

A systematic review of the treatment for female stress urinary incontinence by ACT[®] balloon placement (Uromedica, Irvine, CA, USA)

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Received: 20 May 2013 / Accepted: 10 June 2013 / Published online: 20 June 2013
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Abstract

Purpose (1) To describe the minimally invasive adjustable continence therapy (ACT)[®] balloon placement surgical technique. (2) To analyse the results of ACT[®] balloon in the treatment for female stress urinary incontinence (SUI).

Method A review of the literature was performed by searching the PubMed database using the following search terms: ACT balloons, female urinary incontinence, and female continence.

Results Eight studies were published between 2007 and 2013. The mean follow-up of these studies was 1–6 years. The mean age of the patients ranged between 62 and 73 years; 40–100 % of patients had already been treated surgically for their SUI. A significant reduction in the number of pads used per day was observed after ACT[®] balloon placement, with improvement of short pad tests from 49.6 to 77.3 g preoperatively to 11.2–25.7 g after ACT[®] balloon placement. Fifteen to 44 % of patients considered that their SUI had been cured and 66–78.4 % were satisfied with the result. The explantation rate ranged between 18.7 and 30.8 %. Quality of life was significantly improved, and no major complication was reported.

Conclusion ACT[®] balloons constitute a reasonable, minimally invasive alternative for the treatment for female SUI due to intrinsic sphincter disorder, especially in patients who have already experienced failure of standard

surgical treatment and in clinical settings incompatible with invasive surgical placement of an artificial urinary sphincter (especially women over the age of 80 years). Long-term results are essential to evaluate the efficacy of this treatment.

Keywords Female urinary incontinence · Sphincter deficiency · ACT[®] balloons · Urinary prosthesis

Introduction

According to the International Continence Society (ICS), stress urinary incontinence (SUI) is defined as “the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing” [1].

Stress urinary incontinence is responsible for major disability in many women. The prevalence of SUI is difficult to estimate, but possibly as high as 50 % [2] depending on the definition of urinary incontinence (UI) adopted and/or the age-group studied. This prevalence is probably underestimated.

The anatomical mechanisms responsible for SUI are predominantly excessive mobility of the urethra and/or bladder neck, and intrinsic sphincter deficiency (ISD). ISD is generally due to muscle atrophy, oestrogen deficiency and/or pelvic, and perineal denervation. The main known general risk factors are age, pregnancy and childbirth, menopause, and radiotherapy [2]. ISD is assessed by a negative Marshall or submidurethral tape test and urodynamics. Concerning urodynamics, there is no current consensus on the exact urodynamic definition of ISD. In fact, the concept of ISD is a clinico-urodynamic concept [3].

Various options are currently available for the treatment for SUI, ranging from simple perineal retraining to artificial

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urinary sphincter (AUS), which is the last resort treatment for female SUI due to ISD after failure of several less invasive therapies [3, 4]. The surgical treatment most commonly used for urethral hypermobility is suburethral tape [TOT or tension-free vaginal tape (TVT)] [5]. Suburethral fascial slings have a real place in the treatment for SUI due to ISD [6], but may require subsequent voiding by self-catheterization.

Adjustable continence therapy (ACT)[®] balloons have recently extended the range of treatment options in men [7, 8] and in women [9–15]. They are indicated in women with stage III SUI (pure ISD), or stage II SUI when ISD is predominant after failure of well-conducted retraining, but the place of this modality has not been clearly defined in international guidelines [16]. The objective of this study was to describe the ACT[®] balloon placement surgical technique, analyse the results of ACT[®] balloon in the treatment for female SUI due to ISD, and therefore review the place of this option in the treatment algorithm.

Method

A review of the literature was performed by searching the PubMed database using the following search terms: ACT balloons, female urinary incontinence, and female continence. In view of the small number of published studies in peer-reviewed journals in English and French, all studies, regardless of their methodology, were included in this analysis. The main functional outcomes and complications were reported.

Description of the ACT[®] balloon [9, 17]

The ACT[®] balloon is an implantable medical device developed by Uromedica (Irvine, CA, USA), consisting of a silicone balloon connected to a conduit with a titanium port at its extremity. The conduit comprises two lumens, one containing a stylet to guide insertion of the conduit and the other allowing inflation of the balloon from the titanium port. The balloon has a volume of 8 ml. It is adjustable and can be inflated or deflated by simply inserting a needle into the titanium port, which is placed subcutaneously. The degree of balloon inflation is used to establish an equilibrium between continence and even dysuria, when the balloon is overinflated and persistent IU, when the balloon is underinflated.

Two conduit lengths are available, 7 and 9 cm, chosen according to the patient's morphology. Dedicated implant tools for balloon placement consist of a trocar, a sharp-tipped stylet, a blunt-tipped stylet, and a tissue expanding device (TED, forceps adapted to the trocar allowing

creation of a compartment). Each instrument can be resterilized.

Surgical technique [9–15]

The procedure is performed under general or local anaesthesia, after ensuring a negative urine culture and under prophylactic antibiotics administered at induction. The patient is installed in the gynaecological position with the thighs flexed onto the abdomen. The image intensifier is placed over the pelvis.

The bladder neck is identified by combined fluoroscopy and urethroscopy with the tip of the endoscope placed in the bladder neck. A 16 F Foley catheter is introduced, and the balloon is filled with aqueous radiopaque solution easily visible on fluoroscopy.

The incision is made in the convexity of labia majora, 2 cm anteriorly to the urethral meatus. The trocar is introduced prevaginally, laterally to the urethra, with a finger in the vagina to control progression of the trocar in order to position the trocar tip at the urethrovesical junction, over the bladder neck, ideally at 3 o'clock and 9 o'clock. Urethroscopy confirms correct positioning of the trocar and the absence of urethral or bladder perforation.

When the trocar is correctly positioned, the stylet is removed and the balloon is then lubricated and introduced into the sheath introducer. The balloon port is then pierced with a syringe containing aqueous radiopaque solution (isotonic mixture of 5.7 ml of Omnipaque 300 and 6 ml of pure water). In patients allergic to iodinated contrast agents, the balloon can be filled with normal saline. The tip of the balloon comprises a radiopaque marker allowing control of its position by fluoroscopy.

Once the balloon has been correctly positioned, the trocar is slightly withdrawn (about 2 cm) while maintaining the balloon in place. The balloon is then filled with 0.2 ml of radiopaque mixture (Fig. 1).

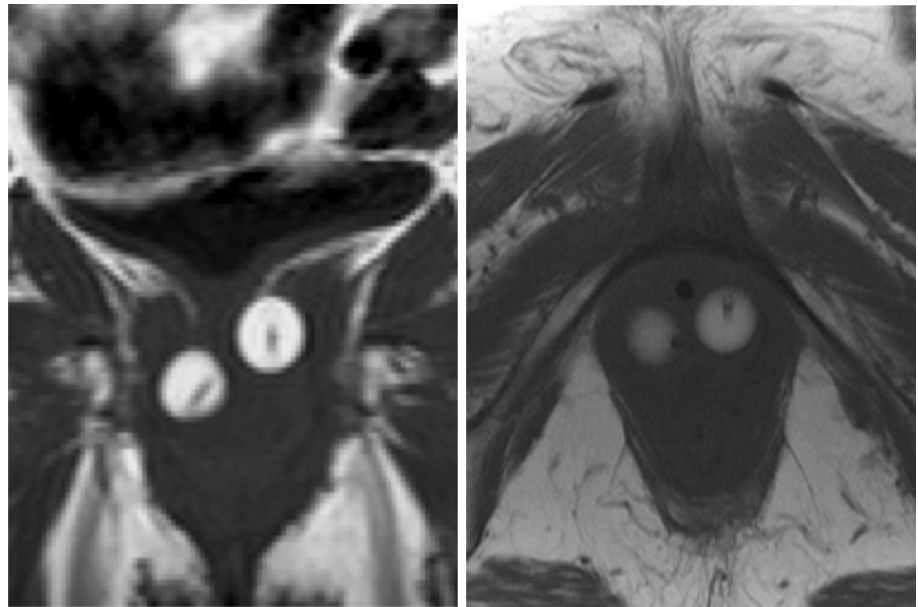
The balloon stylet is then removed, and a subcutaneous compartment is created in the anterior part of the labium majorum to allow placement of the balloon port as accessible as possible for future adjustments.

A 16 F Foley catheter is introduced and left in place for 2–24 h depending on the type of hospitalization.

Results

Only eight studies, published between 2007 and 2013, evaluating the efficacy and complications of treatment for female urinary incontinence by ACT[®] balloon placement were retrieved by our literature search [9–15, 18]. Tables 1, 2, and 3 summarize these studies. All studies were

Fig. 1 Position of ACT[®] balloons on MRI



prospective except for the study by Vayleux, which was retrospective [10]. All studies were open label with a 3 level of evidence, except the retrospective one which was level 4 [10]. The studies were based on comparison of endpoints before/after balloon placement. The mean follow-up ranged from 1 to 6 years. Patients included in these studies presented either isolated or mixed SUI. The mean age of these patients ranged between 62 and 73 years with a certain percentage of patients over the age of 80.

Thirty-eight to 100 % of the patients included in these studies had already undergone surgical treatment for SUI (suburethral sling, Burch colposuspension, AUS, etc.). Patients were evaluated by validated questionnaires (I-QOL, Urinary Symptom Profile[®], Urinary Distress Inventory), the number of pads used per day, a urinary incontinence test (short pad test), patient impression of improvement of incontinence at the end of follow-up (improved or not improved, dry or still bothered by leaks, etc.). The specific feature of this technique is that continence is only achieved after repeated outpatient inflation of the balloons according to the symptoms reported by the patient. The results should therefore be analysed at the end of this adjustment period, ideally after 3–6 months.

Functional results

Balloon efficacy endpoints were heterogeneous and differed from one study to another. The mean number of adjustments was 1–3.8. The mean final balloon volume was not always specified in studies, but ranged between 1.97 and 3.45 ml. Preoperatively, patients presented a mean I-QOL score ranging from 30 to 40. After balloon

placement, the mean I-QOL score was improved and ranged between 65.5 and 71 after 1 year, and 70.4 and 75 after 2 years of follow-up.

The number of pads used per day was significantly decreased from 4.1 to 5.4 preoperatively to 1.2–2.5 after 1 year and 1.1–1.2 after 2 years of follow-up.

The pad test was also improved from 49.6 to 77.3 g preoperatively to 11.2 to –25.7 g after ACT[®] balloon placement.

On intention-to-treat analysis at the end of follow-up, considering only those patients in whom the balloons were still in place at the end of follow-up, 15–44 % of patients considered that they were cured and 66–78.4 % of patients were satisfied with the result and felt improved.

Complications

No major complications were reported. Most intraoperative complications were urethral or bladder perforations, observed in 3–17 % of cases. Note that the 17 % perforation rate was reported in the study by Chartier-Kastler published in 2007 [9], which was the first multicentre, prospective, controlled study evaluating treatment for female SUI by ACT[®] balloon and therefore corresponded to the early experience with this type of management in France. The most recent studies have reported intraoperative perforation rates between 3.7 and 4.5 %.

Aboseif et al. in 2009 and 2011 [11, 12] reported procedure failure rates of 2.5 and 2.2 %, respectively, without specifying the reason for these failures.

Post-operative complications, during the first year, consisted of urethral erosion (2–15 %), cutaneous erosion

Table 1 Characteristics of the patients included in studies evaluating ACT[®] balloons in the treatment for SUI

Reference	Type of study	Level of evidence	N	Mean age (yr)	Type of urinary incontinence	MUCP (cmH2O)	Prior incontinence surgery	Follow-up (months)	Lost to follow
Chartier-Kastler et al. [9]	Prospective	3	68	68.4 (45–88)	SUI Type II + ISD: 34 % Type III: 66 % SUI Mild 31 % Moderate: 16 % Severe: 53 % SUI + ISD: 100 %	23 ± 11	88 %	24	9 at 3 months 15 at 6 months 11 at 1 year 13 at 2 years
Kocjancic et al. [13]	Prospective	3	49	NR	SUI + ISD: 100 %	NR	100 %	40.1 (6–71)	11 at 1 year 16 at 2 years 21 at 3 years 26 at 4 years
Wachter et al. [15]	Prospective	3	41	73 (42–93)	Pure SUI: 70 % Mixed UI: 30 %	NR	38 %	25 (5–60)	0
Aboseif et al. [11]	Prospective	3	162	67.4 (31–94)	SUI	NR	84 % ≥2 Interventions: 44 %	12	8 at 1 year
Kocjancic et al. [14]	Prospective	3	57	62.59 (18–86)	SUI with severe ISD	47.39 ± 24.35	100 %	72 (12–84)	NR
Vayleux et al. [10]	Retrospective	4	67	70.2 (41–90)	Pure SUI: 70 % Mixed UI: 30 % Hypo or bladder acontractility: 45 %	26.14 ± 11	60 %	24.8 (1–89)	6
Aboseif et al. [12]	Prospective	3	89	67.9 (49–86)	Detrusor overactivity: 13.5 % Neurogenic patients: 19.4 % Moderate to severe SUI	NR	100 % ≥2 Interventions: 47.2 %	12	5 at 1 year
Nacir et al. [18]	NR	NR	77	68 (34–87)	SUI: 32 % type I: 23 % type II: 52 % type III: 25 % Mixed UI: 68 %	30	58 % ≥2 Interventions: 22 %	22	None

UI Urinary incontinence, SUI stress urinary incontinence, ISD intrinsic sphincter deficiency, MUCP maximal urethral closure pressure, NR not reported

Table 2 Main complications of ACT® balloons for the treatment for SUI

References	N	Follow-up (months)	Lost to follow	Operative time (min)	Complications during surgery	Post-operative complications						
						Urinary retention	Balloon or port migrations	Infections	Erosions	Balloon perforations	Others	Explantations
Chartier-Kastler et al. [9]	68	24	9 at 3 Months 15 at 6 months 11 at 1 year 13 at 2 years	32 ± 11	17 %	5.8 % (25 % explantations)	20 % (35 % explantations)	8.8 % (50 % explantations)	14 % (90 % explantations)	NR	Inefficiency 11.7 % (100 % explantations)	30.8 %
	49	40.1 (6–71)	11 at 1 Year 16 at 2 years 21 at 3 years 26 at 4 years	20.3 (10–30)	4 %	NR	12 %	NR	4 %	NR	6 % Material dysfunction	20 %
	41	25 (5–60)	0	NR	Percentage not precised	16 %	20 %	NR	NR	12 %	Inefficiency 24 % (100 % explantations)	Rate not precised
Aboseif et al. [11]	162	12	8 at 1 Year	NR	3.7 %	6.1 %	Balloon: 5.6 % Port: 6 %	0.6 %	7.5 %	NR	Material dysfunction: 0.6 % Urinary infection: 2.9 % Pain: 0.6 % Other: 0.6 %	18.3 % with 50 % reimplantations
Kojancic et al. [14]	57	72 (12–84)	NR	20.3 (10–30)	3.5 %	NR	At 3 months: 17.5 % 100 % explantations	NR	At 3 months: urethra: 3.5 % (100 % explantation) port: 3.5 % (100 % explantations)	NR	Labial haematoma: 5.3 % before 3 months De novo urgency: 10.5 % over 3 months Dysfunction: 3.5 % over 3 years	15 Balloons/114 (13.2 %) 12 patients/57 (21.1 %) 3 bilateral explantations et 9 unilateral
Vayleux et al. [10]	67	248 (1–89)	6	NR	Vagina 1.5 % Urethra 1.5 % Bladder 1.5 %	6 %	7 %	8.9 %	15 %	1.5 %	Dyspareunia: 1.5 % Pelvic pain: 1.5 % Dysuria: 1.5 %	Explantations: 19 (28 %) 14 unilateral 5 bilateral with 12 reimplantations (63 %)

Table 2 continued

References	N	Follow-up (months)	Lost to follow	Operative time (min)	Complications during surgery	Post-operative complications						
						Urinary retention	Balloon or port migrations	Infections	Erosions	Balloon perforations	Others	Explantations
Aboseif et al. [12]	89	12	5 at 1 Year	40.6 ± 16.8	4.5 % Bladder, urethral or vaginal perforations	NR	7.9 %	1.1 %	Port: 10.1 % balloon: 4.5 %	NR	Pain/discomfort: 1.1 % Dysfunction: 1.1 % Labial haematoma: 5.1 % Labial infection: 1.3 % Inefficiency: 3.8 %	21.7 % with 50 % reimplantations
Nacir et al. [13]	77	22	None	NR	Vagina 6.5 % Bladder 2.6 %	7.8 %	8 %	5.1 %	16.9 %	2.6 %		28 % with 31 % reimplantation

of the port (3–7.5 %), balloon migration (6.5–17.5 %), device infection (0.6–8.9 %), balloon dysfunction (0.6–6 %), inefficacy of treatment or even worsening of incontinence (2.5–11.7 %), dysuria or even acute urinary retention (1.5–6.8 %), and de novo urgency (10.5 %) in the study by Kocjancic et al. [14].

The explantation rate at the end of follow-up ranged between 18.7 and 30.8 %. The reimplantation rate in these explanted patients was 50 % [11, 12] in the studies by Aboseif in 2009 and 2011.

Discussion

Adjustable continence therapy[®] balloons are a recent treatment modality and are indicated in a specific population of patients with urinary incontinence: difficult situations of primary or secondary failure of treatment for urethral hypermobility by suburethral tape or patients unsuitable for AUS placement (for example, women over the age of 80 years, with cognitive impairments and motor disabilities). Explantation rate can reach 30 %. The risk factors for explantation of ACT[®] balloons have not been clearly identified in women.

In men, several studies suggested that perioperative injuries due to anatomic considerations [11, 18, 19] or difficulties of implantation due to fibrotic tissues secondary to radiotherapy could represent risk factors for explantation. One study reported a statistically significant correlation between urethral erosion and a history of pelvic radiotherapy ($p = 0.005$) [20].

In the light of the above results, the ideal indication for ACT[®] balloons in women would therefore appear to be SUI in which ISD appears to be the predominant mechanism responsible for the patient's symptoms or detected on patient work-up. No comparative study versus another reference treatment for SUI due to ISD (AUS, suburethral fascial sling) was identified. ACT[®] balloons should logically be compared with AUS, although these two techniques are radically different in terms of their degree of invasiveness and their mechanism of action. Adjustable balloons should be preferred whenever the surgical setting appears to contraindicate an AUS, or when the patient refuses AUS and/or when treatment for type II SUI by suburethral sling would likely to be incomplete (see below) due to ISD. But this statement must be assessed by comparative studies. This is an important point, as the mechanism of action of these balloons must comprise bladder neck support as well as periurethral compression, as reflected by the reduction in urine flow rate observed in the majority of implanted patients [9].

No published study has compared the results of treatment for female SUI by ACT[®] balloon to the other

Table 3 Main functional results of ACT® balloons for the treatment for SUI

References	N	Follow-up (months)	Lost to follow-up	% of patient needing balloon adjustments	Mean number of adjustment per patient	Final volume of balloon (ml)	Functional results				
							Type of analysis	% of improved patients	Number of pads/day	I-QoL	Others
Chartier-Kastler et al. [9]	68	24	9 at 3 Months	NR	1.4 ± 1.8	3.4 ± 1.9	AF	Cured: 21 % Improved: 66 % Not improved: 14 %			
								NR	NR	75 (vs. 40)	NR
Kocjancic et al. [13]	49	40.1 (6–71)	11 at 1 Year	62 %	1 to 5	NR	AF	Dry: 68 % Improved: 16 % Unchanged: 16 %			
								16 at 2 years	5.31 Before surgery 0.5 at 48 months	31.4 Before surgery 9.3 at 48 months	NR
								21 at 3 years			
								26 at 4 years			
Wachter et al. [15]	41	25 (5–60)	0	69 %	NR	NR	AF	Continent: 44 % Significant improvement: 15 % Slight improvement: 29 % No improvement: 12 %			
								NR	NR	NR	NR
Abossif et al. [11]	162	12	8 at 1 Year	NR	2.3 (0–9)	3.45 (1–10)	AF	Dry: 52 % Aggravation: 2.5 %			
								NR	11.2 g (vs. 49.6)	71.1 (vs. 36.8)	NR
Kocjancic et al. [14]	57	72 (12–84)	NR	68.4 %	3.8 (1–11)	NR	AF	Dry: 62 % Improvement >50 %: 30 % Unchanged or improvement <50 %: 8 %			
								NR	5.6 before surgery 0.41 at 72 months	Before surgery 27.2	NR
Vayleux et al. [10]	67	24.8	6	73 %	2 (0–9)	1.97 (0–5.3)	AF	Improved: 78.4 % Not improved: 21.6 %			
								NR	1.2	NR	USP SUI 4.16 versus 6.8 OAB 10.84 versus 12.6 Dysuria 0.88 versus 0.96

Table 3 continued

References	N	Follow-up (months)	Lost to follow-up	% of patient needing balloon adjustments	Mean number of adjustment per patient	Final volume of balloon (ml)	Functional results					
							Type of analysis	% of improved patients	Number of pads/day	Pad tests	I-QoL	Others
Aboseif et al. [12]	89	12	5 at 1 Year	78 %	2.03	NR	ITT	Aggravation or unchanged: 3.4 %	2.5	25.7 (vs. 77.3)	65.5 (vs. 33.9)	UDI score 37.1 (vs. 59.8)
Nacir et al. [15]	77	22	None	75 %	2 (1–8)	3	AF	Improved: 64 % Unchanged: 9 % Not improved: 19 %	NR	NR	NR	IIQ score 26 (vs. 56.2) USP SUI improved PGI-I: 69 % satisfied

AF As followed, ITT intention to treat, USP urinary symptom profile, SUI stress urinary incontinence, OAB overactive bladder, UDI urinary distress inventory, PGI patient global impression and improvement

conventional surgical treatments. Over the last decade, the number of colposuspensions, suburethral fascial supports or slings has decreased in favour of the use of synthetic suburethral tape. The ideal surgical treatment must be technically easy to perform, inexpensive, easy to learn, minimally invasive, and effective in the long term with no major morbidity.

Periurethral injections

There are currently no data in the literature in support of the use of periurethral injections as first-line treatment for SUI. Only limited data are available concerning comparison of the various techniques. Published studies are often poor quality with a low level of proof and limited follow-up. Improvement has been reported in 73 % of patients with cure rates ranging from 24 to 36 % [21]. Periurethral injections can sometimes have lasting effects, but repeated injections may be necessary [22, 23]. Periurethral injection is associated with few complications and adverse effects. This technique can be used because of its good benefit/risk balance in frail patients, previously operated patients, and patients refusing surgery. Consequently, after failure of surgical treatment, and/or in the presence of ISD, periurethral injections can be an alternative to another surgical procedure, although the results are considerably inferior to those of ACT[®] balloons or AUS.

Synthetic suburethral tape

The long-term results of suburethral tape, such as TVT, show that 90 % patients remain continent [24]. Randomized studies report that retropubic suburethral tape ensures higher continence rates than Burch colposuspension. Suburethral tape is just as effective as pubovaginal slings, but slings induce a higher rate of bladder emptying disorders. Retropubic TVT tape appears to be more effective in the long term than transobturator tape [25]. ACT[®] balloons may be indicated after failure of suburethral tape. Table 4 compares suburethral tapes to ACT[®] balloons.

Colposuspension and bladder neck fascial sling

In view of the equivalent functional results obtained by suburethral tape and Burch colposuspensions and the greater morbidity of colposuspension, the indications for conventional surgery therefore correspond to contraindications to suburethral tape (marked alteration of vaginal trophicity, history of urethral repair surgery). The indications for bladder neck fascial sling now appear to be very limited.

A comprehensive review of the literature from the Cochrane database [26] indicated that the objective cure

Table 4 Comparison between mid-suburethral sling and ACT[®] balloons for the treatment for SUI

	Mid-suburethral tapes	ACT [®] balloons
Indications	Stress urinary incontinence Urethral hypermobility Or intrinsic sphincter disorder	Stress urinary incontinence with intrinsic sphincter disorder predominant
Type of procedure	Minimally invasive	Minimally invasive: local anaesthesia possible Longer learning curve?
Characteristic of the device	Not adjustable	Adjustable
Evolutive risks	Risk of infection and erosion Does not limit the implantation of other continence device Possibility to remove the tape under general anaesthesia Partially (TOT) Completely (TVT) Voiding dysfunction: de novo urgency (0.8–24 %), dysuria Does not limit the implantation of other continence device	Risk of infection and erosion Does not limit the implantation of other continence device Possibility of total remove under local anaesthesia Dysuria Does not limit the implantation of other continence device
Results	Long-term outcomes available Comparative studies with other techniques 90 % Dry patients (<i>n</i> > 100) Patients' satisfaction: 82 %	Insufficient long-term outcomes available No comparative studies with other techniques 68 % Dry patients Patients' satisfaction: 78 %

rate after colposuspension was between 59 and 100 % (median 80 %) and the subjective cure rate ranged from 71 to 100 % (median 88 %). Open colposuspension provides similar results to those of bladder neck sling and TVT, but better results than anterior colporrhaphy, Marshall-Marchetti operation, needle colposuspension or paravaginal repair [26]. With a follow-up of more than 10 years, the success rate of these techniques is between 55 and 70 % [27]. However, these techniques are invasive and can be responsible for de novo bladder capacity disorders (8–27 %), bladder emptying disorders (2–27 %), and prolapse (2.5–27 %) after colposuspension [27]. ACT[®] balloons could therefore constitute a valuable and less invasive alternative.

Suburethral slings

The conclusions of the Cochrane database concerning suburethral slings are not based on high levels of proof, in view of the small number of publications and their poor quality. Fascial slings are the most extensively studied technique. They represent an effective non-prosthetic technique for surgical correction of urinary incontinence, but at the price of high morbidity in terms of post-operative dysuria and wound complications [28]. The superiority of slings over colposuspensions has not been formally demonstrated. Several studies comparing TVT and fascial

slings demonstrated few significant differences in terms of cure [29, 30]. Suburethral fascial sling, in view of its unfavourable efficacy/morbidity balance, is therefore now performed less and less commonly. However, in patients with persistent SUI after multiple surgical procedures, suburethral fascial sling could be considered, but may possibly require subsequent self-catheterization. AUS can also be considered in this indication.

Artificial urinary sphincter

AUS implantation in women is only performed by experienced teams [4, 31] due to the technical difficulties related to the short female urethra or a history of local surgical, responsible for the morbidity of this operation [3]. However, AUS remains the reference treatment in patients with severe SUI with ISD, often after failure of other surgical treatments. Several studies have reported the long-term results of AUS in women, with continence rates ranging between 61 and 90 % [4, 29–37]. The leading long-term complication of this treatment is explantation of the material in 3–50 % of cases due to various causes (infection, erosion) [32, 39, 40] and the need for revision of the material in 13–63 % of cases [38]. ACT[®] balloon placement, compared to AUS, is associated with lower morbidity, is easier to manage, and can represent a valuable alternative in elderly patients or patients with limited

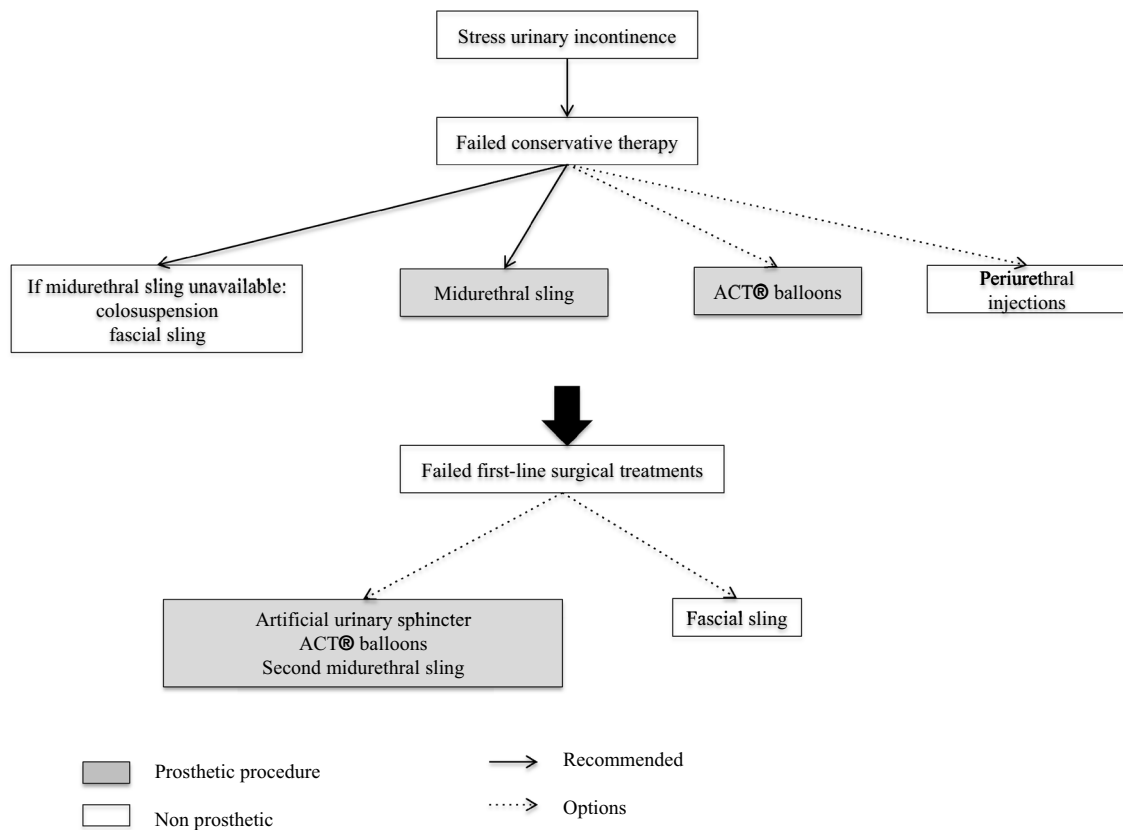


Fig. 2 Flow chart for the surgical treatment for stress urinary incontinence

mental or physical capacities. The age limit of 80 years for AUS implantation [3] could constitute a very good indication for ACT[®] balloons. Figure 2 suggests a flow chart for the surgical management of SUI.

Conclusion

The literature concerning the long-term evaluation of treatment for female SUI by ACT[®] balloon is limited to only a few studies, but which nevertheless report favourable results compared to the other alternative techniques. ACT[®] balloons may be indicated in the management of female SUI due to predominant or isolated ISD, especially in patients with a history of failure of standard surgical treatment and in patients in whom invasive surgery would be contraindicated (age > 80 years). This technique also presents the advantage of being associated with easily managed local morbidity, which does not appear to compromise future use of the patient's periurethral tissues. Nevertheless, the explantation rate can reach 30 %.

Long-term data are essential for more thorough evaluation of this treatment. It would also be interesting to compare the management of stage II SUI with predominant

sphincter deficiency and stage III SUI by suburethral tape and first-line ACT[®] balloons.

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