Reviewer’s report

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

Version: 1 Date: 08 Feb 2019

Reviewer: Research Square

Reviewer's report:

"STATISTICAL REVIEWER ASSESSMENT:

Is the study design appropriate for the research question (considering whether the analyzed population accurately reflects the design and whether you see any problems with control/comparison groups, e.g., likely confounders)?

No - there are minor issues

Are methodologies adequate and well implemented (considering whether assumptions are addressed and whether analyses are robust)?

No - there are major issues

Are the analyses adequately communicated (considering whether reporting details are adequate and whether figures and tables are well labeled and described)?

No - there are major issues

Does the interpretation accurately reflect the analyses without overstatement (considering whether limitations/bias are acknowledged and whether accurate descriptors, e.g., 'significant', are used)?

No - there are major issues

Could an appropriately REVISED version of this work represent a statistically sound contribution?

Maybe - with major revisions
STATISTICAL REVIEWER COMMENTS:

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.

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.

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.

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.

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.

REQUESTED REVISIONS:

Revisions are stated in the comments above, the main issues are the number of patients approached and declined, the reporting of RR in place of ORs and appropriate model to enable this, and details of the hierarchical structure.

ADDITIONAL REQUESTS/SUGGESTIONS:

The English of the manuscript is to a reasonable standard but there are spelling and grammatical errors."
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Not suitable for publication unless extensively edited

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