Reviewer’s report

Title: Clinical evaluation of prostate cancer gene 3 score in diagnosis among Chinese men with prostate cancer and benign prostatic hyperplasia

Version: 0 Date: 30 Jul 2015

Reviewer: Pranav Sharma

Reviewer's report:

This is an interesting retrospective review of PCA3 and its correlation with PSA on a Chinese population as a detection tool for prostate cancer. PCA3 was a predictor of prostate cancer but interestingly did not show any correlation with high-risk (Gleason ≥ 8) prostate cancer.

There are several major issues that need to be addressed:

1) This is not a true screening population. These were patients selected because of a clinical concern for prostate cancer. The median age of the study population is also slightly older than a typical screening population. Additionally, PSA levels are much higher than a typical screening population. Therefore, the conclusions of this paper are only valid in a Chinese population with high clinical suspicion for prostate cancer and not in the general population. This selection bias and limitation should be mentioned by the authors.

2) Did the authors look at PCA3 as a predictor of clinical significant prostate cancer (Gleason ≥ 7). Even though PCA3 was not a predictor of high-risk disease, a more relevant question would be to determine if PCA3 was a predictor of clinically significant disease.

3) How were cut-offs determined from the ROC curve for PCA3? What methodology was used? Typically the Youden method is used to determine cut-offs points (highest combined sensitivity and specificity) but the authors do not comment on this methodology in the manuscript.

4) The authors comment that PCA3 had a better diagnostic accuracy than PSA, but this is not reflected by the results as the difference in AUC was not significant and both variables were independent predictors of prostate cancer in their multivariate model. This wording need to be changed throughout the manuscript to soften the conclusions.

5) Did the authors considering using PSA and PCA3 as continuous variables in their model? Categorizing this variable can often result in a loss of power although it may be more clinically applicable.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

**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 recommend additional statistical review

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Acceptable

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