Peer Review File
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Reviewer A:

Comment 1: The intended narrative review paper has severe limitations.
-Very superficial discussion on various continence devices
-References are not up-to-date and do not take into account landmark papers; needs to discuss the recent 7th International Consultation on Incontinence

Reply 1: We have added more up-to-date papers and gone more in-depth throughout the manuscript, such as the following paragraph regarding the AdVance and AdVance XP slings.

"For fixed models, Rehder and Gozzi first reported a transobturator tape used in cadavers and later in a pilot of 20 men in 2007(16). This was followed by a series of 67 patients(17) and shortly thereafter developed into the AdVance Male Sling (Boston Scientific, Marlborough, Massachusetts, USA)(18). The second-generation AdVance XP (Figure 1) entered the market in 2010(19) with design modifications including a new anchoring mechanism to prevent migration, a liner, and longer mesh arms for easier use in obese patients(13). Overall cure rate (0 pad use) has been reported at 80% with a median follow up of 26 months(19). In comparative work, there are largely no significant differences between the original and XP models, both in terms of outcomes and complications except for higher rates of urinary retention in the XP(20). Adverse events related to these slings include elevated post-void residual, increased bleeding, and decreased satisfaction with a need for subsequent incontinence procedures(21)." (Page 3, Lines 17-27)

21. Del Favero L, Tasso G, Deruyver Y, Tutolo M, Beels E, Schillebeeckx C, et al. Long-term Functional Outcomes and Patient Satisfaction After AdVance and AdVanceXP Male Sling Surgery. Eur Urol Focus. 2022 Sep;8(5):1408–14.

We have also made comment regarding ICI7 to help direct interested readers to this thorough work.

“Additionally, we would like to highlight the continued efforts and innovative work being done by contributors to the International Consultation on Incontinence, with the 7th consultation occurring in November 2021. We look forward to Abrams and colleagues’ updated edition of “Incontinence”, which will provide a far more comprehensive overview of male SUI than a review article could hope to accomplish. And finally, with all of the available devices on the market, continued efforts to refine patient selection and to individualize treatment will improve patient care. ”(Page9, lines 22-27)

Comment 2: Does not provide useful guidance to readers on how to choose the right treatment

Reply 2: We have amended our Methods section to discuss that this manuscript is not intended as a guide on how to choose the correct treatment, we will leave that to shared decision making between providers and patients. but instead to educate our readers on what treatments existed previously and currently in their own markets. This may be helpful as providers may only be aware of what they have learned about in their own training or what is directly available in their market, but not familiar with historic treatments or existing treatments in other parts of the world. This type of information will allow readers to be knowledgeable of the field of SUI and be aware of any questions that their patients may bring forth.

“Further, this review is intended to provide an overview for readers and is not designed to guide or recommend treatment for individual patients as this decision is best left to shared decision making between patient and provider.” (Page 2, Lines 13-15)

Comment 3: Fails to highlight key similarities and differences between these devices - having a table will be useful here

Reply 3: We have split our table now into 3 separate tables to distinguish between fixed slings, adjustable slings, and artificial sphincters. We have

attempted to better display the table to make benefits and complications more readable.

Comment 4: Should propose what needs to be done in future research in this field

Reply 4: We appreciate this suggestion and added comment on future research applications

"The landscape of treatment options for SUI is constantly changing, with innovative research being published daily. Many opportunities for research to improve our care of patients remains. One of the pitfalls when studying SUI is the lack of standardization across studies. This can make comparisons between devices difficult as definitions of "success" are not uniform. Future directions to standardize how we communicate and evaluate SUI and treatment of SUI will benefit providers and more importantly patients. Other areas of future research include more multi-institutional and registry-based studies. Much literature regarding SUI comes from single institutional studies or studies only including a few institutions. Multi-institutional initiatives such as the DOMINO project are applauded, and even larger registry-based studies would be strongly welcomed as this can capture more real-world outcomes in a way that has been lacking. Additionally, we would like to highlight the continued efforts and innovative work being done by contributors to the International Consultation on Incontinence, with the 7th consultation occurring in November 2021. We look forward to Abrams and colleagues' updated edition of "Incontinence", which will provide a far more comprehensive overview of male SUI than a review article could hope to accomplish. And finally, with all of the available devices on the market, continued efforts to refine patient selection and to individualize treatment will improve patient care. "(Page 9, lines 13-27)

Reviewer B:

Comment 1: The authors propose a narrative review of the options available to men with SUI.

Introduction:

Good background on the landscape of SUI.

Reply 1: We thank the reviewer

Comment 2: Methods:

Narrative review is almost a “review of reviews” which also includes guidelines. Recommend including some key words or inclusion/exclusion. Understanding its no a systematic review were some reviews prioritized over others? Did you intentionally exclude options for SUI that are not available worldwide?

Reply 2: Given it is not a systematic review, we did not have a formal exclusion or prioritization process. We did not intentionally exclude options for SUI that are not available worldwide, and in fact did try to seek out options available worldwide.

Comment 3: Conservative Management:

Recommend inclusion of other non-invasive containment systems (AFEX and similar)

Imipramine used off label. Can potentially be more broad with “various off-label medications”

Reply 3: We have removed the discussion of imipramine and instead focused our manuscript on surgical treatments.

Comment 4: Operative Management

For reader clarity it may be beneficial to group all of the slings that are historical or no longer available together. The M sling, the TiLOOP, and INvance. This will help draw attention to reader for what options are still available.

Reply 4: We have moved the historical options to the end of the discussion so that it may be less confusing to readers and have the following paragraph describing them.

"*Historical Devices*

In contrast, older models have since been taken off the market. A historical mention will be made of the InVance male sling (American Medical Systems, Minnetonka, Minnesota, USA)(49). This sling was anchored to bone, but given associations with bone infection and a high failure rate(50), it is no longer available for use. Similarly, the TiLOOP Male (pfm medical, Cologne, Germany) (Figure 11) sling uniquely had a titanium coating designed with the theory that the titanium coating would limit cellular reactions(51–53), like apoptosis and proliferation. This carried the apparent advantage of minimizing inflammation, shrinkage, and sling migration. In a study of 44 patients with midterm follow up, objective and subjective improvement were nearly consistent at 77% and 75% with a median follow up of 25 months(54). Although this device is no longer available on the company website, some argue perhaps it was prematurely disregarded(55). Finally, another fixed sling includes the Surgimesh M-Sling (Aspide Medical, La Talaudière, France), with one study from France available in the literature(56). This sling was designed for direct implantation over the urethral bulb and includes two transobturator and two prepubic arms with divergent traction axes to provide adequate tension. In a study of 77 patients, 34.4% reported a cure (0 pad or daily pad weight <2g) and 71% reported being either "satisfied" or "very satisfied" after 24 months (56). The M-Sling is no longer available on the company website.

" (Page 8, line 17 – Page 9, line 4)

Comment 5: Similarly in lines 207/208 recommend leading with the fact that no adjustable sling is approved in men.

Reply 5: We appreciate this suggestion.

“ There is not yet strong evidence to suggest having an adjustable sling provides additional benefit(3), and no adjustable sling has yet been approved for use in men within the United States, although there is a theoretical advantage. “ (Page 5, lines 2 - 4).

Comment 6: Conclusions
Well contextualized conclusions.

Figures: Would prioritize approved/active devices for figures and leave others as appendices.
Table 1: Add some of these into methods.
Table 2: Recommend breaking into 3 parts correlating with the review sections (conservative, sling, AUS). Will be easier for reader to process information.

Reply 6: We have edited our table as such

Reviewer C:

Comment: Well written narrative review article. Good figures. Descriptions of each treatment option were fairly brief, however given the broad nature of the article, it is difficult to go into significant depth on each and every treatment option. Submission checklist needs to be finalized. Some fields had responses like "will do", "need", or "maybe?".

Reply: Our apologies, we submitted the incorrect form of the checklist. An updated version has been submitted.

Reviewer D:

Comment 1: I contratulate to the efforts to provide an overview on current treatment option of male SUI, although this has already been targeted recently by other groups, such as the EAU-YAU (Ranama'i 2021, Front surgery)
I have the following comments:
Reply 1: We thank this Reviewer for their thorough appraisal of our work and multiple suggestions to improve our manuscript.

1) Bulking agents are actually more frequently used according some published data, such as the Medicare database and is reported in up to 30% (Chugtai et al, 2016 NeurUrol Urodynamics). PLease comment. Furthermore, please add some critical discussion about the efficacy of this treatment option and risk-benefit ratio (rare frozen urethra) and the possibility for secondary surgeries in this context.

Reply 2: We have added further discussion and reference; thank you for this suggestion

"In the first decade of the new millennia, bulking agents were performed in around one-quarter to one-third of men with SUI(11). However, following this initial enthusiasm, there has been limited data supporting the efficacy of these treatments(12) and a need for contemporary literature describing their current applications and efficacies. A recent systematic review by Toia et al. noted a wide variability in reported outcomes with moderate to severe risk of bias (12). The review concluded that there is some evidence for short term improvement in men (up to 83% completely dry in one study) but that the data is scarce with a relatively high risk of bias and that durability of success remains a challenge." (Page 2, line 23 – Page 3, line 2)

2) Please add more information regarding off label use of duloxetin. Importantly to highlight the faster recovery but total SUI impact is not affected by duloxeting.

please comment on pre-operative Physiotherapy in contrast to post-operative physiotherapy and reasonable time frames for its applications. When should physiotherapy stopped and surgical treatment be offered.

Reply 3: We have decided to omit non-surgical options from our review and focus on surgical options only.

In fixed slings, the compression effect is not in front, but the repositioning. (Secondary leading to more compression due to increased blood flow etc..) please describe more in detail. Please differentiate clearly between adjustable (here also additional compression) and fixed sling.
Please consider also the common terminology on fixed and adjustable slings (not non-adjustable).

Reply 4: We have edited terminology throughout to correctly use Fixed and Adjustable for slings. We have edited discussion to better explain mechanism of action for both fixed and adjustable slings.

"Male slings work by compressing and repositioning the bulbar urethra(13). When on appropriate tension, the sling will relocate the urethral bulb proximally into the pelvis and will also provide support to the dorsal distal portion of the membranous urethra(15). " (Page 3, lines 14 - 16)

"These (adjustable) models likewise provide pressure on the bulbar and membranous urethra and contain adjustable mechanisms to personalize the pressure applied for individual patients and supplement a compressive component to the relocating effect of the sling (30). " (Page 5, lines 5 - 7)

5) I suggest to omit non-available devices, or at least just mention it prior existence.

Reply 5: We have moved non-available devices as a paragraph at the end of the section. We still believe this information will be helpful to readers to understand how surgical treatments have changed over time and issues with prior devices.

6) The advance sling is the sling with the largest body of evidence, even providing evidence in up to 3-5 year follow up. I would expect a more detailed presentation and critical discussion of the sling.

Reply 6: We have added more discussion.

“This was followed by a series of 67 patients(17) and shortly thereafter developed into the AdVance Male Sling (Boston Scientific, Marlborough, Massachusetts, USA)(18). The second-generation AdVance XP (Figure 1) entered the market in 2010(19) with design modifications including a new anchoring mechanism to prevent migration, a liner, and longer mesh arms for easier use in obese patients(13). Overall cure rate (0 pad use) has been reported at 80% with a median follow up of 26 months(19). In comparative work, there are largely no significant differences between the original and XP models, both in terms of outcomes and complications except for higher rates of urinary retention in the XP(20). Adverse events related to these slings include elevated post-void residual, increased bleeding, and decreased satisfaction with a need for subsequent incontinence procedures(21).” (Page 3, lines 18 - 27)

Comment 7: Please discuss more critical the indication for fixed vs. Adjustable slings. There is evidence (for example from the DOMINO project) that adjustable slings are utilised in patients with more risk factors, higher degree of incontinence, etc..

-there is evidence from the domino project regarding the ATOMS evaluation, raising the question if Argus-T is more associated with pain than other devices
Furthermore, discuss more critical the outcomes in comparison between fixed and adjustable slings, there is also a publication from the domino project.

-please explain more in detail the differences between the adjustable or also the fixed slings

Reply 7: We appreciate the reviewer’s suggestions. Our review was lacking in references to the strong work by the DOMINO project and we have now included discussion from multiple papers of theirs.

“The DOMINO (Debates On Male Incontinence) project evaluated the differences between fixed and adjustable slings in a large cohort study. They identified no differences in functional outcomes or quality of life but noted that patients with more risk factors and a higher degree of SUI were more likely to be offered an adjustable

sling(30). This analysis included the AdVance and AdVance XP fixed slings as well as the Argus classic, Argus-T, and ATOMS adjustable slings. “ (Page 5, lines 9 - 13)

“In a DOMINO comparison of fixed and adjustable slings, the adjustable slings had significantly more postoperative pain, and the Argus T model in particular had higher pain (43.8% vs 5.3% Argus classic vs 4.1% ATOMS) in a subanalysis. “ (Page 6, lines 11 - 14)

Comment 8: zephyr is more considered being a preconnected two-piece device (no reservoir Furthermore, there is much more literature about zephyr, which should be critically discussed. Including the clinical differences (large pump, etc)

Reply 8:We have included further literature and discussion regarding the Zephyr device

“This device does not require an abdominal reservoir, instead utilizing a pressure-regulating tank and pump placed within the scrotum, and the pre-connected design is intended to both save time and decrease mechanical failure due to poor connection(43). Additionally, the device has an adjustable cuff and an adjustable pressure regulator. An early case series did in fact show decreased operative times and no intraoperative complications. However an explantation rate of over 60% was noted with mean device survival of less than one year(43). Since then, the manufacturer has made iterative updates to improve connections and make the device easier to use. A more recent European multicenter study showed considerable success (cured or improved) in 92.7% of the 109 men recruited with severe SUI and a much lower complication rate with 9 (9.7%) patients requiring explant and 3 (3.2%) requiring revision (44). “ (Page 7, lines 8 – 17)

Comment 9: line 257: please add the manufacturer in brakets and delete „who manufacture Argus)

Reply 9: Manufacturer information included

Comment 10: ProACT regarding migration of the balloons should be more critically discussed

Reply 10: We have included a sentence discussing this complication.

“Further, these devices have the known long-term complication of balloon migration occurring in an estimated 6.5% of patients, which can lead to device explant. “ (Page 8, lines 6 - 8)

Comment 11: Table: please separate per device class, furthermore I expect more details in the table. I suggest to add separate tables for slings (fixed and adjustable) and AUS. Furthermore, I suggest to think about a more appropriate table including more details. It is no possible to identify the extend of evidence available (sample sizes, different results from different Studies etc).

Reply 11: We have edited our table to make it more detailed and readable

Comment 12: Generally, I a missing a critical discussion about the different adverse events expected for each type of device. This is also crucial in the selection of the respective devices and discussion with the patient.

Reply 12: We have included a more thorough discussion of adverse events associated with each device.

Comment 13: I am missing a comment on the problem of generalisation of the results due to the missing standardisation of severity grading or urinary incontinence AND standardised outcome measurement.

Reply 13:We have added a paragraph at the end of the main body discussing future directions for research and include the lack of standardization as an area for improvement. and a sentence in the Methods section

“ This is a consistent issue within the SUI literature as studies lack standardization in both grading of SUI and in terms of outcome measurement. When applicable, we specify how each study defined success or continence to provide context for the reported results. “ (Page 2, lines 10-13)

“ One of the pitfalls when studying SUI is the lack of standardization across studies. This can make comparisons between devices difficult as definitions of “success” are

not uniform. Future directions to standardize how we communicate and evaluate SUI and treatment of SUI will benefit providers and more importantly patients. “ (Page 9, lines 14 - 18)