**Peer Review File**
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## Review Comments
## Reviewer A

The review titled "Artificial Urinary Sphincter and Female Stress Urinary Incontinence over the Past 50 Years: A Narrative Review" aims to provide an overview of the use of the artificial urinary sphincter (AUS) in adult females with stress urinary incontinence (SUI) over the past 50 years. In December 2022 and January 2023, a literature search was conducted using the MedLine and Embase databases, screening for randomized controlled trials (RCTs), prospective and retrospective series, and reviews on female AUS. The author concluded that while the use of AUS in female patients provides excellent functional outcomes, its use has been limited to a few centers. However, recent years have seen a resurgence in the use of AUS thanks to the rise of minimally invasive approaches. The future of AUS looks promising, with technological advances of the device and robotic surgical systems, high-level evidence studies, and joint efforts of the urological community to facilitate its diffusion across the world.

This is a nice review; however, there are a few pieces of information that could be added to make it even better.
Reply: We thank the reviewer for the nice comment

1. The AUS is a silicone device comprised of three main components: a cuff, a pressure-regulating balloon (PRB), and a pump connected with tubing. It is highly recommended to include a figure to help illustrate the structure and components of the AUS system.
Reply 1: We appreciate this comment from the reviewer and added a figure that illustrates the AUS system.
Changes in the text: Figure 1 shows a AMS800™ AUS.

2. Additionally, there are a few typos in the original text, such as the repetition of the word "informing." in this ““, after informing informing the patients”. These should be corrected for clarity and accuracy.
Reply 2: We thank the reviewer for this comment. We deleted the repeated word.
Changes in the text: “Informing” was deleted.

3. There are different types of female artificial urinary sphincter (AUS) systems available, such as:
1) AMS 800: This is a commonly used AUS system that has been in use for several decades. It consists of a silicone cuff that surrounds the urethra, a pressure-regulating balloon that controls the cuff, and a pump that is placed in the labia majora.
2) ZSI 375: This is a newer AUS system that was specifically designed for female patients. It also consists of a cuff, balloon, and pump, but the cuff is made of a different material that may offer advantages in terms of comfort and durability.

3) Virtue sling and AUS: This is a combined procedure that involves placing a mid-urethral sling to provide additional support to the urethra, in addition to an AUS system. This approach may be appropriate for women with complex or severe SUI.
4) FlowSecure AUS: This is another newer AUS system that uses a magnetic valve to regulate pressure in the cuff. This may offer advantages in terms of more precise pressure control and potentially fewer complications.
That information could be added, a table is highly recommended.
Reply 3: We truly appreciate this comment and believe it added value to our work. The reason why we did not mention the other AUS is that almost no data has been published, to our knowledge, with the use of these alternative devices in female patients. However, we acknowledge that mentioning those alternative devices may be of interest for the readers. We added this information in the text and also added a table that summarizes the information (Table 2).

Changes in the text: Currently, there are different types of AUS systems available (11).

The AMS 800 has been the most commonly used AUS device for the last decades. The AMS 800 consists of a circumferential cuff, a pressure-regulating balloon and a control pump, all connected with tubing (11). This is the only AUS with a large body of evidence published in female patients

Alternative AUS designs were introduced in the market since then. The Zephyr ZSI 375 (Zephyr Surgical Implants, Geneva, Switzerland) works by occluding the urethra through hydraulic pressure, similar to the AMS 800 mechanism. However, it does not have an abdominally implanted reservoir and it consists of only two components pre-connected a priori, reducing the operative time and potential abdominal intra-operative complications. The pressure can be increased to improve the patient's continence intra and postoperatively. There are no studies on the Zephyr in SUI female patients (11).

FlowSecureTM (Barloword Scientific Limited, Stone, United Kingdom) is another alternative to AMS 800. This system contains four components: a pressure regulating balloon, a control pump, a urethral cuff and a stress release balloon, which is placed extra-peritoneally and has the ability to adapt to changes in the intra-abdominal pressure. This system also allows for pressure adjustment postoperatively without the need for a new surgery, like the Zephyr ZSI 375. The first implantation of the FlowSecureTM in the bladder neck of a female SUI patient with spina bifida showed successful results (11,12).

Table 2 summarizes the features of these three different devices.

**Reviewer B**

Appreciate the author's efforts to conduct a well-structured narrative review on utilization of the artificial urinary sphincter in women with stress urinary incontinence. Although limited by the retrospective nature of much of the extracted data, this review provides an excellent overview of the use of the AUS in this population. This data will be an excellent basis to derive larger scale clinical trials to measure efficacy of the device for women on a global scale, particularly with the need to establish baselines prior to expansion of the future technologies the authors describe. Additional utility would be provided to the readership by expansion of the section on surgical technique and the associated Figures 1 and 2 providing further granular detail on the exact step-by-step procedure.

Reply: We thank the reviewer for this relevant comment. We added some information about the surgical technique.
Changes in the text: "In the traditional open approach, the bladder is dropped and the Retzius space is dissected until the endopelvic fascia is identified. The assistant surgeon places one finger in the vagina to create tension to identify the vesicovaginal plane, by dissecting on the tip of the finger with cold scissors. The posterior part of the bladder neck is dissected on both sides and the spaces are joined together to place the measuring tape all around the bladder neck. The cuff and the balloon are then inserted and the pump is placed in the labia majora creating a subcutaneous space from the abdominal incision. (10)
In the robot-assisted technique, the patient is placed in a 23º Trendelenburg position. The procedure is performed using a transperitoneal approach with a 0º lens. Five ports are placed: one 12-mm camera port at the umbilicus, three 8-mm robotic ports (one in the right flank, and two at the lateral edge of right and left rectus abdominis muscles), and an additional 12-mm port in the left flank for the assistant (43).
Most of the robotic female AUS series published so far used an "anterior" approach mimicking what was done in the historical open technique with an initial opening of the Retzius space to dissect the bladder neck "from above", a handful of teams have recently reported an alternative "posterior" robotic technique with dissection of the bladder neck being carried out "from below" which involves a dissection of the vesicovaginal space from the vaginal fornix to the posterior aspect of the bladder neck prior to reach the anterior aspect on each side (44-46). The outcomes reported were broadly similar with those of the anterior technique (44,46).
Figures 2 and 3 show two steps in a robot-assisted AUS implantation in a female patient: the dissection of the posterior aspect of the bladder neck and the position of the cuff and the PRB."

**Reviewer C**

Thank you for submitting this paper.
This paper is a narrative review gives an overview of the use of the AUS for SUI in women over the past 50 years and an update since the 2 published systematic reviews in 2018 and by the 2 of the authors.

Please find my comments below:

- Originality of question/topic: Average
- "Robustness" of dataset: adequate, references need updating
- Appropriate methodology: yes
- Importance of findings: provides latest updates on female AUS (namely the new UROACTIVE device and ROBOTIC advances).

TITLE
Artificial urinary sphincter and female stress urinary incontinence over the past 50 years: a narrative review.
The title accurately represents the covered topic.
ABSTRACT
Represents the manuscript and reports the relevant findings and conclusions.
Lines 54-56: suggest changing 'with' (appears twice in the sentence) to 'including' numerous reports.
Reply: We appreciate this comment. . Accordingly, we made the following changes in the text: In recent years, robotic techniques of female AUS implantation have spread significantly with promising outcomes including numerous reports suggesting that it may decrease its morbidity.
1. Please add in methods that you completed the narrative review reporting checklist (I suppose from TAU? Or was it another checklist?).
Reply: We appreciate the reminder. We completed the TAU checklist (Table 1) and added now that information in the methods section of the abstract.
Changes in the text: The search strategy involved a free text protocol and the narrative review reporting checklist was completed.
Results/key contents and findings
You mentioned the narrative findings which could be shortened. Please add your objective findings (no RCT, 2 prospective studies, 3 reviews and n retrospective studies).
Reply: We thank the reviewer for this relevant comment. We added some objective findings as suggested.
We made the following changes in the text: The AUS is a device used over the past 50 years for SUI caused by intrinsic sphincter deficiency (ISD). It has the theoretical ability to mimic the function of a biological urinary sphincter. Although the role of the AUS for females with ISD remains heterogeneous from one part of the world to the other, the existing literature demonstrates that AUS yields satisfactory functional outcomes in female SUI patients, comparable or better to what has been reported in male AUS series. Hence, the main barrier to its adoption has so far been the technical challenge of its implantation at the bladder neck. Regarding results of AUS implantation in females, we included in this review 3 reviews, 23

retrospective studies and 1 prospective study. In recent years, robotic techniques of female AUS implantation have spread significantly with promising outcomes including numerous reports suggesting that it may decrease its morbidity. In the near future, the development of electromechanical devices may further expand the role of AUS in the management of female SUI.

INTRODUCTION

- Brief background to topic, citing relevant literature

Lines 74-76: 'This pathophysiological mechanism is mostly seen in female patients in whom previous anti-incontinence surgical procedures failed or patients with neurogenic SUI`
Please specify which pathophysiological mechanism you are referring to. The authors are probably referring to ISD with urethral HYPOmobility/ISD without urethral hypermobility.
In this section the following reference could be added to illustrate the current debate.

Are Slings Still the Gold Standard for Female Stress Urinary Incontinence? Chartier-Kastler E, Reus C.Eur Urol Focus. 2019 May;5(3):315-316. doi: 10.1016/j.euf.2019.01.017. Epub 2019 Feb 13.PMID: 30772361
Reply: We appreciate the reviewer's comment. We changed this part and added the suggested reference.
Changes in the text: Two common mechanisms for female SUI have been described: urethral hypermobility and intrinsic sphincter deficiency (ISD) (3). Although midurethral sling placement is recognized as the gold standard surgical treatment for female patients with SUI due to urethral hypermobility in most countries, the management of women with SUI related to ISD is less clear (3). The ISD mechanism is mostly seen in female patients in whom previous anti-incontinence surgical procedures failed or patients with neurogenic SUI (3). These patients are most likely not the ideal for midurethral sling, due to the ISD or because they have a fixed urethra, which does not comply with the reestablishment of the vaginal hammock (4).

- Does the Introduction "sell" the importance of the topic/need for the study?

To improve your intro (the urgency of the topic is not appearant i.e why this narrative review now? What does it bring?). The truth is not much new has been published since. I would therefore suggest adding a short paragraph on the following:

- A small summary of the high level-evidence published so far on female AUS (no RCT, 2 systematic reviews (add those references and the other (ref 14).
- the issue of slings and mesh related debate (recalls in the US) which has led many anglo-saxon countries to banish the MUS, therefore offering a larger indication for the AUS today.

- Add a sentence on the fact that the AUS in women is still considered 'off label' in many countries is not FDA approved. Move lines 117-119 to this section.

- Are the objective(s) of the study clearly stated? Yes.

Reply: We appreciate the comment from the reviewer and believe it really improved our work.

We made the following changes in the text accordingly: Female stress urinary incontinence is a public health problem associated with an enormous psychologic and social burden (1). According to the 6th International Consultation on Incontinence (ICI), 25–45% have occasional leakage, with national prevalence studies of SUI reporting 9-29.5% in Europe and 23.1% in the United States of America (USA) (2).

Two common mechanisms for female SUI have been described: urethral hypermobility and intrinsic sphincter deficiency (ISD) (3). However, this is likely to oversimplify the situation because of significant overlap between the two mechanisms (3). Although midurethral sling placement is recognized as the gold standard surgical treatment for female patients with SUI due to urethral hypermobility in most countries, the management of women with SUI related to ISD is less clear (3). Moreover, the impact of the current mesh controversy on future SUI surgical treatment algorithms remains uncertain, potentially offering a larger indication for the AUS (4). The ISD mechanism is mostly seen in female patients in whom previous anti-incontinence surgical procedures failed or patients with neurogenic SUI (3). These patients are most likely not the ideal for midurethral sling, due to the ISD or because they have a fixed urethra, which does not comply with the reestablishment of the vaginal hammock (5). There is still a lack of evidence in the management of recurrent or persistent stress incontinence after a failed midurethral slings (6). Treatment options include injectable urethral bulking agents, insertion of a pubovaginal sling or external urethral compression devices (Adjustable Continence Therapy and AUS) (6).

The AUS was first described 50 years ago (7) and has been used in women since then in several centers. Despite that, the literature on the results of the AUS in women remains scarce. The authors did not find any randomized controlled trial. Three reviews (4, 8,9) were included.

Likely due to the absence of high level of evidence data and to its challenging implantation, the AUS is still considered in most countries as a procedure for highly selected patients and not as a first line option.

The aim of the present report was to provide a narrative review of the use of the artificial urinary sphincter (AUS) in adult females with stress urinary incontinence over the past 50 years.

We present this article in accordance with the Narrative Review reporting checklist.

METHODS

- Level of detail provided: Adequate.
- Critical – are the methods chosen appropriate to address the question of interest? Yes.

Please add a short line on why you chose French as the other language (besides English). You need to specify that historically, France is the first country to have offered the AUS in women (1987 I believe) and has a long history of female AUS implantation. Therefore, it is the

country with the most published data, hence I suppose, the choice of language. I believe over 300 implantations/year are performed in France (you can check the info on the ANSM).
Reply: We thank the reviewer for the suggestion. We added that relevant information.
Changes in the text: Only articles published in English or French and deemed relevant for the present review were included. The French articles were included given the fact that France is the only country whose national guidelines support AUS as a gold-standard treatment in female patients with SUI due to ISD. As a result, the use of AUS in female patients has historically been wider in France than in other country, with more than 300 implantations per year (10).

RESULTS/Key findings and contents:
The authors do not clearly announce their findings in the text. 'Female AUS principles' follows 'methods' without transition.
Please add after line 95 the following title:
KEY FINDINGS & CONTENTS
1. Objective findings (described in Table 2)
The authors have omitted the description of their objective findings, which I think are relevant and support the need for this narrative review/update. Please add a paragraph describing the findings reported in Table 2: no RCT, 2 prospective studies, 3 reviews and n retrospective studies ect…
Reply: We appreciate this relevant comment. We added the objective findings.
Changes in the text: Regarding results of AUS implantation in females, we included in this review 4 reviews (4,8-10), retrospective case series (12-23, 25, 26) and 1 prospective case series (24) (table 3). The authors did not find any randomized controlled trial.
These series included AUS implantation using open abdominal approach, with dry rates ranging from 61 to 86% and explantation rates from 0 to 32%. The laparoscopic and robotic approaches series showed similar dry rates (51-84%) with less complications (explantation rates from 0 to 22%) (12-26) (table 3).

2. Narrative findings/contents (described in Table 2)
In this section you can then further elaborate. Logically I would recommend starting with the origins, then move on to the principles.
2.1 The Origins (move lines 117-119 as suggested above)
2.2 Female AUS principles
2.3 AUS selection:
Line 153: I would remove 'for now' at the end of the sentence as it isn't relevant.
2.4 female versus male AUS
Lines 167 -169: After the last sentence the following should be added. This systematic review included both neurogenic and non-neurogenic cohorts. Another systematic review performed on exclusively non-neurogenic women reported 42-86% zero pad rates with lower explantation rates ranging from 2-27% (Reus et al.).
Lines 170-171: The actual 0-pad rate reported by Averbeck and the Elliot study (Johns Hopkins) report around 57% dry rate for males which is much lower compared to female outcomes. Please add these references.

2.5 Surgical approach

I would move this paragraph just after male vs female paragraph for a more logical flow.

Lines 235-236: add 2 references on robotic female AUS implantations by Chartier Kastler with his newly published paper in April 2023.

BJU Int. 2020 Dec;126(6):722-730. doi: 10.1111/bju.15147. Epub 2020 Aug 3. 3

2.6 Outcomes

Lines 246-253: There were, as mentioned above 2 published reviews, please refer to the reus et al study as well, since it included women with non-neurogenic SUI exclusively. This is relevant, as homogenous studies are uncommon on this topic.

Please add a summarizing sentence transitioning to the next paragraph.

2.7 Current guidelines reports

I would suggest moving this paragraph after the paragraph on the 'female AUS outcomes in the literature' for a more logical flow. The guidelines are based on literature findings.

Please also add a small summarizing sentence to conclude this paragraph.

2.8 Future perspectives

CONCLUSION

Please amend to:

However, the AUS is back in the limelight, due to the waning popularity of slings, as well as the rise of minimally invasive approaches, facilitating its implantation, learning curve and promising outcomes.

Both factors have played a role to the increase of female AUS popularity.

Reply: We thank the reviewer for these great suggestions, we believe they really improved our work.

Changes in the text: We changed the sequence as suggested and completed the parts the reviewer mentioned.

References:

Please update with the above mentioned references.

Reply: We thank the reviewer for these suggestions. We did include the suggested references.