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Consensus Statement

The Asia-Pacific AMS800 artificial urinary sphincter consensus statement

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Abbreviations & Acronyms
AP = Asia-Pacific
AUS = artificial urinary sphincter
PRB = pressure-regulating balloon
PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SCI = spinal cord injury
SUI = stress urinary incontinence

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Abstract: This Asia-Pacific (AP) AMS 800™ artificial urinary sphincter (AUS) consensus statement aims to provide a set of practical recommendations to assist surgeons with the AMS 800 device surgery. The AP consensus committee consisted of key opinion leaders with extensive experience with AMS 800 surgery across several AP countries. The panel reviewed and discussed relevant findings with emphasis on locoregional and specific clinical challenges relevant to the AP region. Recommendations were made in key areas namely (1) patient selection and informed consent process; (2) preoperative assessment; (3) dealing with co-existing urological disorders; (4) surgical principles and intraoperative troubleshooting; (5) postoperative care; (6) special populations; and (7) cost analysis and comparative review. The AMS 800 device should be offered to males with moderate to severe stress urinary incontinence (SUI). Full informed consent should be undertaken, and emphasis is placed on surgical contraindications and high-risk candidates. The presence of a surgical mentor or referral to experts is recommended in complex AUS candidates. Preoperative cystoscopy with or without multichannel urodynamic study is necessary and patients with pre-existing urological disorders should be treated adequately and clinically stable before surgery. Adherence to strict patient selection and safe surgical principles are critical to ensure excellent clinical outcomes and minimize complications. Given that InhibiZone-coated device is not available in many AP countries, the use of prophylactic antibiotics pre-and post-operatively are recommended. The AMS 800 device should be prepared according to the manufacturer's guidelines and remains a cost-effective treatment for male SUI. The AMS 800 device remains the surgical benchmark for male SUI but is associated with certain mechanical limitations and a unique set of complications.

Key words: artificial urinary sphincter, assessment, complications, special populations, urinary incontinence.

INTRODUCTION

The artificial urinary sphincter (AUS), specifically the AMS 800™ (Boston Scientific, previously the American Medical Systems) has been considered by many surgeons as the standard of care for males with stress urinary incontinence (SUI). While the initial AUS prototype was developed in 1972, the modern AMS 800 (known as prototype AS 800) was first introduced in 1982.[1,2] For the past five decades, there have been considerable scientific advances made

in terms of device technology and surgical techniques to improve clinical outcomes and patient satisfaction rates.[3,4] Published literature showed that AMS 800 device has a good long-term track record with a 5-year reported 59%–90% continence rate, 84%–92% mechanical durability, 17%–35% reported reoperation rate, and 85%–95% patient satisfaction rates depending on the degree of urinary continence improvement.[3,4] While its longer-term clinical efficacy, safety, and mechanical durability are well documented, it is not without limitations and complications where 50% of these cases are caused by mechanical complications and 50% by nonmechanical complications.[5–8] Nonetheless, proper patient selection, strict adherence to antimicrobial prophylaxis and surgical technique as well as careful patient education regarding expectations and the possible, even eventual, need for revision surgery, influence the high success rate of AUS implantation.

The 2015 Consensus Conference on AUS[9] highlighted several unique challenges associated with AMS 800 surgery while providing a set of recommendations regarding the clinical indications, management, and follow-up care on AMS 800 implantation or revision surgery. Nonetheless, several important issues were not addressed in this predominantly North American and European-centric consensus statement. Across most countries within the Asia-Pacific (AP) region, the AMS 800 remains the only regulatory approved commercial surgical device due to the lack of availability and/or registration of other continence devices in many AP countries. Furthermore, the AMS 800 is more likely to be performed in complex populations such as those with a history of pelvic trauma and/or prior urethral surgery as well as "neurogenic" subpopulations where inherently there will be higher urethral erosion and prosthetic infection rates.[1,9] This AP consensus statement aims to highlight several major differences and the clinical challenges facing urologists and patients across the diverse surgical landscape in the AP region.

MATERIALS AND METHODS

The AP AMS 800 consensus committee was initiated by the lead author (EC), and key opinion leaders having extensive experience with AMS 800 surgery across Australia, China, Japan, Singapore, South Korea, and Taiwan were invited to participate in this consensus group. All invited urologists agreed to participate in this working committee and over 6 months between 1 February 2021 and 1 September 2021, available literature about AMS 800 was reviewed and the following terms "artificial urinary sphincter", "urinary incontinence", "neurogenic", "female incontinence", "recurrent incontinence", and "complications" were searched in MEDLINE and EMBASE databases. The panel discussed and incorporated relevant findings on AMS 800 implantation with emphasis on locoregional issues relating to AMS800 relevant to the AP region based on specific clinical challenges faced by urologists.

While the organization of this consensus committee received an investigator-initiated educational grant from the Boston Scientific company, all clinical recommendations were made independently by the faculty with no direct input from the device company. The panel was tasked to review specific clinically relevant AUS in key areas namely (1) patient selection and informed consent process; (2) preoperative assessment; (3) dealing with co-existing urological disorders; (4) surgical principles and intraoperative troubleshooting; (5) Postoperative care; (6) Special populations; (7) Cost analysis and comparative review of AMS800 to other contemporary continence devices. As only a few prospective and randomized-controlled trials involving AMS 800 surgery have been published, a full Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol was not adopted for this article; instead, a narrative approach was taken. Clinical findings were internally discussed, and each panelist provided an opinion on each of the subheadings. A consensus agreement was received, and all authors agreed on the list of recommendations (Box 1). The quality of evidence was graded based on the Oxford Centre for Evidence-based Medicine recommendations and a clinical principle was given when available data were insufficient or not suitable to conclude. Recommendations for each category include a brief review of the surgical challenges and strategies to mitigate them.

MAIN RECOMMENDATIONS

Patient selection and informed consent process (Figure 1)

The current literature supports the role of AMS 800 as the standard of care in males presenting with moderate to severe SUI following pelvic surgery or trauma, those who have radiation-induced SUI, and those who have failed conservative management including prior male sling surgery, will benefit from an AUS surgery.[1,7–9] In contrast, patients presenting with SUI following pelvic trauma related to the motor vehicle or pedestrian accidents are often more complex given the underlying mechanism(s) of injury and associated surrounding structures damage in addition to likely having a history of multiple pelvic surgeries.[10] Despite the increasing incidence of prostate cancer cases in the AP region, the number of patients who underwent radical prostatectomy or radiation therapy remains lower than in most developed Western countries.[11] Furthermore, epidemiological studies have shown that pelvic trauma related to accidents is very common in the AP region.[12,13] This form of SUI invariably presents a unique set of challenges compared to the traditional post-prostatectomy-related SUI commonly seen in Western developed countries.

It is generally agreed that patients should wait at least 6 months following post-prostatectomy incontinence and conservative measures such as pelvic floor exercises and lifestyle modifications should have been tried. Observational studies regarding the recovery of urinary continence following radical prostatectomy showed that most men will recover urinary continence by 1 year.[14] While several predictors of continence have been reported in the literature,[15,16] the consensus opinion of the panel is that significant recovery is unlikely in these males who continue to report severe SUI after 12 months. Nonetheless, it remains the duty of care for the surgeon to discuss with the patient whether to wait longer in the hope that further improvement in urinary continence will

BOX 1 Summary of Recommendations on AMS 800 AUS Surgery

1 Patient selection and informed consent process
- The AMS 800 device should be offered to males with normal cognitive function and sufficient manual finger dexterity to operate the device, who complained of moderate to severe SUI following pelvic surgery or trauma, or those who have radiation-induced SUI (Grade B).
- Full informed consent should be carried out and these include discussion on the nature of AUS surgery and other possible treatment options, cost of surgery, and adequate counseling regarding potential complications related to the AUS surgery (Clinical principle).
- Additional care should be provided to the high-risk candidates while those with absolute contraindications should not be offered the AUS surgery (Grade C).

2 Preoperative assessment (including urodynamics study and endoscopic assessment)
- Cystoscopy with or without multichannel urodynamic study is necessary before the AUS surgery (Grade C).

3 Dealing with co-existing urological disorders
- Patients with pre-existing urological disorders should be treated adequately and must remain clinically stable for at least 6 months before an AUS surgery (Grade C).

4 Surgical principles and intraoperative troubleshooting
- Adherence to strict patient selection and safe surgical principles are critical to ensure excellent clinical outcomes and minimize complications (Clinical principle).
- Intraoperative cystoscopy examination is useful to exclude urethral injury and assess AUS cuff occlusion (Grade C).
- Given that the InhibiZone-coated AMS 800 device is not available in many AP countries, the use of prophylactic antibiotics at the start of surgery and as irrigation is recommended (Grade B).
- Individual components of the AMS 800 device should be prepared according to the manufacturer's guidelines to ensure that both the cuff and pump are in working condition and the AMS 800 device should be deactivated at the end of the operation (Clinical principle).

5 Postoperative care
- The AMS 800 device should be activated at 4 to 6 weeks postoperative (Grade C).
- The urethral catheter should be removed within 48 h of the AUS surgery and the use of postoperative antibiotics is recommended since the InhibiZone-coated AMS 800 device is not available in many AP countries (Clinical principle).
- Patients should demonstrate the ability to cycle the AMS 800 device properly and notify the clinician(s) of future urethral catheterization or endoscopic procedures (Clinical principle).

6 Special populations
- The implantation of AMS 800 device in these special populations are often more complex and technically challenging (Clinical principle).
- For an inexperienced or novice surgeon, the presence of a senior colleague or surgical mentor at the time of the AUS surgery or referral to regional centres of excellence or high-volume AUS implanters can be helpful (Clinical principle).
- Female AUS surgery is uncommon and preserving the integrity of the vesicovaginal surgical plane is critical to ensure the correct dissection of the tissue plane and minimize the risk of cuff erosion or extrusion (Grade C).
- The AUS cuff should be placed at the bladder neck (or peri-prostatic tissue) in the neurogenic and pediatric populations in the settings of intermittent self-catheterization for poorly contractile bladder, and upper urinary tract function should be monitored postoperatively (Clinical principle).
- For the elderly incapacitated or those who have developed dementia, it is generally recommended that the AMS 800 device be deactivated (or removed) (Clinical principle).
- The diagnostic evaluation in men with persistent or recurrent UI following the AUS implantation involves a logical stepwise process of confirmation and will require a sufficient understanding of the mechanics of the AMS 800 device, although attention should be paid also to non-SUI lower urinary tract symptoms, which can occur over time (Grade B).

7 Cost analysis and comparative and review of AMS800 device to other contemporary devices
- Despite the limited cost-effective analysis comparing the AMS 800 device and other continence devices and given that many male slings or AUS-like devices are not registered or widely available in many AP countries, the AMS 800 device remains a very effective surgical treatment for male SUI and can salvage failed cases (Clinical principle).

occur. In contrast, there are no clear guidelines for patients who developed non-prostate cancer-related SUI, and most would agree that urinary reconstructive surgery is likely more effective (and challenging) in this complex population.

The 2015 consensus conference stated that AUS should be offered to males with intrinsic sphincter deficiency–associated SUI who have failed conservative measures.[9] While there is no widely adopted agreement on the exact definition of the degree of SUI, most studies listed urinary incontinence greater than 400 mL and less than 800 ml per 24-h pad weight to constitute moderate incontinence; and those greater than 800 ml per 24-h pad weight to have severe urinary incontinence.[17,18]

All patients considered for AUS should have sufficient manual finger dexterity and cognitive function to operate this device as the patient is required to operate the pump to void each time. Patients should receive adequate education on AMS 800 mechanics during the initial counseling process. A full informed consent (and financial disclosure if relevant) should be carried out between the surgeon and patient, and these should include the discussion on available local treatment options, the actual surgical process and adequate counseling regarding potential complications related to the AUS surgery. While AUS surgery aims to achieve complete continence, patients should be counseled that minor incontinence can still occur with certain positions or during strenuous physical activity. Relevant complications should be discussed and not limited to prosthetic infection, mechanical malfunction of device component(s), device erosion, urethral atrophy, persistent and/or recurrent incontinence, sensory change,

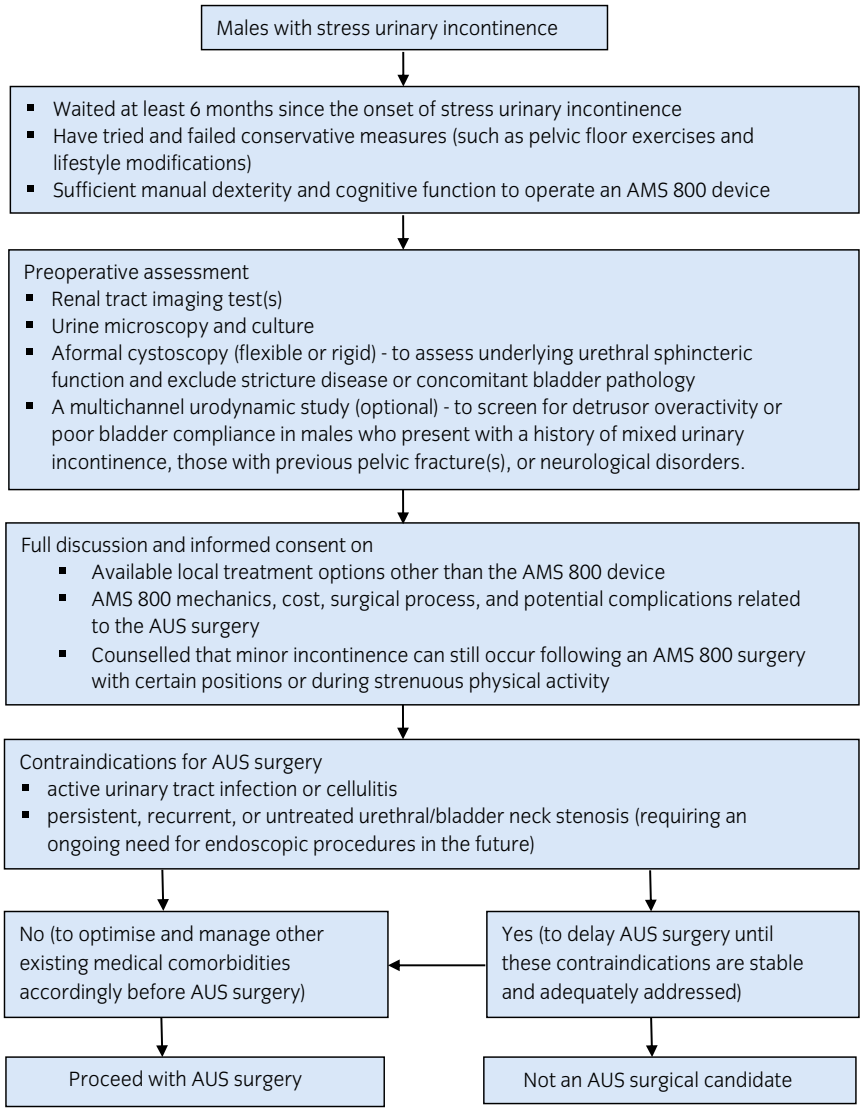

FIGURE 1 Flow diagram on patient selection and preoperative assessment for AMS 800 surgery. AMS, American Medical Systems; AUS, artificial urinary sphincter

sexual dysfunction, and need for future revision surgery. The mean expected AUS lifespan is around 5 to 7 years and longer-term studies reported up to 79% of AUS can remain functional without revision at 5 years.[19–21]

Absolute contraindications for AUS surgery are men with active urinary tract infection or cellulitis; persistent, recurrent, or untreated urethral/bladder neck stenosis where there is a potential need for multiple endoscopic procedures, and the lack of cognitive function or manual dexterity. All existing medical comorbidities (such as diabetes) and medications (including antiplatelet and/or anti-coagulant) will need to be optimized and managed accordingly before the AUS surgery to minimize intra- and postoperative complications. High-risk candidates include patients who have a prior history of radiation, uncontrolled diabetes mellitus, previous pelvic fracture, those with multiple urethra or pelvic surgeries, previous male sling or AUS surgery, recurrent urinary tract infection or cellulitis, need for urethral instrumentation (or catheterisation), and neurological disorders (stroke, wheel-chaired bound, etc).[22,23]

Recommendations (Box 1): The AMS 800 device should be offered to males with normal cognitive function and sufficient manual finger dexterity to operate the device, who complained of moderate to severe SUI following pelvic surgery or trauma, or those who have radiation-induced SUI (Grade B). Full informed consent should be carried out and these include discussion on the nature of AUS surgery and other possible treatment options, cost of surgery, and adequate counseling regarding potential complications related to the AUS surgery (Clinical principle). Additional care should be provided to the high-risk candidates while those with absolute contraindications should not be offered the AUS surgery (Grade C).

Preoperative assessment (Figure 1)

Clinical history should focus on the type, duration, and severity of SUI, excluding other lower urinary tract symptoms such as urgency, urgency incontinence, other associated urological diseases and previous medical or surgical treatments.

Optimization of pre-existing medical conditions in particular diabetic control is essential to minimize infective complications. Simple urinary microscopy and culture will ascertain the presence of urinary tract infection and an appropriate course of oral antibiotics should be prescribed, while measurement of post-void residual urine volume is useful to assess for poor bladder emptying. Preoperative renal imaging with renal tract ultrasonography or computed tomography scan should be organized in high-risk patients with suspected urinary stones, secondary malignancy (such as urothelial cancer) and/or persistent sterile pyuria (such as in neurogenic bladder).[24]

A formal cystoscopy (flexible or rigid) is useful to assess underlying urethral sphincteric function and exclude the presence of urethral or bladder neck stenosis as well as other concomitant bladder pathology. A multichannel urodynamic study is often necessary to screen for detrusor overactivity or poor bladder compliance in males who present with a history of mixed urinary incontinence, those with previous pelvic fracture(s), or neurological disorders. Novice surgeons should consider a urodynamic study as part of the standard preoperative workup for an AUS surgery.[25]

Recommendation (Box 1): Cystoscopy with or without multichannel urodynamic study is necessary before the AUS surgery (Grade C).

Dealing with co-existing urological disorders

Patients with urethral stricture or bladder neck contracture should be treated accordingly so that the disease process is clinically stable for at least 6 months before an AUS surgery.[26] It is essential to confirm the status of the urethra and identify concomitant anastomotic strictures before AUS placement. If an anastomotic stricture is refractory or progressive, it is necessary to treat the stricture first and ensure an adequate recurrence-free period. If the stricture is asymptomatic or not progressive, it is acceptable to implant the AUS device with the maintenance of the current stricture since aggressive excision may worsen a stable urethra. For those who have symptomatic benign prostatic enlargement, appropriate treatment should be undertaken too. Detrusor overactivity and poorly compliant bladder should be treated adequately before the AUS surgery,[27,28] although intravesical botulinum therapy can be administered using flexible cystoscopy in patients with an in-situ AUS.

Caution should be exercised in those with known pelvic trauma or who have a history of urethral reconstruction since the blood supply to the urethra may be compromised and the surgical tissue planes are not always defined. This may result in potentially more difficult dissection and higher complication rates including prosthetic-related complications. For patients who need to perform intermittent self-catheterization, it is generally advisable that the AUS cuff be placed around the bladder neck where the tissue is more robust and has a lower risk of cuff erosion from repetitive urethral catheterizations.

Recommendation (Box 1): Patients with pre-existing urological disorders should be treated adequately and must remain clinically stable for at least 6 months before an AUS surgery (Grade C).

Surgical principles and intraoperative troubleshooting

Surgical principles

Adherence to proper patient selection and safe surgical principles are essential for good clinical outcomes. The presence of a senior colleague or surgical mentor at the time of AUS surgery can provide additional support for an inexperienced or novice surgeon, while a referral to regional centers of excellence or high-volume AUS implanters especially in difficult or redo cases can be associated with better surgical outcomes.[29]

All patients should receive preoperative urine culture to ensure sterility and a skin examination to ensure no active cellulitis or skin pustules.[30] Whereas, the nature of intravenous antibiotics is likely dependent on the local institution antibiotics policy and should ideally be given especially in the high-risk population. Perioperative antibiotic prophylaxis should ideally be given at least 1 h before surgery, with the choice of antibiotics based on common skin organisms and the preference of the operating surgeon or clinical microbiology guidelines.[31,32]

Strict standard surgical protocols such as appropriate surgical attire and limiting the number of staff and traffic within the operating room should be instituted.[31] The surgical site (genitalia and inguinal regions) should be shaved at the time of AUS surgery and ideally, an alcohol-based skin preparation should be used to prepare the surgical field.[31] Ideally, nurse(s) with prior urological prosthetic experience should be scrubbed in theater and the presence of a local representative from the device company will facilitate the preparation of the device during the surgery.

The two surgical approaches for AUS surgery for bulbar urethral cuff placement are perineal (most common) and trans-scrotal methods.[33] The perineal approach allows for more proximal cuff placement along the bulbar urethra while the trans-scrotal approach provides the opportunity to place all three components through the same incision. In the perineal approach for the AUS cuff placement, a separate inguinal incision is recommended for the placement of pressure-regulating balloon (PRB) (in retropubic space) and pump (in scrotum/subdartos pouch). A retropubic approach is necessary to provide surgical access to bladder neck AUS cuff placement which is technically challenging and is routinely performed in females or pediatric (neurogenic) patients.

Adherence to safe surgical principles is important to facilitate a smooth surgical process and ensure a good outcome.[34] A 14 or 16 Fr Foley catheter should be inserted in the bladder to facilitate urethral palpation and periurethral tissue dissection. Periurethral dissection should be done carefully to ensure no urethral injury. This is critical in high-risk patients such as those with known pelvic trauma, diabetes, or prior urethral surgery.[22] A cystoscopy should routinely be performed intraoperatively to ensure no urethral injury, although a peri-catheter urethral water test can be conducted to check for urethral integrity at the time of surgery if cystoscopy is not available. An advertent urethral injury mandates discontinuation of AUS surgery. A primary direct repair of urethral injury should be undertaken to facilitate earlier urethral healing, and a period of

urethral catheterization (between 2 to 3 weeks) will be necessary. It is recommended another attempt at the AUS surgery be delayed for a minimum of 6 weeks.

While the AMS 800 device marketed in most developed Western countries has an InhibiZone coating consisting of rifampicin and minocycline antibiotics, which is highly effective bactericidal activity against Gram-positive skin microbial, an uncoated version of the AMS 800 device is only available in the AP region.[35] There is no conclusive evidence to suggest that antibiotic irrigates will decrease the risk of prosthetic infection, and the choice of antibiotic use is largely based on the surgeon's preference or local hospital infectious disease guidelines.

The AMS 800 device once inserted and connected, should be cycled several times under direct visualization to ensure the normal function of the hydraulic mechanism and decent urethral coaptation. At the end of the operation, the AMS 800 device should be deactivated for 4 to 6 weeks, and the indwelling catheter should routinely be removed within 24 to 48 h postoperatively.

Cuff size

The AUS cuff should be placed in the most proximal portion of the bulbar urethra when technically possible and the proximal bulbar urethra is dissected circumferentially to create a sufficient window to accommodate the measuring tape. The correct measurement of the circumference of the urethra will determine an appropriately sized AUS cuff. For most virgin cases, the standard AUS cuff sizes for bulbar urethral placement are 4, 4.5, or 5 cm. It is important to ensure that the cuff is prepared according to the manufacturer's guidelines and saline has coated all the inner surfaces of the cuff with no/minimal gas bubble.

In revision surgery, a more distal urethral cuff or tandem (second) cuff placement can be considered. The smaller 3.5 cm cuff should be avoided if possible, and the surgeon should consider performing a transcorporal cuff placement or placing the AUS cuff in a "more robust" section of the bulbar urethra. A transcorporal cuff placement should be considered in the very atrophied urethra, in case of previous urethral erosion or urethral stricture disease, and the closure of the corporal tunical layer can be undertaken (if possible) to minimize corporal bleeding and subsequent risk of erectile dysfunction.

Pressure-regulating balloon

The PRB is routinely placed in the retropubic space (or a space created between the abdominal musculature and the transversalis fascia) and care should be taken in men following radical pelvic surgery or prior history of inguinal hernia mesh surgery to avoid inadvertent damage to the underlying bowel or vascular structures. Other sites for PRB placement include a high sub-muscular location or in the pre-peritoneal space.

A 61–70 cmH_2O PRB should be used since most AUS bulbar urethral cuff size falls between 4 and 5 cm and should be filled with 22 to 23 ml saline although additional volume (to a maximum of 27 ml capacity) may be used depending on the number of cuffs and in larger cuff size. It is important to ensure that the PRB is prepared according to the manufacturer's guidelines and saline has coated all the inner surfaces of the PRB with no/minimal gas bubble since aggregation of air bubbles into an airlock can obstruct the functioning of the valve system within the PRB.

A 71–80 cmH_2O PRB may be used in those who received a larger than 6 cm cuff which is usually seen in bladder neck cuff placement. While the PRB can also be increased to the next pressure range to increase the urethral closing pressure, a higher-pressure balloon may increase urethral atrophy or the risk of cuff erosion.

Pump

Patients should be asked at the time of surgery whether they prefer to have the pump placed in the right or left hemiscrotum and whether the patient's dominant or non-dominant hand can manipulate the pump easily. The pump should be easily accessible to ensure ease in pump manipulation and that the deactivation button can be pressed (to deactivate the AUS mechanism).

The pump is routinely placed in the dependent portion of the scrotum, anterior and lateral to the testis. Care is taken to avoid excessive dissection of the subdartos pouch, which may result in pump migration, and it is important to ensure appropriate tubing length before connecting the AUS components. The pump should be prepared according to the manufacturer's guidelines and ensure that the pump can cycle properly. At the end of the procedure, the device is left deactivated for a period of 4 to 6 weeks.

Recommendations (Box 1): Adherence to strict patient selection and safe surgical principles are critical to ensure excellent clinical outcomes and minimize complications (Clinical principle). Intraoperative cystoscopy examination is useful to exclude urethral injury and assess AUS cuff occlusion (Grade C). Given that the InhibiZone-coated AMS 800 device is not available in many AP countries, the use of prophylactic antibiotics at the start of surgery and as irrigation is recommended (Grade B). Individual components of the AMS 800 device should be prepared according to the manufacturer's guidelines to ensure that both the cuff and pump are in working condition and the AMS 800 device should be deactivated at the end of the operation (Clinical principle).

Postoperative care

The prescription of oral antibiotics in the postoperative period is encouraged although this is often regulated by local hospital clinical guidelines and based on the surgeon's preference. If prolonged urinary drainage (>48 h) is required, a suprapubic catheter should be considered and ideally performed under imaging guidance to avoid inadvertent damage to the PRB. Patients should be advised to limit strenuous physical activity (including sexual activity) and avoid significant perineal pressure for 4 to 6 weeks during the postoperative period. Earlier activation of the AMS 800 device before 4 weeks is not advisable due to the potential increased risk of urethral cuff erosion, and patients may have difficulty manipulating the pump due to scrotal discomfort. The activation of the AMS 800 device at 4 to 6 weeks postoperatively is based on the surgeon's preference and patient comfort level.

Postoperative patient education should include teaching patients the proper cycling of the AMS 800 device and to ensure the patient can compress the pump sufficiently to allow for normal voiding. If the pump is high riding, the patient should be instructed to pull the pump downwards into the dependent hemiscrotum aspect. Patients should be reviewed between 3 and 6 months postoperatively after the first postoperative visit, and periodically thereafter as required, to ensure there is no issue with the AMS 800 device. Patients are advised to contact the surgeon directly (or hospital) if they experience any issue with voiding or operating the AMS 800 device. An alert bracelet or warning card on AUS is often useful for patients to have, and they should notify their doctors (or anyone) about future urethral catheterization or endoscopic procedures to ensure the AUS cuff is fully deactivated.

Recommendations (Box 1): The AMS 800 device should be activated at 4 to 6 weeks postoperative (Grade C). The urethral catheter should be removed within 48 h of the AUS surgery and the use of postoperative antibiotics is recommended since the InhibiZone-coated AMS 800 device is not available in many AP countries (Clinical principle). Patients should demonstrate the ability to cycle the AMS 800 device properly and notify the clinician(s) of future urethral catheterization or endoscopic procedures (Clinical principle).

Special populations

Female SUI

AUS is indicated in females with urodynamic SUI following the failure of previous continence surgery (e.g., mid-urethral sling, bulking agent, colposuspension or fascial sling).[22,36] In females who had undergone multiple continence surgeries, the AMS 800 device remains a safe and very effective salvage surgery in a carefully selected group of women.[37,38] Females with urodynamically proven detrusor underactivity and concomitant intrinsic sphincter deficiency should be considered for an AUS surgery as a sling may lead to a high rate of urinary retention.[37] For pre-menopausal patients who wish to become pregnant in the future, elective caesarean delivery, and deactivation of the AUS in the final trimester are generally recommended.[22] AUS is generally contraindicated in females with radiated pelvis or active urosepsis or cellulitis.[38]

The AUS is performed in a retropubic approach with the cuff placed in the proximal urethra or bladder neck location, and the pump in the labial minora. A transvaginal approach for placement of AUS is discouraged since it carries a high risk of cuff extrusion or erosion, especially in post-menopausal women or those with prior history of pelvic radiation.[22] Preserving the integrity of the vesicovaginal surgical plane is critical to ensure the correct dissection of the tissue plane and minimize the risk of cuff erosion or extrusion. At the time of surgery, a cystostomy can be useful to guide the placement of the cuff around the bladder neck and exclude bladder neck or vaginal injury.[39] A suprapubic catheter can be placed at the time of surgery and removed after the AUS activation and when the patient can void normally.

While the traditional approach for AUS in females is open surgery, laparoscopic[40,41] and robotic-assisted[42,43] surgical approaches have been described in the literature. A direct comparison between these surgical approaches is limited, although one pilot study[44] reported a surgical trend for robot-assisted approach over open surgery in recent times due to lower complication rates and earlier recovery rates. Nonetheless, the AUS surgery for female SUI remains uncommon and is often performed in a select few major tertiary hospitals.

Neurogenic and pediatric populations

Patients with spinal cord injury (SCI) can develop neurogenic bladder dysfunction characterized by urinary incontinence and poorly contractile bladder. The AUS can often provide an effective and less invasive continence solution compared to urinary diversion.[45] However, for many patients who perform clean intermittent catheterization, the AUS cuff should be placed at the bladder neck (or peri-prostatic tissue) in a retropubic approach to ensure a lower rate of cuff erosion from frequent urethral instrumentations.[22,46,47] A concurrent suprapubic drainage placement is often advisable at the time of the AUS surgery, and this can be removed when the patient can perform intermittent self-catheterization satisfactory after the AUS is activated and operates normally.

It is generally advisable to avoid offering an AUS to those younger than 18 years old and the patient should have a good cognitive function and manual dexterity to operate the AUS device.[48] It is preferable that a bladder augmentation if needed, should be performed before the AUS surgery, to minimize urine contamination and the risks of prosthetic infection and erosion.[22,49] The upper urinary tract function should be monitored postoperatively, especially in those with a pre-existing situation.[50] The modalities of management must tailor to the unique needs of specific individuals. Moreover, patients with SCI-related urinary incontinence should be counseled regarding the higher risks of nonmechanical device failure and revision surgery with poorer overall continence outcomes in long term compared to the non-neurogenic group.[47,51]

Dementia or incapacitated population

Given that SUI is likely more common in the aging population, coupled with the fact that these patients are often burdened with chronic diseases, invariably many patients will develop a poor state of mind and diminished psychomotor functions.[52] The presence of cognitive decline and/or those with age-related deteriorating manual dexterity is often listed as contraindications for AUS surgery.

For the elderly incapacitated or those who have developed dementia, it is generally recommended that the AMS 800 device be deactivated (or removed) to avoid neglect or non-use of the AUS with subsequent risk of bladder overdistension (or rupture).[53] In most circumstances, a simple measure of a suprapubic catheter placement under radiological guidance with the AUS is completely deactivated can circumvent the need for an AUS explant.[22]

Persistent and/or recurrent SUI post AUS insertion

The two types of SUI that can occur following the activation of the AMS 800 device are either early (persistent) UI or

delayed (recurrent) urinary incontinence. There are many causes of persistent and/or recurrent UI and these can sometimes overlap. The diagnostic evaluation in men with persistent or recurrent UI following the AUS implantation involves a logical stepwise process of confirmation and will require a sufficient understanding of the mechanics of the AMS 800 device.[9,22,54–56] For persistent SUI, the potential causes include deactivation and/or accidental operation of the pump control unit, incorrect PRB size, unrecognized de-novo overactive bladder, improper cuff sizing, cuff erosion or device malfunction.[9,22,54–56] In contrast, those presenting with recurrent incontinence are often related to cuff atrophy, urethral erosion, mechanical failure or worsening of the existing overactive bladder.[9,22,54–56] Attention is to be paid not only to SUI but also to non-SUI lower urinary tract symptoms, which can occur over time.[57]

Careful history taking and focused clinical examination to check the cycling of the AMS 800 device as well as a urine test to exclude urinary tract infection are useful.[9] Inadequate cuff deflation and/or inadvertent activation of the locking mechanism can lead to incomplete bladder emptying and subsequent overflow incontinence. A poorly placed control pump in the scrotum can be accidentally compressed and caused unintentional cuff deflation and urinary incontinence. The patient should be given specific instructions on how to manipulate and care for the pump to avoid pressing the deactivation button. A formal cystoscopy should be undertaken to assess cuff status and urethral integrity, while an imaging test can confirm the fluid status within the PRB unit. Once a diagnosis is made, patients should be adequately counseled, and appropriate treatment should be instituted.

Mechanical failure is typically a late complication[22,54,58] and can be related to a fluid leak in the system (usually the creases in the cuff), tubing fracture, non-functioning pump control unit or subsequent urethral atrophy.[9,22,59–61] Several surgical strategies to manage recurrent incontinence include downsizing the cuff size, repositioning the cuff to a new urethral position, placing tandem (double) cuffs, increasing reservoir pressure, and performing transcorporal cuff placement or interposition of a biologic graft material between the cuff and urethra.[22] Depending on the timeline, a full exchange of all AUS components may not be necessary and following the replacement of the offending (defective) component, all components should be flushed with the filling solution and refilled with sterile normal saline at the time of a revision to avoid the problem of particulate matter occlusion in the AUS device.[22] If the existing AUS has been in-situ for more than 7 to 10 years, replacement of all components with a new AUS is recommended.

Urethral erosions can occur early in the postoperative period from an unrecognized urethral injury while late erosions may be related to the fragile urethra, improper urethral catheterization, or blind manipulation with an activated sphincter.[22,62–64] Patients with poorly controlled diabetes or prior history of urethral surgery or pelvic radiation are considered high-risk subpopulations for urethral erosion.[62–64] The presence of any urethral erosion equates to a device infection with the risks of urosepsis or the development of urethral stricture in the future.[65] While there are no clear guidelines regarding the removal of the entire device versus only the cuff in sterile late erosion cases, it is generally safer to remove all the existing AMS 800 components, especially if the AMS 800 device has been around for several years.[22] A formal urethral repair can be attempted at the time of device explant if surgically feasible although it is likely the outcome will be similar if the urethra is left to heal spontaneously over an indwelling catheter.[22]

Recommendations (Box 1): The implantation of AMS 800 device in these special populations are often more complex and technically challenging (Clinical principle). For an inexperienced or novice surgeon, the presence of a senior colleague or surgical mentor at the time of the AUS surgery or referral to regional centers of excellence or high-volume AUS implanters can be helpful (Clinical principle). Female AUS surgery is uncommon and preserving the integrity of the vesicovaginal surgical plane is critical to ensure the correct dissection of the tissue plane and minimize the risk of cuff erosion or extrusion (Grade C). The AUS cuff should be placed at the bladder neck (or peri-prostatic tissue) in the neurogenic and pediatric populations in the settings of intermittent self-catheterization for poorly contractile bladder, and upper urinary tract function should be monitored postoperatively (Clinical principle). For the elderly incapacitated or those who have developed dementia, it is generally recommended that the AMS 800 device be deactivated (or removed) (Clinical principle). The diagnostic evaluation in men with persistent or recurrent UI following the AUS implantation involves a logical stepwise process of confirmation and will require a sufficient understanding of the mechanics of the AMS 800 device, although attention should be paid also to non-SUI lower urinary tract symptoms, which can occur over time (Grade B).

Cost analysis and comparative and review of AMS800 device to other contemporary devices

There is limited published data on cost-analysis modeling between AMS800 and other surgical or nonsurgical options. It is reasonable to assume that the cost of (nonreusable) incontinence pads is an expensive ongoing expenditure and can be associated with significant psychosocial burden and local issues (odor, rash, environmental impact, etc).[1,8] The AMS 800 device with an InhibiZone antibiotic coating is more expensive than the non-coated device, although this cost difference is not an issue to the patient if the patient is privately insured or there is funding to cover the surgery. However, the InhibiZone-coated AMS 800 device has not received regulatory approval in many AP countries. Moreover, the exact price of the AMS 800 device can vary among the AP countries depending on the local distributor price and payment by a third-party insurer. In countries where various surgical continence devices are available, the AMS 800 device appears to offer a more cost-effective solution than male sling[66] and collagen injection[67] for males with severe SUI, especially in the longer term.

Fascial and synthetic male slings can be an attractive and effective treatment alternative to the AMS 800 device,[68] especially for males with mild to moderate SUI and those without prior pelvic radiation therapy since the sling device is often cheaper and is considered a less invasive surgery. Furthermore, the patient who receives a male sling can void spontaneously without manipulating a pump postoperatively. A recent systematic review and meta-analysis found that AUS is better than slings for moderate male SUI.[69] Multiple sling materials and devices are available with published data showing reasonable effective and safety outcomes,[1,70] although many synthetic male slings are not registered or widely available in the AP region.[71] At present, there is no strong evidence to suggest that one type of male sling is better than another sling.[72–74] While adjustable male slings can provide a higher objective continence rate (since the sling can be re-tightened again), they are associated with higher complication and explant rates.[70] The MASTER noninferiority randomized controlled trial comparing AUS and male sling found both surgical options to be effective although secondary and post hoc analyses were in favor of the AUS.[75] The AMS 800 device is often performed to salvage male sling failure cases, with the placement of AUS, which is not an issue most of the time. It is very rare for a patient to receive a male sling after an AUS failure.

Newer and novel AUS-like devices have shown early promising outcomes[76] and devices such as the Pro-ACT device (Uromedica),[77,78] Zephyr ZSI 375 (Mayor Group),[79] VICTO urinary sphincters (Promedon),[80] and Rigicon ContiClassic or ContiReflex (Rigicon Inc),[81] are designed to overcome some of the limitations of the AMS 800 device by having a simpler design with lesser components, easier device preparation and an adjustable urethral compression component or PRB. Currently, there are limited studies on the long-term clinical efficacy, safety, and mechanical reliability of these AUS-like devices.[1] Like the male slings, many of these AUS-like devices are not registered or commercially available in many AP countries.

Recommendation (Box 1): Despite the limited cost-effective analysis comparing the AMS 800 device and other continence devices and given that many male slings or AUS-like devices are not registered or widely available in many AP countries, the AMS 800 device remains a very effective surgical treatment for male SUI and can salvage failed cases (Clinical principle).

CONCLUSIONS

Significant scientific advances in innovative design, technological modifications, and surgical refinements of the AMS 800 device have resulted in a modern, effective, safe, and durable surgical solution for many males with SUI. Despite the known mechanical limitations and unique set of complications, the AMS 800 device remains the surgical benchmark and continues to improve the quality of life for many patients. The present consensus statement is formulated based on the clinical review of relevant literature to provide a set of practical recommendations to assist surgeons with the AMS 800 device surgery.

AUTHOR CONTRIBUTIONS

Eric Chung: Conceptualization; funding acquisition; writing – original draft; methodology; writing – review & editing; formal analysis; project administration; supervision; investigation; validation; data curation. **Limin Liao**: Writing – review & editing; formal analysis; methodology; validation. **Jang Hwan Kim**: Methodology; validation; writing – review & editing; formal analysis. **Zhong Wang**: Methodology; validation; writing – review & editing; formal analysis. **Takeya Kitta**: Methodology; validation; writing – review & editing; formal analysis. **Alex Tong-Long Lin**: Methodology; validation; writing – review & editing; formal analysis. **Kyu-Sung Lee**: Methodology; validation; writing – review & editing; formal analysis. **Liefu Ye**: Methodology; validation; writing – review & editing; formal analysis. **Peggy Chu**: Methodology; validation; writing – review & editing; formal analysis. **Yasuhiro Kaiho**: Methodology; validation; writing – review & editing; formal analysis. **Mineo Takei**: Methodology; validation; writing – review & editing; formal analysis. **Hai Jiang**: Methodology; validation; writing – review & editing; formal analysis. **Joe Lee**: Methodology; validation; writing – review & editing; formal analysis. **Hitoshi Masuda**: Methodology; validation; writing – review & editing; formal analysis. **Vincent Tse**: Methodology; validation; writing – review & editing; formal analysis; supervision.

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CONFLICT OF INTEREST

None declared.

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