

Peer Review File

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Reviewer A:

Comment: This is a well written review of current trends in management of male SUI. The included topics surrounding male SUI management and device selection and perioperative management are certainly relevant.

If there is additional space in the article a few other notable areas that may be worth discussing are: 1) when is the VUA stable for patients with VUAS and what is an acceptable caliber urethra to proceed with AUS/Sling. 2) Role of ProACT device and where this fits into management paradigm

Otherwise- nice summary of the topics presented.

Reply: We greatly appreciate the helpful comments and feedback. The preselected topics were discussed with the editorial team for this particular TAU series article prior to manuscript creation.

Regarding the VUAS topic, we agree that this is a very important topic to discuss, but feel this would be best covered in a stand-alone separate manuscript on the overall management of concurrent SUI and VUAS/BNC. Given that there are so many variables involved in how the VUAS/BNC is managed and how that potentially impacts what is considered “stable” or an acceptably patent lumen (surgical approach utilized - endoscopic vs. robotic vs open, virgin or refractory case, the use of antifibrotic agents, the use of substitution grafts, history of prior pelvic radiation, presence of prostatic calcifications, etc), it would be difficult to concisely summarize that information and its direct impact on SUI management decisions in this current manuscript in addition to these other topics.

Regarding the topic of adjustable balloon devices, we briefly alluded to adjustable balloons in the 1<sup>st</sup> paragraph of the introduction, added a sentence in the new summarizing paragraph of the AUS vs. MS section in the main body, and also discussed in the conclusion how advances in surgical device technology will have an effect on device utilization patterns in the future, but that published literature that captures this particular information tends to lag behind several years. We considered adding an additional distinct section in the main body on the role of the adjustable balloon devices in the SUI space, as we agree that this is an emerging topic that is mentioned in the AUA Guidelines as a treatment option that can be offered for mild SUI. However, given that the overall clinical experience and available published literature is limited relative to that of the AUS or MS at this time, we felt that it was better to focus our attention on comparing surgical practice patterns of the AUS vs. MS for this particular manuscript. If the clinical experience with adjustable balloon devices becomes more robust and widespread in the future, we agree that this is certainly a topic of interest that should be included in future similar review articles.

Reviewer B:

Comment 1: Thank you for submitting this review.

This is a non-systematic comprehensive review of current practices in surgical procedures for male SUI, attempting to answer the following questions:

- ♣ Artificial urinary sphincter vs. male sling utilization: There is already a RCT published in 2021
- ♣ Prevalence of outpatient procedures (which is more focused on the US market)

♣ 3.5 centimeter artificial urinary sphincter cuff use (prospective study already exist)

♣ Preop urine analysis

♣ Antibiotic prophylaxis

Although well-written, this comprehensive review is a weak attempt to answer these very contemporary & important questions, with low scientific credentials. It would have been of much more value to have addressed these questions with a systematic review and meta-analysis. Furthermore, some of the questions have partially been answered in the 2016 Consensus by Biarreau et. al in NeuroUrology & Urodynamics. The authors fail to address the issue in a solid methodological manner, with an international perspective. As an AUS implantor, I have not learned anything new. However, the above questions are clinically important and need to be addressed as highlighted in my comments in the conclusion.

I would like to see these questions answered in a systematic review and meta-analysis for publication purposes, as this constitutes the first step to identify research criteria prior to RCTs/prospective studies.

Reply 1: We appreciate the reviewer's extremely thorough comments and candor. Unfortunately, it seems that the vast majority of the reviewer's critiques stem from a fundamental misunderstanding of the purpose of this manuscript.

As stated on the title page, this is both a clinical practice review and an invited publication for a specific journal series. Per discussion with the editorial team prior to manuscript creation, this was never intended to be a systematic review and meta-analysis. Based on the available TAU manuscript categories, it was determined that clinical practice review was the best fit for this manuscript and the TAU guidelines for that specific manuscript category were followed. As such, there will certainly be references that are not included in our manuscript as this was never intended to be completely comprehensive systematic review and meta-analysis on these topics. Our main objective was to capture and document the contemporary narrative of each topic, not include and address every available manuscript/guideline/consensus statement/position statement ever published.

Because of this misunderstanding and its impact on the vast majority of the reviewer comments, if any of the reviewer comments below do not have a direct reply to them, it is because these initial paragraphs serve as the reply to those comments instead of repeating these above statements.

Comment 2: Title: Changes and Debates in Male SUI Surgery Practice Patterns: A Contemporary Review

Abstract:

Reads as a 'stand along' representation of the manuscript.

Background and urgency are clearly stated.

Methodology: A contemporary practice review needs more defining. This is obviously a comprehensive literature review of current practices on the subject.

Conclusion: what are the conclusions supported by the data provided? A line or 2 concluding your findings would be recommended.

Reply 2: Given that this manuscript covers multiple different topics each with its own conclusions, it would be too challenging to summarize each of those topic conclusions succinctly in the abstract setting in "a line or 2". This is best reserved for each section of the main body as is addressed in later comments.

Comment 3: Introduction:

The intro gives a short word on causes of male SUI, conservative and surgical management options. It needs more solid references as outlined below.

Line 63-68: references need completing. If you compare AUS and MS the RCT from Constable et al. needs to be mentioned (MASTER trial, Eur. Urol 2021) and Van der Aa's systematic review, 2013.

The authors wish to answer the following questions:

- ♣ artificial urinary sphincter vs. male sling utilization: worldwide or just in the US?
- ♣ the prevalence of outpatient procedures: worldwide or just in the US?
- ♣ 3.5 centimeter artificial urinary sphincter cuff use
- ♣ preoperative urine studies utilization:

which ones? Can you specify? Do you also include urodynamics? This would be of interest. Most high-volume centers proceed as such.

- ♣ intraoperative and postoperative antibiotics: will the authors also address the question of the antibiotic coated AUS?

I would like to see a small paragraph on what the literature reports on the above points and cite a few more papers. Much has been written on 3.5 cm AUS cuffs. The authors should additionally also comment on ICS, NICE and European Guidelines on preoperative investigations as well as antibiotic use (not only AUA guidelines, but the authors also need to include an international perspective), as well as a word on 'Artificial Urinary Sphincter: Report of the 2015 Consensus Conference' published in 2016 (Biardeau) to illustrate the lack of consensus on the matter.

#### Methodology

You are not conducting a thorough literature review. If that were the case, you would have conducted a systematic review (SR) with meta-analysis (the last conducted by Van der Aa in 2013). This constitutes a major weakness in this study. It has been nearly 10 years since the last SR. It would be of greater scientific value if the authors could conduct such a study focusing on the questions they wish to answer.

The methodology by the authors is a comprehensive literature review focusing on current AUS practices, such as pre-operative workup/evaluations, prophylactic antibiotics and the use of the 3.5 cm cuff among other issues/themes on the subject. Please specify and clarify your methodology. A 'thorough literature review' does not suffice. I would also add ICS guidelines.

You need to specify your search terms: did the authors use MeSH terms? Please specify and double check that your search terms correspond to the MeSH requirements.

#### Main body

AUS/MS

Line 93:

the MASTERS study is the only RCT to date comparing AUS and MS. This today is THE study of reference on which AUA, EAU and NICE guidelines will be based upon. It would be nice if the authors could expand more on the findings and mention if the above queries (pre-op investigations for example, preop urodynamics, antibiotic usage, cuff sizes ect... were reported if I am correct) have been addressed in Constable/Abram's paper or not. It was concluded that both therapies were equivalent with the AUS being superior in moderate to severe SUI. The MS leads to more SUI recurrences in the long-term compared to AUS. This needs to be mentioned in your paragraph.

Until now there were only retrospective comparative studies, which have less scientific credentials. Are there any prospective comparative studies the authors could mention and comment on? It is worth adding these in your references.

Reply 3: A new section has been added to summarize the MASTER study findings in more detail.

Comment 4: Line 103: Does this apply to AUS data alone? I think it should have more international data as the USA is not the only country to carry out AUS/MS procedures. Please add other international data.

Lines 117-153

Could the authors summarize the trend in the USA, is this trend like the rest of the world?

Please add a conclusion paragraph.

Reply 4: A conclusion paragraph has been added.

Comment 5: Outpatient AUS/MS volume

All the studies reported by the author are based on small cohort retrospective studies.

Do the authors have any prospective study data?

I would like a small conclusion paragraph here too: one cannot draw any conclusions on the outpatient volume trend due to retrospective quality of current data. However, an increase trend of outpatient procedures could be expected in the future but additional more robust data is required.

Could you comment on how this could be relevant in today's urological practice (there is an obvious financial incentive). Is it safe for the patient? Are the long-term functional and qualitative outcomes beneficial compared to inpatient SUI surgery? How would you counsel the patient with regard to outpatient SUI procedure? Could you comment?

Reply 5: A conclusion paragraph has been added.

Comment 6: 3.5 cm cuff

Do AUA, EAU, NICE guidelines mention anything?

Missing references:

♣ Biardeau (consensus 2016)

♣ Dan Elliott's series from Johns Hopkins (a study including over 1830 men)

Please add a small summary of your findings

Reply 6: A conclusion paragraph has been added.

Comment 7: Post-op catheterization practices

I would add the catheter size recommendations by the manufacturer (see Instructions for Use, AMS 800, 2017 version)

Perhaps the Biardeau consensus 2016 comments on this?

To my knowledge, there are no multicentric prospective study on the subject. The best is for the authors to look into

published data by 3-5 high volume centres world-wide (Dan Elliott at Johns Hopkins, Chartier-Kastler in France, to name but a few) to be able to draw a conclusion on current trends and practices by Key Opinion leaders.  
Please state not only AUA guidelines, but also EAU, ICS, NICE guidelines (grades of recommendations ect..)

A small conclusion at the end of the paragraph would be nice.

Preop urine studies

I agree that there are few studies on the matter. The authors could also comment on the findings published in the MASTERS trial which failed to report the usage of pre-op antibiotics. Perhaps writing to the MASTERS study authors to ask for additional unpublished information could shed some light?

Please state not only AUA guidelines, but also EAU, ICS, NICE guidelines (grades of recommendations ect..)

Add a small summarizing line.

Reply 7: A conclusion paragraph has been added.

Comment 8: Antibiotics

Also the Biardeau et al consensus from 2016 makes a short and good summary on the subject which the authors have not commented on. I would also like to see a paragraph on the use of antibiotic coated AUS, which is also a contentious subject.

This reference below should be added

Wolf JS, Bennett CJ, Dmochowski RR, et al. Best practice policy statement on urologic surgery antimicrobial prophylaxis. *J Urol* 2008;179:1379–90.

Reply 7: A more up to date reference is used instead.

Comment 8: Please state not only AUA guidelines, but also EAU, ICS, NICE guidelines (grades of recommendations ect..).

Also add a summarizing line at the end of the paragraph

Conclusion

1. This is a comprehensive literature review focusing on current practices regarding SUI procedures, namely outpatient trends, preoperative urine analysis and antibiotic prophylaxis, the use of the 3.5 cm cuff and postoperative indwelling catheter periods.
2. Although there are very few RCT and prospective studies available, the authors were unable to answer the above questions.
3. An updated systematic review of the literature with a meta-analysis would have been an appropriate first step, focusing on the above questions, which the authors have not conducted, which is a shame. This type of review helps define criteria required to design a RCT/prospective multicenter studies.

Unfortunately RCTs are costly and difficult to conduct in surgical settings for obvious ethical reasons. Multi-centric prospective trials could also shed light on the matter. Finally, working groups similar to the Consensus in 2016 could help review current practices in the US and world-wide.

Reviewer C:

Comment 1: Desai and colleagues deal in their review “Changes and Debates in Male SUI Surgery Practice Patterns: A Contemporary Review” with current trend in incontinence surgery for men. They focus on comparison of artificial urinary sphincter vs. male sling. Moreover on prevalence of outpatient procedures, 3.5 centimeter artificial urinary sphincter cuff use, preoperative urine cultures, and perioperative antibiotics.

I really enjoyed reading this review. It addresses relevant controversial issues. However, I would recommend summarizing each section. As for example in section “AUS vs. MS Utilization”, Abrams publication is quoted. I would favour to have stressed at the end of the section, that best evidence shows equal results for both AUS and MS.

Reply 1: We greatly appreciate the helpful comments and feedback. Summary paragraphs have been added to each section in the main body, with the exception of the sections on postoperative catheter utilization and perioperative antibiotics as the limited data and studies that comprise these sections already serve as effective summaries.

Comment 2: Moreover, there are some minor issues:

Page 10, line 219: The correct name is Queissert (not “Quessert”).

Reply 2: This has been corrected.

Comment 3: The second reference is not necessary. I think there is enough published (and therefore peer reviewed) literature on SUI.

Reply 3: This reference has been removed.