sina Valiee (Reviewer 2)

The sampling is convenience or consecutive? You had not have the list of all patients so you cannot chose all consecutive.

This is the same comment from round one. The sample is consecutive sample. All participants who admitted during the data collection period were checked for the inclusion and exclusion criteria and the ones who met the inclusion criteria and agreed to participate were included in the study till we reached the required sample size. Figure 1 Patient flow diagram was added to clarify this point

Sampling

Reviewer comment  Action/response  Location in manuscript

There is no need to theoretical definition of variables. It's better to mention the practical definition of variables.

This is the same comment from round one. Again we did not define the variables theoretically, only operational definitions were included in table 1
The authors follow a cohort of 300 consecutive patients who consent to participate. It would be useful to know how many patients were approached and declined. This would give some indication of the representativeness of the sample.

Figure 1 Patient flow diagram was added to clarify this point. There were no differences between those who dropped and those who included in regard to major characteristics of the study.

**Sampling**

Best statistical practice would be to report the relative risk ratio rather than the odds ratio. The authors chose to use a logistic regression from which ORs are derived. Since the rate of complications is more than 10-15% (it is 38%), the OR can differ greatly from the RR and so is more difficult to interpret. The authors might consider a log transform rather than a logit transform.

- We used the logistic regression in the study because we want to control for all covariates in study based on the literature that might affect the development of complications which is the outcome of interest in this study. If we used RR alone, we will not be able to control for these covariates and the design of the study will be very weak and subject to criticism by medical filed professionals.

- Almost all previous studies conducted on the same topic and development of complications used logistic regression with OR reported even with higher incidence that reached up to 60%. These studies were reported in the current study as references. Moreover, if you have a look at table 5, most of the percentage of the complications developed is less than 20%. Only two complications were more than 20%.

**Reviewer comment**  
**Action/response**  
**Location in manuscript**

The authors state that a hierarchical model has been used but it is not clear what the hierarchy is. What is the higher level? The surgeon, the technician, the cath lab? No information about the higher level (random) effects is presented, yet could be of considerable interest.

This was fixed by adding a paragraph in the results section clarifying the three blocks of the hierarchical model and what was included in each block. The sheath removal conditions were entered in the last block because they are the most important predictors based on the literature.

Results section page 14 and 15
The sample size calculation does not justify N=300, but on the other hand there has been no adjustment for the hierarchical nature of the data which would inflate the sample size.

- More details were added about the sample size calculation and how we adjusted for the hierarchical nature of the data.
- Moreover, Figure 1 Patient flow diagram was added.

Sample and sampling page 7 and fig 1

The authors identify that there may be nonlinearity in the effects of age and SBP. Categorization is a sensible way to handle this and enable easy interpretation. They might state that nonlinearity is the reason for categorization.

Fixed accordingly Results

The English of the manuscript is to a reasonable standard but there are spelling and grammatical errors."

The manuscript was reviewed and fixed where appropriate

Whole manuscript.