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Platinum Priority – Review – Incontinence

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The Artificial Urinary Sphincter After a Quarter of a Century: A Critical Systematic Review of Its Use in Male Non-neurogenic Incontinence

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Abstract

Context: The artificial urinary sphincter (AUS) has historically been considered the gold standard for the surgical management of non-neurogenic stress urinary incontinence (SUI) in men. As new surgical alternatives attempt to offer alternatives to treat male SUI, a contemporary assessment of the evidence supporting the use of AUS appears mandatory for clinical decision making.
Objective: To conduct a critical systematic review of long-term outcomes after AUS implantation in male patients with non-neurogenic SUI.
Evidence acquisition: A literature search was conducted in PubMed/Medline and Embase databases using the keywords *urinary incontinence* and *urinary sphincter, artificial* and *male*, restricted to articles published in Dutch, English, French, and German between 1989 and 2011. Studies were included if they reported outcomes after AUS implantation in patients with non-neurogenic SUI with a minimum follow-up of 2 yr. Studies with heterogeneous populations were included if information about non-neurogenic patients was displayed separately.
Evidence synthesis: Twelve reports were identified, gathering data about 623 patients. Only three studies were prospective. Continence, evaluated only by patient-reported pad use and various questionnaires, was achieved in 61–100% of cases (no pad or one pad per day). Dry rates (no pad) were only available in seven studies and varied from 4% to 86%. A pooled analysis showed that infection or erosion occurred in 8.5% of cases (3.3–27.8%), mechanical failure in 6.2% of cases (2.0–13.8%), and urethral atrophy in 7.9% (1.9–28.6%). Reoperation rate was 26.0% (14.8–44.8%). Patient satisfaction was evaluated in four studies with four different tools and seems to improve after AUS implantation.
Conclusions: Quality of evidence supporting the use of AUS in non-neurogenic male patients with SUI is low, based on heterogeneous data, low-quality studies, and mostly out-of-date efficacy outcome criteria. AUS outcomes need to be revisited to be compared with new surgical alternatives, all of which should be prospectively evaluated according to current evidence-based medicine standards.

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1. Introduction

The artificial urinary sphincter (AUS) has been used since 1972 for the treatment of severe urinary incontinence [1]. After several technical evolutions that led to significant improvement of surgical and functional results, the device reached maturity in 1987 with the release of the narrow-back cuff (NBC) AMS800 device (AMS, Minnetonka, MN, USA) [2]. The device is largely unchanged in current practice apart from small changes (eg, antibiotic coating). Some innovative devices such as FlowSecure and Zephyr ZSI 375 have been presented as potential alternatives, but only a few preliminary results are available [3,4]. It is currently estimated that >150 000 patients worldwide have been implanted with an AUS, the vast majority with AMS800 [5]. This large number of cases, potentially with extremely long follow-up, is barely reflected in the literature, and most data on AUS outcomes come from older retrospective cohort studies. Randomized controlled trials (RCTs) were not performed due to the lack of a comparator [5]. Nonetheless, AUS implantation has been the standard of care for refractory male stress urinary incontinence (SUI) for a considerable time.

In recent years, new surgical alternatives claim to be safe and effective [6,7]. Among these new devices, male slings are increasingly used and have been given the same level of recommendation (grade B) as AUS, according to the 2012 European Association of Urology guidelines [5]. However, given the respective histories of the two techniques and the differing profiles of the most suitable patients, the equivalent grading of their recommendation obscures an uncertain picture.

To clarify this situation and pave the way for a reliable comparison between AUS and other options, our objective was to conduct a systematic review of AUS efficacy and safety outcomes in the context of non-neurogenic male SUI management after a minimum follow-up of 2 yr. Concurrently, we compared the evidence available with the currently active recommendations about clinical research in the field of SUI, to elaborate the apparent strengths and weaknesses of AUS in the contemporary era.

2. Evidence acquisition

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis statement [8].

A literature search was conducted in PubMed/Medline and Embase databases in October 2011, using the association of keywords *urinary incontinence* (Medical Subject Headings [MeSH] AND *urinary sphincter, artificial* [MeSH] AND *male* [MeSH]). Our literature search was restricted to articles published between 1989 and 2011 in English, French, Dutch, or German. Conference abstracts were considered. The reference list of articles was screened for additional relevant articles. When more than one paper reported results about the same series, the most recent paper was included. For pragmatic reasons, we included studies if they had a mean follow-up of at least 2 yr after AMS800 (NBC device; ie, after 1987) using the bulbar implantation via perineal approach with a 61- to 70-cm water pressure–regulating balloon in men with non-neurogenic SUI. We believe these practices are the most widespread used, making the conclusions generally relevant. If a study involved heterogeneous cases (women, both neurogenic and non-neurogenic SUI cases, various surgical approaches, various device types or balloons of differing pressure), the study was included if specific data satisfying the selection criteria could be extracted from the published data set. Otherwise the study was excluded. Studies reporting a combined procedure with AUS implantation were excluded.

Articles were first screened and selected based on their abstract, and then studied in detail. Two independent researchers evaluated the articles and afterward discussed eligibility, with one researcher making the final decision. Every paper selected was evaluated on the following aspects: study design, baseline patient evaluation, reports of perioperative data (such as balloon pressure, cuff positioning, double- or single-cuff placement, scrotal or perineal incision, antibiotic prophylaxis regimen), study outcome criteria for safety and efficacy, follow-up, dropout rate (if applicable), ethics, and results. All articles were graded according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system [9]. Efficacy and safety results were reported for each paper, and a pooled analysis was conducted on the following end points: infection/erosion rate, mechanical failure, urethral atrophy, reintervention rate, *social continence* rate (defined as the proportion of patients wearing no pad or one pad per 24 h), and *dry* rate (defined as the proportion of patients wearing no pads), and quality of life. For pooled analysis, only patients with non-neurogenic SUI receiving primary bulbar implantation of a single cuff and a 61- to 70-cm water pressure–regulating balloon AMS800 device by a surgical approach combining perineal and abdominal incisions were included.

Results of the systematic review were analyzed regarding study methods, ethics, and outcome assessments in the context of the currently active clinical research recommendations provided by the 4th International Consultation on Incontinence [7].

3. Evidence synthesis

3.1. Literature search results

The flow diagram is presented in Figure 1. After excluding duplicates, a total of 313 articles were screened, and 38 articles reporting a series of AUS implants were identified. Many studies included patients with various etiologies of SUI (neurologic, trauma, after prostatic surgery, or other) without proper stratification. Most of the studies published before 2000 included patients implanted before and after 1987 (without and with an NBC, respectively) without distinction. These heterogeneous studies providing potentially confounding results were excluded from our

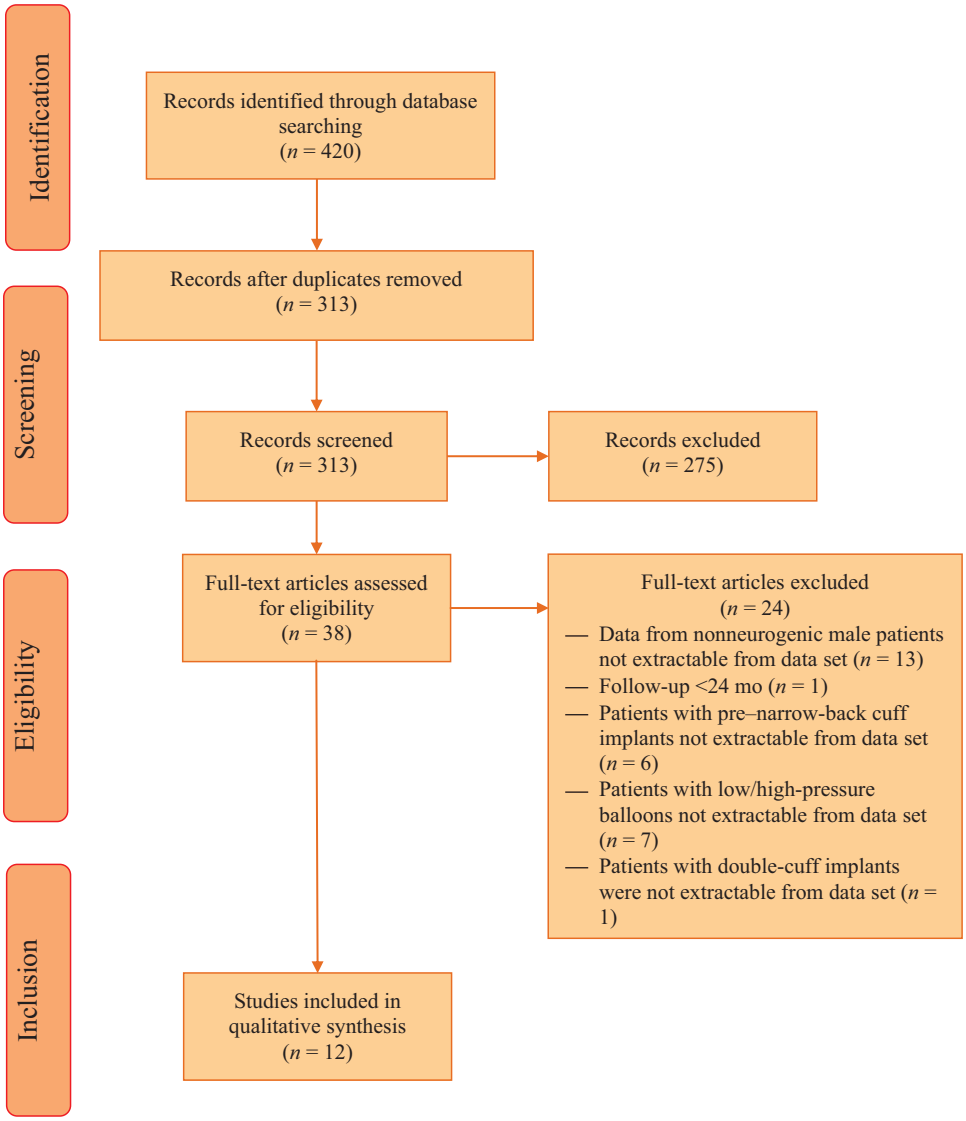

Fig. 1 – PRISMA flow diagram.

analysis. Supplementary Table 1 shows the detailed reasons for exclusion of particular studies.

3.2. *General description of included studies*

Twelve articles included specific data about 623 male patients with non-neurogenic SUI who had been implanted with a bulbar single-cuff 61- to 70-cm water pressure balloon AMS800 with combined perineal and abdominal approach [10–20].

3.2.1. *Study design*

Most of the studies were designed as single-center retrospective chart reviews (Table 1) and were hence subject to the specific biases of this methodological approach. In particular, loss of follow-up for database reviews and the response rate for surveys was unclear and poorly reported (Table 1). Among the three prospective studies, one was a multicenter survey providing few details on methods and patient characteristics. Cases were not consecutive and follow-up data was not displayed [21]. The second prospective study was approved by an ethical review board, and it provided an adequate description of preoperative work-up, methods, and results. The cohort was homogeneous, uniquely made of consecutive post–radical prostatectomy SUI cases, but it reported outcomes for only 40 patients [15]. The last prospective study was an RCT between AUS and Macroplastique injections, with clear inclusion criteria, adequate preoperative evaluation, and a well-standardized report. This study lacked a clear hypothesis, however, and it did not contain information about randomization, power calculation, or flowchart. The number of patients included was low, and follow-up differed between the treatment arms [18]. No study satisfied the International Consultation on Incontinence recommendation for the design of clinical research concerning implantable surgical devices (ie, independent large-scale prospective multicenter case series when RCTs are not feasible [7]).

Table 1 – Main characteristics of included studies

Study	Level of evidence per GRADE system	Study design	Subjective outcome/quality of life			Objective outcome*		
			Evaluation tools	QoL preimplant	QoL postimplant	Outcome definition based on patient-reported pad use at last follow-up	Dry	Dry and improved
Gomes et al. [10]	Low quality	Retrospective single center	AUA QoL I	Median: 5 (3–6)	Median: 1 (0–6)	Quantitative comparison vs baseline	N/R	N/R
Lai et al. [11]	Low quality	Retrospective single center	Not performed	N/R	N/R	Success = ≤1 pad	N/R	N/R¥
Mottet et al. [21]	Low quality	Prospective multicenter survey	Not performed	N/R	N/R	Dry = no pads and no leakage reported Social continence = no pad but leakage Minimal leakage = 1 pad/d Significant leakage = 2 pads/d Failure = >2 pads/d	59/103	74/103
Ramsay et al. [12]	Low quality	Retrospective single center	Not performed	N/R	N/R	Social continence = ≤1 pad	N/R	27/27
Singh and Thomas [14]	Low quality	Retrospective single center	Not performed	N/R	N/R	Continent = no pads Occasional incontinence = 1 or 2 pads	18/21	20/21
Trigo Rocha et al. [15]	Low quality	Retrospective single center	Visual analog scale	5.0	0.7	Dry = no pad Improved = 1 pad	20/40	36/40
Walsh et al. [16]	Low quality	Retrospective single center	Q1: "Very or somewhat satisfied?" Q2: "Would you undergo the same surgery again?" Q3: "Would you recommend AUS to a friend?"	N/R	Q1: 91% "yes" Q2: 89% "yes" Q3: 87% "yes"	Cure = no pads Improved = pad use reduced >50%	17/91	81/91
O'Connor et al. [40]	Low quality	Retrospective single center	Not performed	N/R	N/R	Cured = no pad Improved = ≤1 pad	7/29	24/29
O'Connor et al. [17]	Low quality	Retrospective single center	International Incontinence Questionnaire-7	Mean: 14.8	Mean: 4.1	Dry = no pad Improved = 0–1 pad Failed = >1 pad	1/23	14/23
Imamoglu et al. [18]	Low quality	Randomized controlled trial	QoL scale	Mean: 26.75	Mean: 6.81	Dry = 0 pads Socially continent = <1 pad	18/22	21/22
Aaronson et al. [19]	Low quality	Retrospective single center	Not performed	N/R	N/R	"Social continence" without definition	N/R	11/18
Gousse et al. [20] †	Low quality	Retrospective single center	Telephone survey/ nonvalidated questionnaire	N/R	N/R	No incontinence = no pad Mild incontinence = 1 pad Moderate incontinence = 2–3 pads Severe incontinence = >3 pads	N/R	N/R

AUA = American Urological Association; GRADE = Grading of Recommendations, Assessment, Development, and Evaluation; N/R = not reported; QoL = quality of life.

* Based on secondary category of success.

¥ Success rate only available in the whole series, not separately for patients after nonneurogenic stress urinary incontinence.

† This study was included because complications could be assessed. However, data from narrow-back cuff cases were not extractable to assess efficacy.

3.2.2. Patient characteristics and inclusion criteria

Most studies included patients with various medical histories, with prostatic surgery the most frequent non-neurogenic etiology (Table 1). Except in two prospective studies [15,18], no clear inclusion criteria were applied to select the study populations. Preoperative work-up did not include bladder diary, pad tests, or validated gender-specific instruments for the evaluation of symptoms and bother, as recommended [7]. In particular, the severity of incontinence was not adequately assessed in most of the studies.

3.2.3. Data collection, end points, and efficacy outcome criteria

Outcome criteria differed for most of the studies. Most studies did not use standardized definitions for the key measures; nor did they state explicitly definitions of terms as applied in the study. Thus direct comparison of rates of key outcomes between studies is not possible because they may have used differing outcomes. Accordingly, several caveats were identified in the current literature (Table 1). A comprehensive evaluation of both subjective and objective outcomes, combined with assessment of bother/quality of life and satisfaction, has not been conducted systematically. Patient-reported pad use (often by telephone interview) was the most frequently studied efficacy end point, but almost every paper used a different definition of success. To compare objective end points, dry rate (zero pads) should always be reported alongside improvement rate, with a clear definition given for improvement rate. In the four studies evaluating quality of life, four different tools were used. The lack of preplanned objectives in these descriptive studies led to a bulky presentation of results, always including redo cases in the final evaluation, so that the outcomes of primary AUS implantation are difficult to establish. Available studies were not reported using an intent-to-treat analysis, and the statistical handling of dropout cases was unclear.

3.2.4. Follow-up

Although it is now widely recognized that a minimum follow-up of at least 1 yr (for all patients) is mandatory for the evaluation of efficacy in the field of urinary incontinence [7], this protocol has not been always respected (Table 1). Many studies displayed mean values for follow-up associated with wide ranges due to outliers or incomplete data. These results should be put in perspective with the new concept of long-term follow-up in pelvic floor disorders. *Long term* was defined as 12-mo follow-up in 1999 [22], and contemporary reports state that 5 yr of follow-up would be more informative [23].

As a whole, the level of evidence supporting the use of AUS for non-neurogenic SUI was low. Most of the reports were subject to methodological bias and failed to report the results accurately. These observations highlight the wide gap existing between published studies and current standards for clinical research [7], and they must be kept in mind for the interpretation of the available literature, especially versus contemporary reports.

3.3. Efficacy data

3.3.1. Continence

Continence rates at last follow-up, when displayed, were gauged by patient-reported pad use in all cases. Definitions of continence based on pad use were heterogeneous (Table 2). For practical reasons, we assessed the dry rate (ie, no pad) when available and the "dry or improved rate," gathering all

Table 2 – Description of cohorts of patients included in the current evaluation

Study	Etiology of stress urinary incontinence							Patients, no.	Included patients*	Follow-up, mo†	Dropouts *n*/total (%)
	PPI	BPH surgery	Trauma	Other	Neurogenic	Cystectomy	RT				
Gomes et al. [10]	24	6	0	0	0	0	0	30	30	26 ± 12 [12–56]	3/33 (9.1)
Lai et al. [11]	176	0	0	31	11	0	0	218	176	39 (SD and range unknown)	52/270 (19.3)
Mottet et al. [21]	103	0	0	0	0	0	0	103	103	Not specified: between 12 and 36 mo	N/R
Ramsay et al. [11]	15	9	2	0	11	0	1	38	23	Not specified: probably around 4 yr	N/R
Singh and Thomas [14]	2	26	0	0	0	0	0	28	21	41 [6–79]	N/R
Trigo-Rocha et al. [15]	40	0	0	0	0	0	0	40	40	53 ± 21 [27–132]	0/40 (0)
Walsh et al. [16]	85	13	0	0	0	0	0	98	98	46 [5–118]	N/R
O'Connor et al. [40]	29	0	0	0	0	0	0	29	29	60 [12–132]	4/33 (12.1)
O'Connor et al. [17]	25	0	0	0	0	0	0	25	25	74 (SD and range unknown)	3/28 (10.7)
Imamoglu et al. [18]	12	33	0	0	0	0	0	45	22	60 [8–120]	0
Aaronson et al. [19]	14	0	0	0	0	0	4	18	14	31 (SD and range unknown)	N/R
Gousse et al. [20]	71	0	0	0	0	0	0	71	42	92 [6–192]	N/R
Total	596	87	2	31	22	0	5	743	623	N/R	N/R

BPH = benign prostatic hyperplasia; N/R = not reported; PPI = postprostatectomy incontinence; RP = radical prostatectomy; RT = radiotherapy alone; SD = standard deviation.

* Included patients for pooled analysis were those with non-neurogenic stress urinary incontinence treated by artificial urinary sphincter without an associated procedure via perineal approach and bulbar position that were extracted from the total number of patients.

† Mean ± SD [range] or median [range].

Table 3 – Dry rates in selected series

Study	No. of patients dry	Total no. of patients	Percentage of patients dry, %
Singh and Thomas [14]	18	21	85.7
O'Connor et al. [17]	7	29	24.1
O'Connor et al. [40]	1	23	4.3
Imamoglu et al. [18]	18	22	81.8
Walsh et al. [16]	17	91	18.7
Mottet et al. [21]	59	103	57.3
Trigo Rocha et al. [15]	20	40	50.0
Total	140	329	42.5

patients with one pad or less because this definition was a common denominator for most of the studies. When the term *social continence* was used in the report without an accurate definition, these cases were considered to fall in the *dry or improved* category.

Dry or improved rates were computed as 79%, ranging from 61% to 100% in the literature, based on data from seven studies including 262 patients (Table 4). Dry rates were also reported in only seven studies, including 329 patients (Table 3), and varied from 4.3% to 85.7%. The considerable range highlights the need for stringent application of standardized definitions to enable comparisons. The lack of a uniform definition of cure and the reliable use of more objective tools (eg, standardized pad testing) prevent the estimation of cure rate after AUS implantation from the current literature. Results of the prospective studies suggest a dry rate" of about 50% after midterm follow-up, but a cautious approach to this value is needed due to the same limitations regarding the lack of standardized definitions.

A more systematic and up-to-date approach thus appears necessary to improve knowledge about AUS efficacy outcome. An accurate definition of cure is mandatory if pad use is considered the primary end point. Recent reports have shown an impact on quality of life even by the use of one pad [24]. Results should therefore reveal the number of patients with no pad use, occasional pad use (including security pads), or regular pad use (assessing number of pads per day). The use of terms like *social continence* and *improved rates* should be avoided or clearly defined. Beyond pad use assessment, the use of objective measurements such as a bladder diary, pad tests (according to standard recommendations), and validated symptom questionnaires should be promoted.

3.3.2. *Quality of life and patient satisfaction*

Three studies meeting the selection criteria have published some preoperative and postoperative quality-of-life data [10,15,17]. Gomes et al. retrospectively analyzed the American Urology Association quality-of-life index in 30 patients. The median (range) index improved from 6 (3–6) preoperatively to 1 (0–6) ≥2 yr after AUS implantation [10]. Trigo Rocha et al. [15] prospectively measured the impact of incontinence on quality of life with a six-item Likert scale, showing a significant improvement after surgery (5.0 ± 0.7 preoperatively, 1.4 ± 0.9 postoperatively; $p < 0.001$). O'Connor et al. reported postoperative Incontinence Impact Questionnaire Short Form (IIQ-7) results in a retrospective study on 25 patients [17]. Mean score dropped from 14.8 to 4.1 after surgery ($p < 0.001$). In a study reported by Walsh et al., patient satisfaction was 91% after 4-yr follow-up [16].

High satisfaction rates were also described in studies with wider inclusion criteria (ie, not restricted to non-neurogenic SUI) [16,25–28]. Reinterventions do not seem to have had an important impact on final quality of life, as long as patients have a functional AUS after revisions [20,29]. These results overall support the idea that quality of life globally improves after AUS implantation in a cohort of patients, but the mean or median values have little relevance to the individual patient. Further research is needed using validated tools, notably to investigate the determinants of satisfaction and more deeply understand the patient's experience during follow-up, baseline characteristics, and the potential effects of complications. The patient's choices and expectations will probably change with the ongoing introduction of alternative surgical approaches [30].

3.4. *Safety outcomes and reinterventions*

3.4.1. *Infection and erosion*

Data about infection and erosion were available for 562 patients among the 12 articles selected in this review. In a pooled analysis, the mean rate of erosion and infection after AUS implant in male non-neurogenic patients was 8.5% (range: 3.3–27.8%) (Table 4). Some papers did not report erosion and infection separately. Infection and erosion generally occurs within the 2 yr after implant placement, although much later cases have been reported [31]. The time frame of complications was seldom reported

Table 4 – Pooled analyses of artificial urinary sphincter outcomes*

Outcomes	Results, % [range]	No. of included participants (no. of studies)	Study
Infection/erosion	8.5 [3.3–27.8]	562 (10)	[10,11,14–19,21,40]
Mechanical failure	6.2 [2.0–13.8]	562 (10)	[10,11,14–19,21,40]
Urethral atrophy	7.9 [1.9–28.6]	456 (6)	[11,14–16,19,21]
Reintervention (for any reason)	26.0 [14.8–44.8]	549 (10)	[10–12,14,16–19,21,40]
No. of patients social continent (≤1 pad/24 h)	79.0 [60.9–100]	262 (7)	[12,15,17–19,21,40]
No. of patients completely dry (0 pads/24 h)	43.5 [4.3–85.7]	336 (7)	[14–18,21,40]

* The population considered for the analysis was men with nonneurogenic stress urinary incontinence primary implanted with a single-cuff 61- to 70-cm water pressure balloon AMS800 device via perineal approach. Mean follow-up was not extractable from the different subgroup data sets, but all included studies have a mean follow-up >24 mo.

clearly. Trigo Rocha et al. reported one immediate infection and two late infections after 12 and 23 mo, respectively [15].

Antibiotic prophylaxis during surgery and for 24 h after surgery significantly reduces infection rates in orthopedic surgery [32]. It is not proven that longer antibiotherapy further diminishes surgical implant infection rates [33]. In the analyzed literature, most reports did not mention anything on antibiotic prophylaxis for AUS placement, or they state only that antibiotic prophylaxis was administered without any specifics [14]. Whenever antibiotic prophylaxis was specified, preoperative intravenous administration with or without rinsing the operative field and AUS components with antibiotic solutions was followed by 1 wk or 2 wk of oral treatment [15,16]. These measures are based on expert opinion and institutional habits only.

It is not clear whether antibiotic coating diminishes erosion and infection rates. From penile implant surgery, we know that antibiotic coating reduces infection risk, especially in high-risk groups (eg, diabetic patients) and in salvage procedures [34,35]. The AMS800 device is on the market with a rifampicin and minocycline coating on the cuff and pump components, but not on the pressure-regulating balloon and its tubing. It is not clear whether a partially coated device is useful in preventing erosion/infection. A randomized trial to prove this concept would be most welcome, particularly because antibiotic coating increases the cost of the implant.

Surgeon experience probably is an important factor in preventing early infection and erosion. Sandhu et al. recently suggested that the learning curve for this kind of surgery does not reach a plateau, even after >200 surgeries [36]. The vast majority of implants are done by surgeons who never reach this number in their entire career [37,38].

Walsh et al. reported an increased risk of infection and erosion in irradiated patients. However, placement of a urethral catheter without due consideration of the AUS cuff may have accounted for three cases of late erosion [16]. The putative increased risk of erosion with prior or subsequent radiotherapy has never been proven in well-designed and powered cohort studies with homogeneous patient populations.

Due to the retrospective nature of almost all series, the surmised incidence of infection or erosion might be underestimated. Prospective data collection has to be performed to establish rates accurately and evaluate potential risk factors. Many surgeons perform a series of measures before, during, and after implant surgery to diminish infection rates. However, they are based on beliefs and assumptions, not on evidence. In the era of evidence-based medicine and expensive health care systems that require cost savings, this approach needs to be validated. The benefit of new adaptations has to be proven in prospective randomized trials of adequate power and at least a 2-yr follow-up before they are implemented in clinical settings.

3.4.2. Urethral atrophy

Urethral atrophy is a well-known late complication after AUS implantation, typically presumed when SUI recurrence occurs during follow-up with a functioning AUS [15]. Urethral tissue hypoxia is seen as the main pathophysiologic mechanism [39]. We could extract data on 456 non-neurogenic SUI cases, based on six articles where urethral atrophy was adequately reported. In this pooled analysis it occurred in 7.9% of cases (1.9–28.6%) [11,14–16,19,21]. Urethral atrophy was diagnosed after 3–23 mo of follow-up where stated, but most of the studies did not report timing of this complication. In 6 of the 12 selected studies, data on urethral atrophy were not extractable from the presented data set. Some studies do not mention any occurrence of urethral atrophy, raising the issue of the definition used and the possibility that such cases were included in the *mechanical failure* category.

Determining urethral atrophy rate is a complex issue because it is potentially influenced by follow-up duration, device pressure, implantation technique, and patient characteristics. In the only prospective study, reported by Trigo Rocha et al., two patients developed urethral atrophy after a mean of 29.4 mo [15]. A history of radiation therapy has been proposed as a risk factor for urethral atrophy. In our pooled analysis of the selected data, three studies, reporting on 303 patients, gave information on urethral atrophy and irradiation status. Urethral atrophy was observed in 7 of 93 of irradiated patients (7.5%) and in 20 of 210 nonirradiated patients (9.5%) [11,16,40].

Hence current knowledge about urethral atrophy in non-neurogenic patients remains limited, based on weak retrospective data. Further studies should be conducted to assess the rate of urethral atrophy using a standardized definition and a prospective design to minimize collection bias. Identifying risk factors, preventive, or curative measures for urethral atrophy would represent an even bigger endeavor, necessitating a huge caseload to adjust for the numerous potential confounding factors and a prospective design to assess causality.

3.4.3. Mechanical failure

Mechanical failure of an AUS can occur within one of the sphincter components, in the tubing, or in one of the connections. The present review included only series using the post-1987 AMS800 device. Mechanical failure rates were clearly reported in 10 studies including a total of 562 patients. Rates varied between 2.0% and 13.8% (Table 4), with failures reported from 11 mo to 68.1 mo postinsertion. Due to the retrospective nature of these studies, the mechanical failure rate might be underestimated. A prospective registry with predefined criteria of mechanical failure could overcome these uncertainties and provide data about actuarial survival without failure to estimate the life span of the device and deliver the best information possible to patients.

The number of mechanical failures has decreased substantially with advances in AUS design. Bosch et al. performed a Kaplan-Meier analysis for the 5-yr *primary adequate function* rates (defined as satisfactory continence in combination with an adequate function of the initially implanted AUS with no need for revision) in a heterogeneous patient group implanted with an AUS before and after the introduction of the NBC design, and they found a

significant difference in favor of the new design (33% vs 61%; log-rank test $p = 0.03$) [41].

3.4.4. Reinterventions

Global reintervention rate provides an overview of complications that occur following AUS implantation needing invasive treatment, and they should be regarded as an important end point for comparison with other surgical alternatives. In a pooled analysis of 549 patients (10 studies) with non-neurogenic SUI, the mean reintervention rate was computed as 26.0% (range: 14.8–44.8%) (Table 4). The timing of reinterventions was mainly influenced by the underlying cause. Whenever reinterventions were performed, patients needed a mean of 1.5 reinterventions. However, a major drawback of the existing literature is the inadequate reporting of both reintervention rate and number of reinterventions per patient.

Minimizing the number of reinterventions necessitates processes to minimize mechanical failure, erosion/infection, and urethral atrophy, or approaches to less invasive management of these problems. Prospective work is needed to estimate the actual rate and reasons for reintervention in contemporary series, but also to estimate the impact of reinterventions on patient satisfaction. Some previous work has shown that patient satisfaction is linked primarily to the presence of a functional AUS. A total of 84–98% of patients have a functional sphincter at >2 yr of follow-up, independent of the need for reintervention. The need for reintervention probably does not have an impact on final patient satisfaction [16,20,29]. Therefore, reintervention and complication rates should be regarded as essential secondary outcome criteria, but device function results remain the primary objective of future studies.

3.5. Paving the way for further clinical research in non-neurogenic male stress urinary incontinence

After 25 yr of widespread use, the modern version of the AMS800 AUS has de facto proven to be a reliable surgical option for the management of non-neurogenic SUI in men. However, the evolution of the therapeutic armamentarium and the current concepts in the field of incontinence management may lead to reconsideration of its gold standard status. The present review highlights the numerous caveats of the literature about AUS, highlighting a low level of scientific evidence that is apparent in a large proportion of surgical research. Emerging alternatives, namely, male slings, periurethral balloons, and stem cell injections, have generated an exponential number of recent publications. Frustratingly, the newer approaches likewise rely on a poor-quality evidence base. To face future challenges and facilitate comparisons for best surgical approaches, further research about AUS should be conducted according to the following requirements:

- Prospective studies are needed, although large caseload retrospective series could be useful as an intermediate step.
- Patient selection should be improved, stratifying SUI etiologies, SUI severity, and baseline symptoms by validated objective and subjective tools.
- Primary end points of future studies should be focused on continence, with an accurate preplanned contemporary definition of success and appropriate methodology for its measurement.
- Symptoms, subjective cure, satisfaction, and quality of life should be assessed by validated tools supported by professional consensus.
- Early and late complications should be identified using prespecified definitions, providing individual patient data and clear descriptive reporting of the timing.
- Follow-up should aim to exceed 1 yr for every patient, and long-term results beyond 5 yr of follow-up for every patient are highly desirable.
- Intent-to-treat principles should be used and handling of absent data due to dropout carefully addressed.

4. Conclusions

The AMS800 AUS has been the main comparator for the treatment of severe non-neurogenic male stress incontinence. Large amounts of data regarding efficiency, complications, and patient satisfaction have been published, but the quality of these reports does not meet current standards of evidence-based medicine. As research is being reported for new surgical alternatives and evidence supporting their use gets stronger, the evidence base for AUS likewise needs to be revisited using contemporaneous techniques to enable the profession to gauge the best use of surgical options for particular patient groups. Further research is warranted to improve the knowledge in the field, based on large, structured, and collaborative studies.

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Analysis and interpretation of data: Van der Aa, Cornu.
Drafting of the manuscript: Van der Aa, Cornu.
Critical revision of the manuscript for important intellectual content: Van der Aa, Drake, Kasyan, Petrolekas, Cornu.
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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.eururo.2012.11.034.

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