Male urinary incontinence: Artificial sphincter

Incontinência urinária masculina: Esfíncter artificial

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The Guidelines Project, an initiative of the Brazilian Medical Association, aims to combine information from the medical field in order to standardize procedures to assist the reasoning and decision-making of doctors.
The information provided through this project must be assessed and criticized by the physician responsible for the conduct that will be adopted, depending on the conditions and the clinical status of each patient.

Introduction

Patients with intrinsic sphincter deficiency include men who have undergone retropubic radical prostatectomy (including laparoscopic or robot-assisted radical prostatectomy), radical perineal prostatectomy, or transurethral resection of the prostate (TURP), patients with previous pelvic trauma or history of pelvic radiation, women who have undergone failed anti-incontinence procedures, and patients with spinal cord injury, myelomeningocele or other causes of neurogenic bladder, in which intrinsic sphincter dysfunction may also exist. Urinary incontinence after radical prostatectomy (UIRP) is the most common indication for artificial urinary sphincter (AUS) implantation.[1,2] The main etiology of UIRP is sphincter deficiency in up to 90% of cases, either alone or combined with detrusor overactivity (DO).[3]

The placement of the artificial urinary sphincter should be postponed for at least 6 months to 1 year, given that a portion of the patients redevelop urinary continence in this period. The American Medical Systems 800 (AMS 800) artificial urinary sphincter is the most widely-used device and is considered the gold standard in the treatment of urinary incontinence caused by intrinsic sphincter deficiency, working based on hydraulic mechanics.[4] The system consists of a cuff connected to a reservoir balloon through a pump. The three components are connected with torsion resistant tubes.[5] The sizes (lengths) of the cuffs range from 3.5 cm to 5.5 cm in 0.5 cm increments. The cuff can be implanted in the bulbar urethra (most common) or in the bladder neck. During rest, the reservoir pressure is transmitted to the cuff, causing continence. Digital compression of the pump promotes the transfer of liquid from the cuff to the reservoir, relieving urethral compression and allowing urination. After a period of time (3-5 minutes), the liquid is transferred back into the cuff by compressing the urethra or bladder neck, providing continence. The reservoir balloons come in three preset pressures: 51-60, 61-70, 71-80 cm of water; the lowest pressure required to close the urethra should be used. Migration of components may occur if the cuff is poorly dimensioned, if the pump or balloon is not positioned correctly or if the pipe lengths are incorrect.[6]

The standard placement of an AUS involves a small incision made in the patient's perineum or scrotum. Perineal access is considered the most common;[7] however, authors have also described the scrotal technique, thus, the advantages and disadvantages of each should be considered by the surgeon.[8]

The "cuff," which is the portion of the device that surrounds and obstructs the urethra, is usually placed directly around the urethra (i.e., the "standard" placement). Another variation for cuff placement is the transcorporal (TC) approach. This technique avoids the posterior urethral dissection as well as of the corpora cavernosum. The dorsal dissection plane for cuff placement is through the septum of the corpora cavernosa from one side to the other, resulting in a portion of the ventral tunica albuginea acting as a cushion between the cuff and the dorsal

corpus spongiosum. The transcorporal placement of the cuff was developed in an attempt to improve continence in patients with recurrent incontinence secondary to erosion, urethral atrophy, inadequate urethral coaptation, after radiotherapy, or for patients undergoing revision, in whom more proximal placement could not be achieved.[9]

Proper patient counseling and careful attention to intraoperative and postoperative details are important to achieve good outcomes and high rates of patient satisfaction. Several case series with long-term monitoring have demonstrated efficacy of the AUS and patient satisfaction even when surgical revisions are needed.[10] However, implantation of the AUS is an invasive procedure that can result in complications, such as postoperative infection, urethral erosion and explantation.[11] Furthermore, previous urethral damage (such as failed surgical procedures, urethral atrophy or history of pelvic radiotherapy) may potentially result in technical difficulties and/or reduced surgical efficacy. Urinary incontinence (UI) that can occur after artificial urinary sphincter activation is classified as either early (persistent) or late onset (recurrent).[12] In the case of persistent UI, patients never regain urinary continence following AUS activation, with urinary loss often similar to that experienced prior to implantation and during the deactivation period. Persistent incontinence is usually attributed to a surgical failure or inability to identify detrusor overactivity or any other lower urinary tract abnormality in the preoperative diagnostic evaluation.[13] On the other hand, recurrent or late-onset UI generally occurs after several months or years after the AUS implantation. There are several causes of persistent and/or recurrent UI: unsuitable or accidental pump operation, urinary tract infection (UTI) with detrusor overactivity, overactive bladder, urethral atrophy, urethral erosion of the cuff, inadequate cuff size, insufficient pressure of the reservoir balloon, development (recurrence) of urethral or bladder neck stenosis, as well as device failure with fluid loss or obstruction of the control unit flow.[12,14,15] Revision rates between 8 and 45% have been reported due to mechanical failure, while those derived from non-mechanical complications such as erosion, urethral atrophy and infections are reported between 7 and 17%.[1,16-18]

Certain complications have been described, with the most significant being erosion and/or extrusion of the sphincter, infection and urethral atrophy. In certain situations, there is a need to remove the device.[19] The following are risk factors for complications: pelvic radiotherapy, urethroplasty or any urethral manipulation and antecedent erosion or infection in individuals previously submitted to artificial sphincter implantation.[20-22]

Objective

The objective of our evaluation is to establish guidelines regarding the most important issues related to artificial urinary sphincter implantation: the best practices in the choice and preparation of the AMS 800 urinary sphincter components, preoperative care for patients with indication of artificial sphincter, the best approach for implantation of the artificial urinary sphincter (perineal or transescrotal), to compare the transcorporal placement of the cuff with the "standard" placement (directly around the urethra), regarding efficacy and safety, to assess the best conduct in the perioperative and postoperative period of artificial urinary sphincter implantation, to assess the best conduct in the management of therapeutic failure (early or late onset urinary incontinence) and to evaluate the best strategy against suspected erosion or extrusion, infection and urethral atrophy, considering primary studies.

Method

The initial eligibility criteria for studies were: PICO components (**P**atient, **I**ntervention, **C**omparison, **O**utcome), observational comparative studies (cohort and/or before-and-after), comparative experimental studies (clinical trial), absence of restriction applied to the period of studies, no language restriction and availability of the full text.

Medline (via PubMed), Embase, Central (Cochrane), Lilacs (via BVS) and manual search were the sources of scientific information consulted in this study.

The search strategies used Medline – (Artificial Urinary Sphincter OR Artificial Urinary Sphincters OR Artificial Genitourinary Sphincter OR Artificial Genitourinary Sphincters OR Artificial sphincter OR AMS 800 OR AMS800); other computerized databases – 'artificial AND urinary AND sphincter', and manual search – reference within references, revisions and guidelines.

For study selection initially we searched by the title, then by the abstract, and finally by its full text, the latter being subject to critical evaluation and extraction of results related to the outcomes.

The strength of the evidence from observational and experimental studies was defined taking into account the study design and corresponding bias risks, the results of the analysis (magnitude and precision), relevance and applicability (Oxford/GRADE).[23,24]

The global evidence summary will be presented at the end of the results. The global evidence summary will be elaborated considering the evidence described.

The strength (Oxford/GRADE)[23,24] will be estimated as 1b and 1c (grade A) or strong, and 2a, 2b and 2c (grade

B) or moderate, weak or very weak. The strongest evidence will be considered.

We defined seven main questions regarding male urinary incontinence and artificial urinary sphincter as follows:

1. AMS 800 Model.
2. Preoperative period.
3. Perineal versus scrotal approach.
4. Transcorporal approach.
5. Perioperative and postoperative care.
6. Evaluation and conduction of therapeutic failure after AUS implantation.
7. Complications.

1. AMS 800 Model

The objective of our evaluation is to assess the best practices in the choice and preparation of the AMS 800 urinary sphincter components, considering primary studies.

Clinical question

What conduct should be adopted in the choice and preparation of the components of the artificial urinary sphincter model AMS 800? This question was answered in this evaluation using the PICO method, where P stands for patients with urinary incontinence due to sphincter deficiency, I refers to intervention with implantation of the AUS model AMS 800, C is the comparison with implantation of different components and the preparation of such (cuff and balloon), and O is the outcome of incontinence control and complications. Based on the structured question, we identified the keywords used as the basis for searching for evidence in the databases and after the eligibility criteria (inclusion and exclusion), which were selected to answer the clinical question (Annex I).

Results

In all, 1,757 studies were retrieved. Of these, 20 were selected by title and eight by summary, with reading of the full text in the second case. After the analysis of the full texts, 14 studies were included in our evaluation.[25-38] The main reasons for exclusion were: studies aiming only to describe the surgical technique, a series of cases with a small number of patients included (n < 10), and a narrative review.

The surgeon determines the appropriate cuff size to be used by measuring the circumference of the tissue around the urethra or the bladder neck. A belt is used for cuff measurement, available in the device implantation kit, which should surround the entire urethra circumferentially for proper assessment of its caliber. Additional clearance is required to accommodate the patient's urethral tissue between the transurethral device and the cuff. The thickness of the urethral tissue is patient-specific and requires a surgeon's assessment to determine its impact on sizing. In transcorporal implantation (TC) one must not undersize the cuff size, considering a size 1⁄2 cm greater than the measured value. This is particularly true for older men, since the postoperative urinary retention rate is significantly higher in these patients (32% [TC] vs. 8% in peri-urethral implantation, NNH = 4, 95CI 2-28).[25] **(B)**

A before-and-after study showed that the percentage of patients using two or more pads/day was lower in the larger cuff size group (5.0 to 7.0 cm) compared to patients with a cuff size of less than 5 cm, at a median follow-up of 6.8 years (9.1 vs. 20.5%, NNT = NS). In addition, cuff size did not significantly affect the risk of complications.[26] **(B)**

In a historical cohort (N = 45 men), one group evaluated implantation of the 3.5 cm cuff in primary and revision surgery, after repeatedly observing that loose cuffs led to more severe postoperative incontinence. In this study, compared to a larger one the 3.5 cm cuff showed no difference in explantation rate (9% in both groups; NNT = NS), due to infection and/or erosion, in an average follow-up of 12 months.[27] **(B)**

Another historical cohort (N = 59 men) evaluated the association of the difference between the urethral circumference and the cuff size chosen (ΔC), in its effect on postoperative incontinence in a median follow-up of 4.2 years. The median size of the urethral cuff was 3.8 cm and 66% of the patients had a 4.0 cm cuff implanted. In a long-term follow-up, when ΔC was < 4 mm, a higher rate of urinary retention, erosion and atrophy was observed, and when ΔC was ≥ 4 mm, better continence and satisfaction were observed ($p<0.05$). The results of this study suggest that a moderate increase in cuff size can produce better results in the long run. Furthermore, it demonstrated improvement in continence rates when surgeons opted for a larger cuff size when the urethral circumference was between two cuff sizes.[28] **(B)**

A historical cohort (N = 176 men) evaluated results comparing 100 cuff measuring 3.5 cm with 76 cuffs of larger sizes. Although there was no difference between the two groups regarding continence rates (83 vs. 80%, NNT = NS), patients with a history of irradiation who underwent 3.5 cm cuff implantation (N = 100) presented a 17% increase in the risk of erosion through the cuff (NNH = 6; 95CI 3-22).[29] **(B)**

The pressure-regulating balloon (PRB) determines the amount of pressure applied by the cuff. The surgeon usually implants the PRB in the pre-vesical space. A more recent PRB placement technique (pressure of 61-70 cm of H_2O and filled with 24 cc saline) is high submuscular placement below the rectus abdominis muscle using a

high scrotal incision. This technique was followed for 24 months with no difference in continence rates.[30] **(B)** The surgeon usually selects the lowest balloon pressure needed to maintain closure of the bulbar urethra or bladder neck. The most commonly used balloon pressure is 61-70 cm / H_2O (45-51 mmHg) (94% of cases worldwide). A pressure of 71-80 cm of H_2O may be preferred in patients with a cuff implanted in the bladder neck.[31] **(D)**

The prosthesis may be filled with isotonic sterile sodium chloride solution or contrast, at the surgeon's discretion. The solution must be isotonic to minimize the transfer of fluid through the semipermeable silicone membrane. Some contrast materials are hypertonic and viscous, representing a risk of poor transmission of fluid in the device and transfer of fluid through the reservoir membrane. System pressure changes may occur over time if the balloon is filled with radiopaque solution at an incorrect concentration.[32] **(C)** A history of adverse reactions to the radiopaque solution prevents its use as a filling medium for the prosthesis. If contrast solution is used, the manufacturer's recommendations must be observed.[6] **(D)**

The filling volume of the PRB with the empty cuff should be 22-27 cm, depending on the size and number of cuffs.[31] **(D)**

The manufacturer's recommendation is for the PRB to be filled with 22.5-23 cc of solution while the cuff is empty, subsequently allowing it to fill with at least 2 cc of solution remaining within the PRB in order to maintain the desired pressure range. In selected cases, intraoperative cuff pressurization may be considered to help determine the appropriate volume of total system solution.[6] **(D)**

The length of hospital stay will depend on the time of removal of the urethral catheter. A 12-Fr urethral catheter can be placed at the end of the procedure and left in position overnight. Others advocate not using a catheter, allowing the patient to attempt emptying after recovery from anesthesia. If the patient fails to do so, a new catheter is replaced and a further attempt at emptying it is repeated in 24-48 hours. In the event of persistent urinary retention (catheter > 48 h), a suprapubic cystostomy is preferred in order to reduce the risk of early erosion.[32] **(C)** [33,34] **(B)** The "AUS Consensus Group" (2015) recommends the use of a ≤ 14-Fr catheter and suggests removing it after a brief period (usually overnight) if the surgery was uneventful, as removal on the same day may increase the risk of urinary retention due to pain or inflammation.[31] **(D)**

Several before-and-after studies show an average time of six weeks for activation of the system.[35-38] **(C)** A before-and-after study applied a longer period of primary deactivation (12 weeks) in irradiated patients. There is no evidence to support a primary deactivation period greater than six weeks. The "AUS Consensus Group" (2015) recommends the activation of the system between 4 and 6 weeks for patients undergoing the first AUS implant.[31] **(D)**

Global evidence summary

The choice of cuff size should be made through the precise measurement of the circumference of the tissue around the urethra or the bladder neck. When in doubt, choose the largest size, avoiding placement of a cuff smaller than the measurement of the urethral circumference. **(B)**

The surgeon should select the lowest balloon pressure needed to maintain closure of the bulbar urethra or bladder neck. The most commonly used balloon pressure in the bulbar urethra is 61-70 cm/H_2O and 71-80 cm of H_2O may be preferred in patients with a cuff implanted in the bladder neck. **(D)**

The prosthesis may be filled with isotonic sterile sodium chloride solution or contrast, at the surgeon's discretion. **(C)**

The filling volume of the PRB with the empty cuff should be 22-27 cm, depending on the size and number of cuffs. **(D)**

The catheter left in the postoperative period can be ≤ 14-Fr and should be removed after a brief period (usually overnight). **(D)**

In the case of persistent urinary retention, the placement of suprapubic cystostomy is preferable in order to reduce the risk of early erosion. **(B)**

The AUS can be activated between 4 and 6 weeks in patients submitted to their first implant. **(D)**

2. Preoperative period

The objective of our evaluation is to suggest preoperative care for patients with indication of artificial urinary sphincter, based on primary studies.

Clinical question

How should the preoperative evaluation be performed in patients who will undergo artificial urinary sphincter implantation? This question was answered in our evaluation using the PICO method, where P stands for patients with moderate to severe urinary incontinence; I to intervention with artificial urinary sphincter; C to comparison with taking or not taking certain preoperative conduct; and O to the beneficial or harmful outcome in the postoperative period. Based on the structured question, we identified the keywords used as the basis for searching evidence in the databases and after the eligibility criteria (inclusion and exclusion), which were selected to answer the clinical query (Annex II).

Results

In total, 1,757 studies were retrieved. Of these studies, 28 were selected by title and 20 by summary, with reading of the full text in the second case. After the analysis of the full texts, 17 studies were included in our evaluation.[16,18,24,36,38-44] The main reason for exclusion was lack of response to the PICO.

The AUS should be offered to individuals with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) who have failed conservative treatment.[39] **(A)** Patients must have sufficient cognitive ability and function to operate the device.[40] **(D)** There is a risk of mechanical failure of the device after five years and this may be related to other possible (non-mechanical) complications such as infection and erosion or atrophy of the urethra.[18] **(B)** The rate of reoperation for all causes is 26% (varying between 14.8 and 44.8%).[16] **(A)** It is worth mentioning that irradiated patients may constitute a group with a higher risk of complications.[38,41] **(A)** This information must be provided to the patient.

The pre-implantation evaluation includes a clinical history and, occasionally, voiding diary (urine time and volume, diaper use, urinary incontinence episodes), physical examination, pad test, urinalysis, and urodynamic evaluation.[36] **(B)** [42] **(A)**

Cystoscopy and/or urethrocystography prior to AUS implantation are advised when concomitant urethral stenosis is suspected, which may complicate placement or put the AUS at risk of subsequent damage. For example, it was verified that up to 32% of patients presented urethrovesical anastomotic stenosis in the cystoscopy after radical prostatectomy (RP).[43] **(C)** Urethrovesical anastomotic stenosis should be stable prior to implantation.

Sphincter deficiency can be diagnosed by urodynamic examination.[24] **(B)** Less frequently, changes in bladder compliance are described, as well as the occurrence of detrusor overactivity.[44] **(C)**

All sites of infection, including the urinary tract, should be treated prior to the procedure to protect the operative field from bacterial contamination. Prophylactic antibiotic therapy should be administered 60 minutes before the incision; however, there is no standard antibiotic for this procedure.[45] **(B)**

Global evidence summary

The AUS is indicated in urinary incontinence due to intrinsic deficiency of the sphincter, after failure of the conservative treatment. **(A)**

Patients should have sufficient cognitive capacity and function to operate the device. **(D)**

They should be informed of the possible complications (mechanical or otherwise), as well as irradiated patients with greater risk. **(A)**

Advise of the possibility of not remaining 100% dry. **(A)**

The recommended evaluation includes a clinical history and physical examination. Urinary voiding and absorbent tests can be used but are not required. Urodynamics enables the diagnosis of sphincter deficiency. Cystoscopy and/or urethrocystography may be indicated in the analysis of urethral stenosis or vesicourethral anastomosis when these changes are suspected. **(A)**

All infection sites, including the urinary tract, should be treated prior to the procedure. **(B)**

3. Perineal versus scrotal approach

The objective of this evaluation is to suggest the best approach for implantation of the artificial urinary sphincter, considering primary studies.

Clinical question

What should be the surgical approach to artificial urinary sphincter implantation? This question was answered based on the PICO method, where P corresponds to patients with urinary incontinence due to sphincter deficiency; I to intervention with implantation of an artificial urinary sphincter via the scrotal method; C to comparison with implantation via the perineal method; and O to the outcome in relation to control of incontinence and complications. Based on the structured question, keywords were identified and constituted the basis of the search for evidence in the databases. After applying the eligibility criteria (inclusion and exclusion), articles were selected in order to answer the clinical question (Annex III).

Results

1,757 studies were retrieved. Twenty were selected by title and 15 by summary, with reading of the full text in the second case. After the analysis of the full texts, eight studies aiming only to describe the surgical technique were included in our evaluation.[7,8,31,46-50] Series of cases with a small number of patients included (n < 20) and a narrative review were the main reasons for exclusion.

A recent historical cohort study[7] **(B)** including 27,096 adult male patients compared the perineal approach (N = 18,373) to the scrotal approach (N = 8,723) in primary implantation of the AUS. The perineal incision reduced the risk of infection by 1.0% (RRA = 1.0%, 95CI 0.006-0.014; NNT = 100, 95CI 72-161), as well as the risk of cuff erosion by 2% (RRA = 2%, 95CI 0.014-0.024; NNT = 53, 95CI 41-73). There was also a reduction in the risk of explantation of

5.7% (ARR = 5.7%, 95CI 0.048-0.066; NNT = 18, 95CI 15-21) and risk of revision of 2% (ARR = 2%, 95CI 0.12-0.028; NNT = 50, 95CI 36-83). There was no difference between the groups regarding the risk of atrophy.[8] **(C)**

Another historical cohort[46] **(B)** included data from 84 patients with stress urinary incontinence after prostate surgery, monitored for an average of 39.7 months and submitted to AUS implantation (5% primary). In a subgroup analysis, perineal access (N = 24) compared to scrotal access (N = 60) reduced the risk of erosion by 20% (ARR = 20%, 95CI 0.099-0.301; NNT = 5, 95CI 3-10). There were no significant differences between the groups in the number of irradiated and/or anticoagulated patients, nor in the number of patients submitted to double-cuff placement (p=0.44, 0.22 and 0.76, respectively).[46] **(B)** Also, a recent historical cohort[47] **(B)** compared perineal (N = 152) and penoscrotal access (N = 99) in the single cuff implantation. The comparison of the two groups showed that the perineal route reduced the risk of explantation by 10.6%, in the 6-month follow-up (RRA = 10.6%, 95CI 0.017-0.195; NNT = 9, 95CI 5-61).[47] **(B)**

A historical cohort study compared the scrotal to the perineal approach in a total of 126 artificial urinary sphincter cuffs (120 procedures, including double cuff placement in six), implanted in 94 patients, 63 of which were placed via the penoscrotal approach and 63 via the perineal approach.

In the subgroup analysis with patients undergoing a primary or revision procedure with a single cuff, the number of patients "completely dry" (without using pads) was higher in the "perineal" group (ARA = 28%, 95CI -0.48 to -0.07; NNH = 4, 95CI 2-14). Furthermore, perineal access also showed a greater number of "completely dry" patients (ARA = 28.7, 95CI -0.53 to -0.03; NNH = 3, 95CI 2-27). The number of patients in the trans-scrotal group and in the perineal group who required double cuff implantation due to incontinence was 18 and 3%, respectively (p=0.6, without statistical significance).[48] **(B)**

A before-and-after study (N = 30)[8] **(C)** reported excellent results with an improved technique using a single scrotal incision, allowing a more proximal placement of the cuff and the attainment of a continence rate similar to those obtained with the perineal approach found in the literature.[8] **(C)**

Another before-and-after study[31] **(C)** evaluated 83 highrisk patients (69% prostatectomy only and 31% with radiotherapy and/or cryotherapy) who underwent AUS implantation with a single transverse scrotal incision. In an average follow-up of 18.8 (14.6) months, the number of pads per day decreased from a mean of 6.7 in the preoperative period to 1.1 in the postoperative period. Overall, 83% of the patients (79% of the irradiated ones and 85% of the nonirradiated ones) used ≤ 1 pad/day after surgery.[49] **(C)**

Authors have evaluated the implantation of AUS and inflatable penile prosthesis simultaneously through a single trans-scrotal incision. They included 22 patients with urinary incontinence and erectile dysfunction resulting from radical prostatectomy in 21 patients and radical cystectomy in one. The average follow-up time was 17 (12-36) months. The total revision rate was 14%, due to urethral erosion in two patients and migration of the reservoir in one. All patients reported improvement in urinary loss, requiring ≤ 1 pad/day. No patient suffered prosthesis infection in the postoperative period.[50] **(C)**

A consensus of the International Continence Society (ICS) recommends that the penoscrotal approach be reserved for reoperation; patients with conditions that prevent placement in the lithotomy position (morbid obesity, spine or limb deformities, neuromotor conditions); and patients who will undergo the AUS implantation and inflatable penile prosthesis through a single penoscrotal incision.[31] **(D)**

Global evidence summary

The implantation of the AUS via the penoscrotal route can increase the risk of erosion, infection and explantation. **(B)**

The penoscrotal technique may not provide an advantage in relation to efficacy, and is associated with a lower continence rate than the perineal approach. **(B)**

The penoscrotal approach can be reserved for cases of reoperation; patients with conditions that impede placement in the lithotomy position (morbid obesity, spine or limb deformities, neuromotor conditions); patients who will undergo AUS implantation and inflatable penile prosthesis through a single penoscrotal incision; and patients with a previously implanted sling. **(D)**

The perineal approach should be the usual one. **(B)**

4. Transcorporal approach for cuff placement

The aim of our evaluation is, based on primary studies, to compare the transcorporal placement of the cuff with the "standard" placement (directly around the urethra), regarding efficacy and safety.

Clinical question

What is the best approach for cuff placement in artificial urinary sphincter implant surgery? This question was answered based on the PICO method, in which P stands for patients with moderate to severe urinary incontinence; I is the intervention with transcorporal cuff implantation; C is the comparison with "standard" cuff implantation;

and O stands for the outcome of control of incontinence and complications. Based on the structured question, keywords were identified and constituted the basis of the search for evidence in the databases. After applying the eligibility criteria (inclusion and exclusion), articles were selected in order to respond the clinical doubt (Annex IV).

Results

In all, 1,757 studies were retrieved; ten were selected by title and eight by summary, with reading of the full text in the second case. After the analysis of the full texts, six studies were included in our evaluation.[9,51-55] The main reasons for exclusion were: studies aiming only to describe the surgical technique, a series of cases with a small number of patients included (n < 10), and a narrative review.

The transcorporal approach was introduced by Guralnick ML et al. in an effort to treat patients with previous urethral atrophy or erosion. In a before-and-after study, the results after transcorporal cuff placement were reviewed in 31 patients with an average follow-up of 17 months. A success rate of 84% (26 of 31 patients) was reported, defined as patients with no incontinence or occasional incontinence, requiring 0 to 1 pad per day. In addition, 25 of 26 patients surveyed were very satisfied with the outcome. It is noteworthy that seven of these patients had undergone primary double cuff placement. There were no cases of infection or erosion. Of the 31 patients, 27 had no preoperative erectile function, one had normal erections, one had partial erections with the intra-urethral drug delivery system and two had a penile prosthesis. Postoperative erectile function deteriorated in one patient and remained unchanged in the others.[9] **(C)**

A historical cohort increased the original indications, including not only patients requiring reimplantation around the distal bulbar urethra, but also those submitted to primary cuff placement in the proximal bulbar urethra, with a history of radiotherapy or with a high risk of erosion by the cuff due to previous urethral mobilization for urethroplasty (N = 30; 26 with prostate cancer therapy). Twenty-six (26) patients were compared: 18 with "cuff standard setting" versus eight with "transcorporal approach," after a minimum follow-up of 12 months and a mean follow-up of 31 and 28 months, respectively. Approximately 50% of these patients had a history of radiotherapy. Most of the patients in the transcorporal group had two or more urethral surgeries prior to AUS placement, with a primary indication for TC prior anastomotic urethroplasty. Success rates for social continence (< 2 pads per day) were 61% using the standard approach and 87.5% for the transcorporal group (NNT = NS [not statistically significant]). AUS device explantation due to erosion or infection, retention (need for urethral catheter or suprapubic cystostomy), atrophy and incontinence were more common in the standard technique group. However, the data should be interpreted with caution (NNT = NS for all outcomes), since neither group is balanced. The results of this study showed that the TC group, despite a higher rate of previous urethral surgery and radiotherapy, has reasonable results.[51] **(B)**

In another study, authors evaluated data from 30 patients identified as having a "fragile urethra" post-prostatectomy (pelvic irradiation, prior AUS implant failure, previous urethroplasty or cystoscopic and/or clinical findings of urethral atrophy). Thirteen (13) of these patients underwent transcorporal AUS (TCAUS) and 17 had a "standard" approach to the cuff. Seventeen (17) patients had irradiation, eight had erosion and ten had previous urethroplasty. Five patients had multiple risk factors for urethral erosion. The follow-up time was 34.1 months (range 2-95 months) and 42.2 months (range 4-94 months) in the "standard" and TCAUS groups, respectively. When the TCAUS and "standard AUS" groups were compared, there was no difference in continence rates (≤ 1 pad/day) (NNT = NS), improvement (any reduction in the number of pads/day) (NNT = NS), explantation (NNT = NS) or erosion (NNT = NS), despite a higher proportion of previous urethroplasties in the TCAUS group.[52] **(B)**

The authors prospectively evaluated incontinence control and erectile function after prior surgical failure using the TC approach in AUS cuff implantation. 23 patients with a mean age of 70 were included (age [SD], 60-85 [7]). Of these, 18 patients had urethral atrophy and/or erosion after AUS placement (11 patients), male sling (four patients) or both (three patients), and five patients had severe urethral atrophy after pelvic radiotherapy. There were no perioperative complications. After an average follow-up of 20 months (2-59 [15]) including data from 17 patients, eight were perfectly dry (no pads and no symptoms), five achieved social continence (0-1 pad/day) and four still had incontinence (required two or more pads/day). Among the six patients who had good preoperative erectile function and were sexually active, four had no decrease in the International Index of Erectile Function Questionnaire (IIEF-5) score. Therefore, TC cuff placement is a useful alternative after failure of prior surgical treatment, urethral atrophy or erosion. Erectile function can be maintained using the TC approach.[53] **(C)**

Of the 37 male patients treated with transcorporal AUS cuff, 20 had primary placement of transcorporal cuff, one of them with surgical indication due to previous

radiation, and 25 patients had a secondary procedure after failure of AUS or urinary incontinence surgery. After a median of 32 months (minimum follow-up of two years), the continence rate (0 to 1 pad/day) was 69.7%. A total of 88% of patients reported satisfaction with the AUS. Patients with primary implant due to irradiation were no more prone to revision than non-irradiated patients. Erection preservation was reported in half of the potent patients.[54] **(C)**

A before-and-after study included 18 patients who had implanted AUS with dual cuff, being one or both cuffs placed using the TC approach. Ten patients had a distal cuff implanted transcorporally to complement a proximal bulbar urethral cuff implanted using standard technique. The main indication for this approach was erosion or infection with prior AUS. None of the patients had preoperative erectile function and median follow-up was 26 months (IQR 14-30). Results of 16 patients were analyzed, with continence rate (0 to 1 pad/day) at 38% (one completely dry). In addition, five (31%) patients needed 2 pads/day, and five (31%) used 3 pads/day. Before the implantation of the dual TC cuff, the median daily pad use was 5.0 (IQR 3.5-5). Complications included four (22%) reoperations, one erosion and two infections.[55] **(C)**

Global evidence summary

The TC approach for cuff implantation may be indicated for men with a history of urethroplasty, previous urethral erosion, those treated with radiotherapy, with urethral atrophy, and tissue involvement. **(B)**

An important consideration regarding the use of a transcorporal approach is the erectile function of patients. They should be warned that this approach can lead to erectile dysfunction. **(C)**

5. Perioperative and postoperative care

The objective of this evaluation is to assess the best conduct in the perioperative and postoperative period of artificial urinary sphincter implantation, considering primary studies.

Clinical question

What conduct should be adopted in the perioperative and postoperative period of the implantation of the artificial urinary sphincter in order to reduce the risks of the procedure? This question was answered based on the PICO method, where P stands for patients with moderate to severe urinary incontinence, I is the intervention implantation of the AUS model AMS800® and O is the perioperative and postoperative conduct that can reduce the risks of implantation. Based on the structured question, keywords were identified and constituted the basis of the search for evidence in the databases. After applying the eligibility criteria (inclusion and exclusion), articles were selected in order to answer the clinical question (Annex V).

Results

For this issue, 1,764 studies were retrieved, 35 were selected by title and 32 by summary, with reading of the full text in the second case. After the analysis of the full texts, 29 studies were included in our evaluation.[1,17,26,31,34,45,56-76] Absence to respond to the PICO criteria was the main reason of exclusion.

Evidence on perioperative antibiotic prophylaxis for urinary prosthesis placement is variable, with data extrapolated from meta-analyses on hernioplasty with the use of mesh and orthopedic implant surgeries.[45,56,57] **(A)** Thus, the adequate duration of postoperative antibiotics after implantation remains unknown.[58] **(D)**

The rate of infection in contemporary studies is between 1 and 8%[57] **(A)** [34,59-61] **(C)**, with rates < 2% in high-volume centers.[1,17,62] **(C)** Gram-positive bacteria such as *Staphylococcus aureus* and *Staphylococcus epidermidis* represent the majority of infections, with methicillin resistance (MRSA) reported in 26% of the microorganisms.[63] **(C)** Gram-negative infections account for 26% of infections.[63] **(C)** Perioperative antibiotics are routinely administered; however, there is no standardized antibiotic regimen, and the choice depends on the surgeon's preference. It is recommended to provide both Gram-positive and Gram-negative coverage, including coverage for methicillin-resistant *Staphylococcus*.[31] **(D)** According to the guidelines of the American Urological Association on antimicrobial prophylaxis, this should consist of an aminoglycoside and a first- or second-generation cephalosporin or vancomycin, and should be administered within 60 minutes before skin incision.[64] **(D)**

Perioperative antibiotic therapy and attention to meticulous sterile techniques are the pillars of infection prevention. Authors have reported that a group of patients who rubbed the skin (five minutes rubbing the perineal and abdominal skin twice a day during the 5-day period immediately prior to AUS implantation) preoperatively with 4% topical chlorhexidine were four times less likely to suffer perineal colonization during surgery compared to a group receiving normal hygiene procedures (water and soap) [OR 0.23, p=0.003].[65] **(B)** More recently, it has been demonstrated in a randomized study that alcohol chlorhexidine solution reduced the presence of coagulase-negative staphylococci at the surgical site better than iodopovidone (topical PVP-I).[66] **(A)**

There is no evidence to support routine oral antimicrobial therapy postoperatively, especially in the absence of catheter placement and/or patient risk factors.[31] **(D)** The periods of oral antibiotic therapy (quinolones, cephalosporin or trimethoprim-sulfamethoxazole) in the postoperative period of AUS implantation vary in terms of extension, and are inconsistently reported in before-and-after studies.[67-70] **(C)** Meta-analyses of inguinal hernia repair using mesh[56] **(A)** and orthopedic surgery[57] **(A)** confirm that antimicrobial prophylaxis is beneficial when foreign material is implanted. A prolonged course of antimicrobials has been used by many professionals after penile prosthesis insertion, but evidence from orthopedic literature suggests that prophylaxis for 24 hours or less is adequate.[71] **(D)**

Trauma caused by catheterization or endoscopic manipulation in patients with an activated or malfunctioning device are considered as potential causes of urethral lesions, facilitated by tissue devascularization due to urethral athrophy.[26,72,73] **(C)** Even catheters suitably placed for short periods can be detrimental to the long-term survival of the device. Authors have demonstrated a greater risk of erosion in patients who were catheterized for more than 48 hours at any time after the placement of the AUS.[74] **(C)** Therefore, in situations when catheterization is absolutely necessary, a catheter of the appropriate caliber should be put in place for the shortest possible period of time (although there is no definition of how many days it should remain and this varies depending on the clinical situation). Intermittent urinary catheterization is not a contraindication in the presence of an artificial urinary sphincter, as long as the cuff remains deflated during the procedure.[31] **(D)** Most patients undergoing intermittent catheterization are neurogenic, so the cuff is usually placed around the neck of the bladder, reducing the risk of urethral erosion in comparison with positioning in the bulbar urethra.[74] **(C)** [66] **(D)**

The AUS must remain deactivated for six weeks. The first postoperative clinical visit occurs between 1-2 weeks, when the abdominal and perineal incisions are inspected, assessing the integrity of the skin and the possibility of infection. At the 6-week follow-up, the sphincter is activated by applying a firm and strong grip to the control pump, with the patient being instructed in the proper use of the device by the physician.[75] **(D)** Difficulty in handling the pump leads to inadequate emptying of the cuff, which is the most common cause of postoperative urinary incontinence and sphincter malfunction. In order to identify early complications requiring revision in the first few months of use, 3- and 6-month visits are the most critical, with subsequent frequency adjusted based on individual clinical circumstances. Ideally, standard follow-up should be conducted annually.[31] **(D)** The immediate identification of infection and/or erosion facilitates intervention before other local or systemic consequences occur. Some surgeons advocate nighttime sphincter deactivation, but others believe that this approach is ineffective and imposes unnecessary nighttime incontinence on the patient. A study comparing the two approaches demonstrated a tendency towards a decrease in atrophy with nocturnal deactivation, but the study does not have sufficient power and does not achieve statistical significance (ARR = 27%, 95CI -0.056 to 0.600; NNT = NS; power = 33.57%).[76] **(A)**

Global evidence summary

Perioperative antibiotics are routinely administered; however, there is no standard antibiotic regimen. **(D)**

It is recommended to provide both Gram-positive and Gram-negative coverage, including coverage for methicillin-resistant *Staphylococcus* spp. This should be administered within 60 minutes before cutaneous incision. **(D)**

Alcohol chlorhexidine solution reduces the presence of coagulase-negative staphylococci at the surgical site, and is better than iodopovidone (topical PVP-I). **(A)**

There is no evidence to support routine oral antimicrobial therapy postoperatively, especially in the absence of catheter placement and/or patient risk factors. **(D)**

Trauma caused by catheterization or endoscopic manipulation in patients with an activated or malfunctioning device are considered as potential causes of urethral lesions. **(C)**

In situations where catheterization is absolutely necessary, it is important to place a catheter of the appropriate caliber for as short a time as possible. **(C)**

Intermittent urinary catheterization is not a contraindication in the presence of an artificial urinary sphincter, provided that the cuff remains deflated during the procedure.[66] **(D)**

The first postoperative clinical visit takes place within 1-2 weeks. The device should remain disabled for six weeks after surgery. **(D)**

In order to identify early complications requiring revision in the first few months of use, 3- and 6-month visits are the most critical, with subsequent frequency adjusted based on individual clinical circumstances. **(D)**

Standard follow-ups should be performed annually. **(C)**

6. Evaluation and conduction of therapeutic failure after AUS implantation

The objective of this evaluation is to assess the best conduct in the management of therapeutic failure (early or

late onset urinary incontinence) after artificial urinary sphincter implantation, considering primary studies.

Clinical question

What conduct should be adopted for therapeutic failure of urinary incontinence after implantation of the artificial urinary sphincter? This question was answered in this evaluation using the PICO method, where the P stands for patients with moderate to severe urinary incontinence presenting therapeutic failure after implantation of the AUS model AMS800®, I to intervention with evaluation and conduct during failure and O to outcomes with resolution of persistent or relapsed incontinence. Based on the structured question, we identified the keywords used as the basis for searching for evidence in the databases and after the eligibility criteria (inclusion and exclusion), which were selected to answer the clinical query (Annex VI).

Results

In all, 1,764 studies were retrieved. Of these, 30 were selected by title and 26 by summary, with reading of the full text in the second case. After analysis of the full texts, 24 studies were included in this evaluation.[9,15,17,23,24,53,77-90] The main reason for exclusion was that they did not respond to the PICO.

A careful clinical history and a focused physical examination guide the subsequent investigations necessary to determine the cause of incontinence after implantation of the AUS.

Inadequate AUS operation is the most common cause of immediate UI post-activation. Patients should be taught to completely deflate the cuff and need to understand that emptying the bladder takes time, knowing that repeated recycling may be necessary.

The control pump, if poorly placed in the scrotum, may also be accidentally compressed and cause involuntary deflation of the cuff and UI. When this happens the patient will complain of incontinence in certain body positions. The sitting position, with support directly on the urethral cuff, can also trigger its opening (direct compression). This can be solved by avoiding hard or pointed seats.

Overactive bladder (OAB) symptoms occur in up to 25% of post-prostatectomy patients and may be associated with urinary tract infection. Symptoms of *de novo* OAB, such as urgency, frequency, nocturia and urgency incontinence may develop in up to 23% of patients who did not present these symptoms preoperatively. Those with preoperative OAB will have persistent symptoms in up to 71% of cases.[91] **(C)** A history of urgency urinary incontinence prior to AUS implantation may suggest the diagnosis of detrusor overactivity. Whenever the pathophysiology remains doubtful, urodynamic evaluation is recommended in order to guide treatment.[31] **(D)** Treatment should be similar to that of any overactive bladder.[31] **(D)**

If the patient does not present continence after AUS activation (4-6 weeks post-implantation) in the postoperative period, the most common problem is a very large cuff or a very small reservoir. If the urethral cuff is too large, the coaptation of the urethra becomes insufficient, resulting in persistent incontinence.[17] **(C)** The diagnosis of a cuff with a loose fit can be done by reviewing the surgical notes, urethral pressure profilometry (performed with the cuff in the inflated and deflated modes), urethroscopic evaluation and retrograde perfusion sphincterometry with flexible cystoscope.[77] **(C)** In some cases, the reservoir balloon may not offer sufficient pressure for adequate urethral coaptation, which can be viewed cystoscopically.

Loss of system fluids may present with persistent or recurrent incontinence. Fluid loss sites may include the urethral cuff, any area of the connecting tubing, tubing connections, the reservoir balloon, or rarely the control pump. Once the fluid has been lost from the system, the pumping characteristics will change until the pump is empty. Simple abdominal radiography may exclude fluid loss from the reservoir if the contrast solution is used as the filling medium.[78] **(C)** If isotonic sodium chloride solution is used as a fluid medium, the radiographic evaluation does not help, because the silicone components are not radiopaque. X-rays with insufflation-deflation are necessary to assess the function of the sphincter. When the cuff is closed, a contrast ring should be visible at the cuff site. When the cuff is open, the pump and reservoir should contain some fluid, and the cuff should have minimal fluid. If radiographic contrast is absent, leakage has occurred.[79] **(C)** When an isotonic (sodium chloride) solution is used as the fluid medium, lower abdominal ultrasonography[80] **(C)** or non-contrasted computed tomography (CT) of the abdomen and pelvis can help to assess the volume in the balloon and diagnose fluid loss.[81] **(D)** However, the image will not help to determine the exact location of the leak. During the operative (revision) act, use of the electrical conductance test (ohmmeter) assists in identifying the defective component and the location of the leak.[81] **(D)** If an ohmmeter cannot be used to identify leakage location, the pressure in the reservoir can be measured by connecting the tubes to a pressure transducer or by aspirating and measuring the volume of the balloon.[82] **(C)** Surgical exploration is required when fluid loss occurs. The "AUS Consensus Group" (2015) recommends that the entire AUS device be removed if loss of fluid is evident.[31] **(D)** Nevertheless, studies have argued

that in specific cases when the leakage of a component can be identified intraoperatively and the AUS has been placed for a period of < 3 years, replacement of a single component can be considered.[83,84] **(C)**

Urethral sub-cuff atrophy is defined as a progressive loss of initial continence after AUS implantation in the absence of erosion, mechanical malfunction or leakage and/or bladder-related causes leading to worsening of urinary continence.[31] **(D)** Tissue atrophy results in a loss of urethral compression and occlusion of the lumen. The progression of incontinence increases slowly over months or years and there is often a change in the number (increase) of pump activations required to open the cuff.[15] **(D)** A simple pelvic X-ray will show more fluid in the cuff compared to an immediate postoperative radiograph (if contrast fluid is used). Urethroscopy discards erosion and confirms the diagnosis of atrophy when poor coaptation of the mucosa at the cuff level is observed with it fully inflated.[31] **(D)** Urethral withdrawal pressure profiling can be performed with the cuff in inflated and deflated modes, although it is currently a rarely used resource. A minimal pressure change between the two modes suggests sub-cuff atrophy or sphincter dysfunction.[15] **(D)** A more conservative initial therapeutic approach is preferred, such as reducing the cuff size or replacing the position so that it is more proximal, whenever possible.[17,85] **(C)** Other procedures such as double-cuff[86-88] **(C)**, transcorporal (TC) cuff placement[9,53,89] **(C)** or higher pressures in the reservoir may be considered. The literature is not clear as to the best method for cuff revision. A historical cohort study showed that the placement of a "double-cuff" was more effective than either a "smaller size" (in relation to mechanical failure; p=0.01) or compared to "replacement with a new location" (in relation to continence, p=0.02).[90] **(B)** Another historical cohort compared placement of a double-cuff versus a single-cuff in patients with post-prostatectomy urinary incontinence as initial therapy. In a long follow-up (74-58 months), the study did not show a difference in the continence rate between the groups (NNT = NS). However, the double-cuff group had a higher number of complications requiring additional surgery (ARI = −0.53 to 0.008; NNH = NS; without statistical significance).[88] **(B)**

Global evidence summary

Inadequate AUS operation is the most common cause of immediate UI post-activation. **(D)**

In patients with overactive bladder and persistent UI, when the pathophysiology remains doubtful, a urodynamic assessment is indicated in order to guide treatment, which should be similar to that of any patient with overactive bladder. **(D)**

If the patient does not show continence after AUS activation (4-6 weeks post-implantation) in the postoperative period, the most common problem is a very large cuff or a very small reservoir. **(C)**

The diagnosis of a cuff with a loose fit can be performed by reviewing the surgical notes, urodynamic study, urethroscopic evaluation and retrograde perfusion sphincterometry with a flexible cystoscope. **(C)**

Simple abdominal radiography may exclude fluid loss from the reservoir if the contrast solution is used as the filling medium. **(C)**

When an isotonic (sodium chloride) solution is used as the fluid medium, lower abdominal ultrasonography **(C)** or non-contrasted computed tomography of the abdomen and pelvis can help to assess the volume in the balloon and diagnose fluid loss. **(D)**

The "AUS Consensus Group" (2015) recommends that the entire AUS device be removed if a loss of fluid is evident. **(D)**

In specific cases, when the leakage of a component can be identified intraoperatively and the AUS has been placed for a period of < 3 years, replacement of a single component can be considered. **(C)**

Urethral sub-cuff atrophy is defined as a progressive loss of initial continence after AUS implantation in the absence of erosion, mechanical malfunction or leakage and/or bladder-related causes leading to worsening of urinary continence. **(D)**

A simple pelvic X-ray will show more fluid in the cuff compared to an immediate postoperative radiograph (if contrast fluid is used). Urethroscopy can rule out erosion and confirm the diagnosis of atrophy when poor coaptation of the mucosa at the cuff level is observed with the cuff fully inflated. **(D)**

In atrophy, a more conservative initial therapeutic approach is preferred, such as reducing the cuff size or replacing the position to make it more proximal, whenever possible. **(C)** Other procedures such as a double-cuff **(C)**, transcorporal placement of the cuff **(C)** or higher pressures in the reservoir may be considered.

7. Complications

The objective of our review is to evaluate the best strategy against suspected erosion or extrusion, infection and urethral atrophy.

Clinical question

What is the best strategy against suspected erosion or extrusion and infection? This question was answered in this evaluation using the PICO method, where the P stands

for the patient with urinary incontinence due to sphincter deficiency; I for intervention with an artificial urinary sphincter; and O for urethral erosion and infection. Based on the structured question, we identified the keywords used as the basis for searching for evidence in the databases and after the eligibility criteria (inclusion and exclusion), which were selected to answer the clinical question (Annex VII).

Results

The usual procedure in the treatment of urethral erosion consists of the surgical removal of the cuff, plus passage of a Foley catheter or suprapubic cystostomy.[19,92] **(B)** However, removal of the remaining components is not mandatory, as long as they are not infected. Although the risks and benefits of complete removal have been debated for a long time, acceptance of the maintenance of certain components has been growing.[93] **(C)** A retrospective observational study that analyzed outcomes related to individuals submitted to the installation of urological prostheses in five-year period (penile prostheses installed in 300 individuals and artificial urethral sphincter in 251) verified that among the 120 individuals who required surgical re-attachment due to persistent urinary incontinence, erosion, urethral atrophy, malfunctioning of the prosthesis and pain, 45% of cases (n = 55) did not require complete removal of all components.[94] **(C)** The regulatory balloon, normally placed in the suprapubic region, can be abandoned, provided there is no infection. The pump, however, is commonly removed together with the cuff and connecting tubes between them. Another retrospective study that analyzed 10 years of experience with artificial sphincter implantation found that 31.6% of patients (n = 25) required at least one additional procedure because of urethral atrophy (22.8%) or erosion or infection (8.9%).[95] **(C)** In this analysis, two individuals submitted to the artificial sphincter implant were monitored clinically for several years even after identification of the erosion of the cuff. In this case, both refused surgical treatment and remained continent and uninfected despite chronic erosion for more than five years (15 and 5 years, respectively).[95] **(C)** The maintenance of the cuff is an exception and is not supported in the literature. The usual treatment is removal of the eroded urethral cuff. Urethral erosion may result in stenosis at the affected site and require additional procedures to correct it. Authors have reported that more than 80% of the patients presenting erosion followed by removal of the cuff developed stenosis of the urethra.[96] **(C)** Other authors have described urethroplasty at the same time as removal of the device to prevent subsequent stenosis.[97] **(C)**

With regard to infection, this may occur in the perioperative period or even years after implantation of the device.[37] **(B)** Infection rates in contemporary series have been reported between 1 and 8%, which may be less than 2% in series involving a large number of patients.[17,31,59,63,98] **(C)** [37] **(B)** Gram-positive microorganisms such as *Staphylococcus aureus* and *Staphylococcus epidermidis* are most commonly associated with infection, and Gram-negative bacteria may be identified, such as *Pseudomonas aeruginosa* and *Escherichia coli*.[67] **(C)** In the presence of superficial infection, oral or intravenous antibiotic treatment may be the approach of choice. However, if there is any doubt about the device's impairment, it should be removed, given the possibility of biofilm formation on the prosthesis.[67] **(D)**

Global evidence summary

The recommended conduct for urethral erosion is removal of the cuff and preferably of the other components. In selected cases, parts of the device may be retained. Do not remove the eroded cuff is an exception. In the presence of superficial infection, clinical treatment may initially be attempted. However, the recommended treatment in most cases is removal of the device, providing coverage for Gram-positive and Gram-negative bacteria.

Annex I

AMS 800 Model

Clinical question

What conduct should be adopted in the choice and preparation of the components of the artificial urinary sphincter model AMS 800?

Structured question (PICO)

- **P**atient – Patients with urinary incontinence due to sphincter deficiency.
- **I**ntervention – Implantation of the AUS model AMS 800.
- **C**omparison – Different components and preparation of such (cuff and balloon).
- **O**utcome – Control of incontinence and complications.

Data extraction

The results obtained from the studies included were related to the number of patients who obtained benefit or harm with different components (e.g. better cuff size) or preparation (better balloon pressure and filling liquid of the system).

Data analysis and expression

The results are expressed as absolute risk reduction or increase with their respective 95% confidence intervals. The number needed to treat (NNT) or number needed to harm (NNH) will be calculated.

Description of evidence

The available evidence will follow some principles to be displayed:

- It will be shown based on benefit or harm outcomes.
- It will be presented according to study design (randomized controlled trial, clinical trial, before-and-after trial).
- It will include the following components: number of patients, type of comparison, magnitude (NNT), and precision (95CI).

Annex II

Preoperative period

Clinical question

How should the preoperative evaluation be performed in patients who will undergo artificial urinary sphincter implantation?

Structured question (PICO)

- **P**atient – Patients with moderate to severe urinary incontinence.
- **I**ntervention – Artificial urinary sphincter.
- **C**omparison – Taking or not taking certain preoperative conducts.
- **O**utcome – Benefit or harm in the postoperative period.

Data extraction

The results obtained from the studies included were related to the preoperative evaluation used and the number of patients who obtained benefits or harm from this measure.

Data analysis and expression

Preoperative care most frequently used in the included studies as well as possible benefits or harm related to this conduct were discussed.

Description of evidence

The available evidence will follow some principles to be displayed:

- It will be shown based on benefit or harm outcomes.
- It will be presented according to study design (randomized controlled trial, clinical trial, before-and-after trial).

Annex III

Perineal versus scrotal approach

Clinical question

What should be the surgical approach to artificial urinary sphincter implantation?

Structured question (PICO)

- Patient – Patients with urinary incontinence due to sphincter deficiency.
- Intervention – Implantation of artificial urinary sphincter via the scrotal approach.
- Comparison – Perineal implantation approach.
- Outcome – Control of incontinence and complications.

Data extraction

The results obtained from the included studies referred to the number of patients who obtained benefits or harm from one of the two approaches.

Data analysis and expression

The results are expressed as absolute risk reduction or increase with their respective 95% confidence intervals. The number needed to treat (NNT) or number needed to harm (NNH) will be calculated.

Description of evidence

The available evidence will follow some principles to be displayed:

- It will be shown based on benefit or harm outcomes.
- It will be presented according to study design (randomized controlled trial, clinical trial, before-and-after trial).
- It will include the following components: number of patients, type of comparison, magnitude (NNT), and precision (95CI).

Annex IV

Transcorporal approach

Clinical question

What is the best approach for cuff placement in artificial urinary sphincter implant surgery?

Structured question (PICO)

- **P**atient – Patients with moderate to severe urinary incontinence.
- **I**ntervention – Cuff implantation using a transcorporal approach.

- **C**omparison – "Standard" cuff implantation.
- **O**utcome – Control of incontinence and complications.

Data extraction

The results obtained from the included studies referred to the number of patients who obtained benefits or harm from one of the two approaches.

Data analysis and expression

The results are expressed as absolute risk reduction or increase with their respective 95% confidence intervals. The number needed to treat (NNT) or the number needed to harm (NNH) will be calculated.

Description of evidence

The available evidence will follow some principles to be displayed:

- It will be shown based on benefit or harm outcomes.
- It will be presented according to study design (randomized controlled trial, clinical trial, before-and-after trial).
- It will include the following components: number of patients, type of comparison, magnitude (NNT), and precision (95CI).

Annex V

Perioperative and postoperative care

Clinical question

What is the best approach for cuff placement in artificial urinary sphincter implant surgery?

Structured question (PICO)

- **P**atient – Patients with moderate to severe urinary incontinence.
- **I**ntervention – Implantation of the AUS model AMS800.
- **C**omparison –
- **O**utcome – Perioperative and postoperative conduct that can reduce risks of implantation.

Data extraction

The results obtained from the studies included were related to the number of patients who obtained benefit or harm with different procedures in the perioperative and postoperative period.

Data analysis and expression

Whenever possible, the results will be expressed as the reduction or increase of the absolute risk with their respective 95% confidence intervals and number needed to treat (NNT) or number needed to harm (NNH) calculated.

Description of evidence

The available evidence will follow some principles to be displayed:

- It will be shown based on benefit or harm outcomes.
- It will be presented according to study design (randomized controlled trial, clinical trial, before-and-after trial).
- It will include the following components: number of patients, type of comparison, magnitude (NNT), and precision (95CI).

Annex VI

Evaluation and conduction of therapeutic failure after AUS implantation

Clinical question

What conduct should be adopted for therapeutic failure of urinary incontinence after implantation of the artificial urinary sphincter?

Structured question (PICO)

- **P**atient – Patients with moderate to severe urinary incontinence presenting therapeutic failure after implantation of the AUS model AMS800®.
- **I**ntervention – Assessment and conduct during failure.
- **C**omparison –
- **O**utcome – Resolution of persistent or recurrent incontinence.

Data extraction

The results obtained from the included studies were related to the number of patients who obtained benefits or damages with different procedures in the evaluation and conduction of the therapeutic failure after implantation of the AUS.

Data analysis and expression

Whenever possible, the results will be expressed as the reduction or increase of the absolute risk with their respective 95% confidence intervals and number needed to treat (NNT) or number needed to harm (NNH) calculated.

Description of evidence

The available evidence will follow some principles to be displayed:

- It will be shown based on benefit or harm outcomes.

- It will be presented according to study design (randomized controlled trial, clinical trial, before-and-after trial).
- It will include the following components: number of patients, type of comparison, magnitude (NNT), and precision (95CI).

Annex VII

Complications

Clinical question

What is the best strategy against suspected erosion or extrusion, infection and urethral atrophy?

Structured question (PICO)

- **P**atient – Patient with urinary incontinence due to sphincter deficiency.
- **I**ntervention – Artificial urinary sphincter.
- **C**omparison – None.
- **O**utcome – Urethral erosion and infection.

Data extraction

The results obtained from the included studies referred to the number of patients who obtained benefits or harm from one of the two approaches.

Data analysis and expression

The results are expressed as absolute risk reduction or increase with their respective 95% confidence intervals. The number needed to treat (NNT) or number needed to harm (NNH) will be calculated.

Description of evidence

The available evidence will follow some principles to be displayed:

- It will be shown based on benefit or harm outcomes.
- It will be presented according to study design (randomized controlled trial, clinical trial, before-and-after trial).
- It will include the following components: number of patients, type of comparison, magnitude (NNT), and precision (95CI).

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