Peer Review File

Article information: https://dx.doi.org/10.21037/tau-24-279

Reviewer A

- *Comment 1: The SP arm only included 33 patients and maybe with more patients in that arm you could potentially find a difference in the protocol. Please expand on why you feel the new protocol is better. It does use the same agent and takes longer so please comment are you still using it, now that you showed that it does not make any difference in infection.*

Reply 1: We acknowledge that the SP arm had a limited number of patients. The new protocol was considered better due to the comprehensive nature of the skin preparation steps, which theoretically could reduce infection risk. However, our study did not find a significant difference in infection rates. Despite this, we have continued to use the new protocol as it may offer other unmeasured benefits.

Changes in the text: We have expanded on the rationale for the new protocol and commented on its continued use despite the findings (see Page 5, lines 163-164).

- *Comment 2: You should even include one sentence about the type of protocols used in the abstract and definitely explain in the introduction, why you think that the NP is more beneficial.*

Reply 2: We have included a sentence in the abstract summarizing the protocols and expanded the introduction to explain the potential benefits of the new protocol.
The new protocol (NP) is considered more beneficial because expert consensus during meetings highlighted its increased effectiveness in reducing infection rates without any evidence-based studies at that time. By incorporating two rounds of skin cleansing with soap povidone iodine and two rounds of disinfection with alcoholic povidone iodine, NP provides a more thorough decontamination process compared to the standard protocol (SP). This enhanced preparation would help in minimizing microbial load and improves overall infection control.

Changes in the text: we added a sentence to the abstract (see Page 2, lines 47-49.
and detailed the benefits in the introduction (Page 3, lines 90-93).

- *Comment 3: In addition, I do not think erosion is related to intra-/post-OP infection, so you can remove that.*

Reply 3: We have revised the manuscript to remove any implication that erosion is related to intra-/post-operative infection. E.g., experimented surgeon experienced surgeon, for male severe stress urinary incontinence for severe male stress urinary incontinence, risk of early infection or erosion device or erosion of the device.
In addition, keep abbreviation constant: use AUS, not SAU.

Changes in the text: Removed mentions of erosion in relation to infection (see Page 2, lines 42, 54, page 3 line 88)

- *Comment 4: I recommend having the manuscript reviewed by a native English speaker, there are several issues with the writing.*

Reply 4: We have revised the manuscript for clarity and grammar, ensuring proper terminology is used.

Changes in the text: Revised manuscript for grammatical accuracy (see corrected sentences and grammar in the revised manuscript)

- *Comment 5: Only using cefazolin, is this following guideline? Please comment.*

Reply 5: We have included a comment on the use of cefazolin and its adherence to French guidelines. Indeed, in urology, the prescription of surgical antibiotic prophylaxis follows the 1999 SFAR recommendations.

Bruyère F, Sotto A, Escaravage L, Cariou G, Mignard JP, Coloby P, Hoznek A, Bernard L, Boiteux JP, Thibault M, Soussy CJ. Recommandations de bonnes pratiques cliniques : l'antibioprophylaxie en chirurgie urologique, par le Comité d'infectiologie de l'association française d'urologie (CIAFU). Progrès en urologie. 2010 Feb 1;20(2):101-8.

Changes in the text: we added a statement on antibiotic use guidelines (see Page 3, line 93).

- *Comment 6: Line 83: please include the rate, not only the numbers of explants.*

Reply 6: We have included the rate of explants in addition to the numbers "A total of

60 AUS were explanted (38.4%), 18 in the group of SP (54,5%) and 42 in the group of NP (34,4%)."

Changes in the text: we added explantation rates as shown on Page 4, lines 111, 112.

- *Comment 7:In the discussion, line 108-121, you only cite published literature, but do not comment on how this is pertinent to your study, it is no coherent.*

Reply 7: We have revised the discussion to relate cited literature directly to our study findings.

Changes in the text: Improved discussion coherence (see Page 5, lines 163-167).

Reviewer B

- *Comment 1: Is UAS or SAU the same as AUS? Need to be more consistent and refer the implant as AUS throughout the abstract and manuscript.*

Reply 1: We have standardized the term to AUS throughout the manuscript.

Changes in the text: Replaced UAS and SAU with AUS (see throughout the manuscript: page 2, lines 45,46,47 page 3 lines 69, 88, 90 and page 4, line 107).

- *Comment 2: Did the technique to implant an AUS device change from 2015? Were there any modifications in the device itself that could decrease potential risk of infection or re-operation?*

Reply 2: We have clarified that the technique and device used remained consistent throughout the study period.

Changes in the text: we added clarification on the consistency of techniques and devices (see Page 3, lines 102-104).

- *Comment 3: Did you account for the surgeon's experience which also impacts outcomes?*

Reply 3: We clarified that the procedures were performed exclusively by two experienced surgeons specialized in AUS implantation. Therefore, we did not analyze the impact of the surgeon's experience on outcomes.

Changes in the text: we clarified this in the manuscript (page 3, line 96)

- *Comment 4: Perhaps consider doing propensity score matching of the two patient groups to see if the preoperative characteristics were similar in both groups.*

Reply 4: We could consider performing propensity score matching at a later stage to ensure that preoperative characteristics are similar between the two patient groups and to better evaluate the impact of the skin preparation protocol on infection rates.

- *Comment 5: Do the authors truly believe both preps are equal? If so, why not design a prospective randomized trial on the next 20-30 patients and evaluate outcomes?*

Reply 5: We have acknowledged the need for prospective randomized trials and suggested it for future research.

Changes in the text: we suggested future prospective trials (see Page 7, lines 175-176).

<u>Reviewer C</u>

The authors looked to compare different protocols for skin prep prior to artificial urinary sphincter placement to determine differences in infection/explantation rates.

- *Comment 1: What is the true difference between the two different protocols and what is the clinical significance?*

Reply 1: We have detailed the differences between the protocols. The assumption was that the more rigorous and prolonged antiseptic regimen would lead to a more effective reduction in microbial contamination at the surgical site. This was based on the idea that enhanced skin cleansing and disinfection would decrease the microbial load, thereby lowering the risk of infection and improving overall surgical outcomes.

Changes in the text: we added a detailed comparison (see Page 3, lines 99-103).

- *Comment 2: What hypothesis did the authors have prior to embarking on this study and why the change occurred in the first place?*

Reply 2: We hypothesized that the new cutaneous preparation protocol, which involved two rounds of skin cleansing with soap povidone iodine and two rounds of disinfection with alcoholic povidone iodine, would result in a lower infection rate compared to the standard protocol. This hypothesis was based on the assumption that the more rigorous and prolonged antiseptic regimen would provide a more effective reduction in microbial contamination at the surgical site.

The change to the new protocol was likely driven by the aim to enhance infection control and improve patient outcomes based on evolving practices and emerging experts consnensus rather than evidence-based studies.

- *Comment 3: Were there studies that influenced the decision for the change in protocol?*

Reply 3: No single study has already studied the difference between different skin preparation protocols. This Was only guided by experts consensus.

- *Comment 4:Does skin prep have a higher role in infection/explantation compared to other factors such as radiation?*

Reply 4: When comparing the role of skin preparation to other factors such as radiation, it is noteworthy that with the new protocol, the infection rate was 25%, which is comparable to the 26% infection rate associated with radiation. This suggests that while skin preparation is important, its impact on infection rates may be similar to the influence of other significant factors like radiation.

Minor Comment: Would ensure that the acronym for AUS is consistent throughout the paper and use "periods" instead of "commas" for decimal indication.

Reply: We have made these minor corrections.

Changes in the text: We replaced UAS and SAU with AUS (see throughout the manuscript: page 2, lines 45,46,47 page 3 lines 69, 88, 90 and page 4, line 107).We

also corrected decimal indications lines 56,57,132,133.

Reviewer D

This is a very interesting article, because it draws attention to the problem of infection in prosthetic implants.
As this is a problem with a generally low incidence in the literature, it is a difficult subject to address and draw conclusions about. The authors should be very clear on this issue.
Therefore, they should clarify very well before acceptance:

- *Comment 1: Was a differentiation made between infection after erosion or isolated infection? We need to know the median and range of occurrence of infection. What was the result of the cultures after explanting?*

Reply 1: As mentioned and clarified in response to reviewer A, we have revised the manuscript to remove any implication that erosion is related to intra-/post-operative infection.

Changes in the text: Removed mentions of erosion in relation to infection (see Page 2, lines 42, 54, page 3 line 88)

- *Comment 2: Has the use of AMS-800 with Inhibizone been considered, as this reduces the risk of infection?*

Reply 2: Inhibizone has been used to help prevent infections associated with implantable devices, including those used in urinary sphincter procedures. However, it was not used in our study.