Reviewer's report

**Title:** Comparing the efficacy of mydriatic cocktail-soaked sponge and conventional pupil dilation in patients using tamsulosin - a randomized controlled trial

**Version:** 1  **Date:** 3 May 2013

**Reviewer:** Sabyasachi Sengupta

**Reviewer's report:**

The authors have performed a good study and the study question under consideration is very relevant to most ophthalmologists, especially cataract surgeons.

However, the statistical analysis and results section need to be significantly improved to determine the potential hidden in the data.

- **Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)**

  1. Using permuted blocked randomization is useful with small sample size. However, the authors must provide the size of the blocks used. If these were small, block adjusted statistics (such as Contingency Chi2 test for categorical variables, stratified ANOVA and linear rank test for continuous variables) need to be performed to overcome the intra-block correlations (i.e. R). These can be ignored if the sizes of the blocks are large. Hence the authors must mention the size of the blocks. (see attached supplement material on blocked randomization and analysis of results)

  2. A more detailed description of the masked randomization would be appreciated. Exactly how the randomization was executed. The surgeon not being masked is a big drawback in the study design (mention this in the methods as well). However, were the surgeons involved in the dilatation process or were they only operating?

  3. Please mention the type of anesthesia used for cataract surgery. A retro/peribulbar block can cause pupillary dilation by itself which may potentially confound the results.

  4. While reporting percentages, please use a decimal point i.e. a dot rather than a comma (see introduction)

  5. I recommend performing 2 sets of statistics i.e. between group 1 and 2 & then between group 1 and 3. This will answer the following 2 questions:

     a) Whether cocktail with or without wick is better in eyes with tamsulosin and

     b) Whether eyes with tamsulosin differ from normals using wicks in both groups.

  6. In the results section, many p values are lacking. As per Table 1, the authors seem to have compared all 3 groups simultaneously. There should be one more
column for p value for each row. Comparing 3 groups cannot be done with student T test as mentioned by authors. It requires Kruskal – Wallis or ANOVA which is not mentioned by the authors.

7. The authors have divided the pupillary size into 3 categories (ordinal variable). Comparing these across groups requires Chi2 (Contingency Chi2 test for blocked randomized data). This is not mentioned and there are no p values comparing poor, sufficient and satisfactory mydriasis between the 3 groups at the 3 time points. These parameters could perhaps be shown in a graph (bar or boxplot) for easy comprehension by the readers.

8. The authors mention in methods that they have used multiple regressions. However, there is no evidence of this in the results section, except for the last line of results. Please mention whether linear or logistic regression was performed. If logistic regression was used, please mention whether ordinal or multi-nominal logistic regression was used (as outcome is ordinal)? Also please provide a table showing results from univariate and then multivariable analysis to show which variables were considered and how the multivariable models were set up. I recommend performing separate statistics between groups 1 and 2 and then between groups 1 and 3 (see above). Regression analysis is not a must for such a small data set and may be omitted by the authors if not feasible.

• Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. The sentence starting with “Histologic examination of cadaveric eyes with history of tamsulosin treatment showed a decreased iris dilator muscle thickness ….” Is not relevant to the study and is out of context in the introduction. This may be deleted.

2. Spelling mistakes need to be corrected. Eg. “horisontal chop”

3. Suggest using STATA or SPSS for statistics with a statistician to improve results and discuss the new results appropriately

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

No financial interests to declare with respect to this manuscript