WJCU BPH RESPONSE TO REVIEWERS QUERIES

Reviewer 00468558

1) I wonder why Authors employed the non bladder continuous irrigation policy if they state that the continuous irrigation itself is effective. It must be explained in the text. 2) The trial has not been registered 3) There is no mention in the text about the Helsinki declaration of the world medical association 4) Moreover, there is no mention of the study design. How was the dimension of the population obtained ? Which was the expected difference in the 2 groups? Which was the main end point of the study (transfusion rate, reoperation rate, etc)?

Response

1. OSP without CBI is preffered to OSP with CBI. The reason for this and appropriate references have been added to the discussion ,paragraph 3 line 6-9.
2. The trial protocol was reviewed and approved by Ebonyi state University Research Committee(UREC) and the certificate will be uploaded if required.
3. Helsinki declaration – The statement with reference to the Helsinki declaration has been added to the methods section.
4. Details of study design and sample size determination have been added to the methods section. the. The primary end point of the study was clot retention episodes and clot retention episodes requiring bladder syringe evacuation. These details have been included in the Patients and Methods section.

Sample size calculation.

The study will be with a power of 95% i.e.(1-β) = 0.95 and at a level of significance, α, of 0.01% to sufficiently detect a difference of 8%[4,9,10] Vs 47%[5] in the proportion of those developing clot retention after open simple prostatectomy without bladder irrigation, in subjects drained by combined 2-way urethral catheter and suprapubic catheter versus those drained by 2-way urethral catheter only.

The sample size required to detect the above effect size was determined using the following formula[22];

$$n = \frac{f(\alpha,\beta\,)[P0(100-P0)+P1(100-P1)]}{(P0-P1)2}$$

Where

P_0 = proportion of participants in Group 2 expected to develop clot retention = 47%

P_1= proportion of participants in Group 1 expected to develop clot retention = 8%

f (α, β) = 17.8

n= $17.8[47(100-47) + 8(100-8)] / (47-8)^2$

n = $17.8 \times [(47 \times 53) + (8 \times 92)] / (39)^2$

n= 17.8 x 3227/1521

= 37.8

This returned a sample size of approximately 40 participants per arm of the study and 80 participants in both arms.

Ref.

22.Altman DG. Practical statistics for Medical Research. London: Chapman and Hall; 1991.Chapter 10,section 10.3,p232-235.

Reviewer 00505650

The endpoints of the study should be clearly outlined - How many surgeons performed the surgery and with what experience? - The Authors should specify why continuous irrigation is an issue for underdeveloped countries (Cost? Management?) And a mention of the additional cost of the use of an extra catheter per patient should be done - The Authors should cite in the discussion the possible difference of a Millin (bladder sparing) approach - Was the study statistically powered for statistical significance? (i.e. is 42 per arm statistically sound?) - Complications should be reported using the Clavien Dindo score and furthermore should be statistically compared (see table and text) - Why was a IPSS score not used? - The Authors should omit results from the discussion section - Overall the discussions section can be improved in a more articulate fashion, adding a pharmaco-economical view to highlight

the rationale of the study - References are updated - Followup outcomes should be summarized in a separate table.

Response.

-The study endpoints have been added to the Materials and Methods section under operative technique paragraph 3. Line 4-8. The primary outcomes were number of participants with clot retention episodes, and number of clot retention episodes requiring bladder syringe evacuation.

- Only one surgeon, the author**.** With 12 years post fellowship experience at the commencement of the study performed the surgeries.

-The Controversies over Continous irrigation have been added to the discussion. Please see discussion paragraph 3 line 6 to 9.

-The additional catheter used is a silicone coated size 22F catheter costing approximately 50cents.We did not think it necessary to do a cost benefit analysis for this extra catheter because of the insignificant cost.

- We have not studied the possible difference of a Millin (bladder sparing) approach, but theoretically there should be no difference.

-Sample size calculation and power of the study have been added to the Materials and Methods section.

- Complications and their Clavien Dindo score and statistical comparison has been incorporated in table 2.

- Majority of patients, more than 98% had been on catheter for months and therefore did not qualify for evaluation with the IPSS questionnaire.

-An attempt has been made to do a pharmaco-economic view to highlight the rationale of the study.Paragraph 7.Line 7-14.

Reviewer 00505655

However, I suggest some minor revisions in order to improve the quality of the manuscript:

- Sample size calculation has been added to the methods section.

- Table 1 lists baseline patients characteristics.

-Complications are listed in table 2.

Dr Obi AO

Answer:

I have already clarified the questions by reviewers and responded to the suggestions.If there are new clarifications or suggestions please kindly let me know.

Dr Obi A.O.