Urologia Internationalis

Review Article

Urol Int 2023;107:653–665
DOI: 10.1159/000529712

Received: September 27, 2022
Accepted: February 6, 2023
Published online: June 2, 2023

Adjustable Continence Therapy Balloons in Female Patients with Stress Urinary Incontinence: A Systematic Review

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Keywords
Adjustable Continence Therapy · Periurethral balloons · Female urinary incontinence · Minimally invasive approach

Abstract

Introduction: The aim of this study was to perform a systematic review of studies reporting the outcomes of ACT® balloons in female patients with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). ***Methods:*** In accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) standards, a systematic search of the PubMed (Medline) and Scopus electronic database was performed in June 2022. Terms used for the query were ("female" or "women") and ("adjustable continence therapy" OR "periurethral balloons"). ***Results:*** Thirteen studies were included. All were retrospective or prospective case series. The success rates ranged from 13.6% to 68% and the improvement rates from 16% to 83%. The intraoperative complication rate ranged from 3.5 to 25% and consisted of urethral, bladder, or vaginal perforations. The rate of postoperative complications varied from 11 to 56% without major complications. Between 6% and 38% of ACT® balloons were explanted and subsequently reimplanted in 15.2–63% of cases. ***Conclusion:*** ACT® balloons can be considered as an option to treat SUI due to ISD in female patients with a relatively modest success rate and quite a high complication rate. Well-designed prospective studies and long-term follow-up data are needed to fully elucidate their role.

Introduction

Stress urinary incontinence (SUI) is a widespread health problem that affects women's quality of life and can lead to social isolation. Most studies report that 25–45% of women worldwide would be affected [1]. It is also associated with a considerable financial cost [2].

Two pathophysiologic mechanisms underlying SUI have been identified over the last decades: urethral hypermobility and intrinsic sphincter deficiency (ISD). ISD is commonly encountered in cases of recurrent SUI in patients with a history of anti-incontinence surgery and in patients with neurological diseases. While the management of SUI related to urethral hypermobility is well standardized, the one related to the ISD is more controversial.

Multiple medical and surgical approaches have been developed over time including first-line conservative therapies such as pelvic floor rehabilitation [3], dietary measures [4], and topical oestrogen for postmenopausal women [5]. In case of failure, several surgical

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interventions can be offered including minimally invasive procedures such as periurethral bulking agents, more invasive urethropexy procedures, adjustable and nonadjustable mid-urethral slings, fascial slings, and the artificial urinary sphincter (AUS). Variable success rates have been reported in the literature for these procedures from 60% to more than 90% depending on the length of follow-up and definitions of the cure.

Adjustable Continence Therapy (ACT®) balloons have been developed by Uromedica (Irvine, CA, USA) in the mid-2000s and are one of the available options [6]. This is a medical device composed of two silicone balloons which are implanted on each side of the bladder neck through the perineal route. It has the advantage of being easily adjusted in the office with a percutaneous needle injection to optimize continence. The role of ACT® balloons in the therapeutic algorithms of female SUI due to ISD remains unclear, and their use is limited to a small number of Western countries. Our aim was to perform a systematic review of studies reporting the outcomes of ACT® balloons in female patients with SUI resulting from ISD.

Methods

Search Strategy

This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement [7]. We searched the PubMed/Medline and Scopus electronic databases on June 1, 2022, for studies investigating ACT® balloon for female SUI. After a first screening based on the study titles and abstracts, all papers were assessed based on full texts and excluded for reasons when inappropriate; a further check of the appropriateness of the papers based on full-text revisions was performed after data extraction. Two investigators (S.G. and Z.K.) carried out this process independently. Disagreements were resolved by a consensus meeting with a third investigator or by referring to the senior author (B.P.). The following keywords were used in our search strategy: ("female" or "women") and ("adjustable continence therapy" OR "periurethral balloons").

Inclusion and Exclusion Criteria

The PICOS approach was used as per the PRISMA statement [7]. All articles published in English and in French evaluating adult female SUI patients (P) undergoing ACT® balloon implantation (I) were included. Studies on male populations or mixed populations (i.e., including both male and female patients) were excluded. All types of comparators were allowed including single-arm studies with no comparator (C). The primary endpoint was success as subjectively defined by the investigators (O). Randomized controlled trials as well as prospective and retrospective comparative and non-comparative studies were included (S). Letters, editorials, case reports, abstracts, and reviews were also excluded.

Quality Assessment

The Newcastle-Ottawa Scale (NOS) was used to assess the quality of the included studies according to the Cochrane Handbook for Systematic Reviews of Interventions for the included nonrandomized studies [8]. The scale focuses on three factors: selection (1–4), comparability (1–2), and exposure (1–3). The total score ranges from 0 (lowest) to 9 (highest).

Data Collection

For each selected article, patient's characteristics studied were number of subjects, mean age of patients, proportion of patients with a history of incontinence surgery, radiation therapy, and neurogenic bladder. The surgical data collected were anaesthesia type, operative time, intraoperative complications, initial and final injected volumes in the balloons, number of inflation sessions, time before the first inflation, and time between each inflation session. The surgical technique descriptions were also analysed.

The functional outcomes collected were subjective patients' impression of improvement, pad count, pad tests, validated questionnaire results, and Stamey score. The validated questionnaires used were the urinary Improved Quality of Life (IQOL) scale, the mean numeral rating scale (NRS), the Patient Global Impression of Improvement (PGII), the Urinary Symptom Profile (USP) questionnaire, the Urogenital Distress Inventory (UDI), and the Incontinence Impact Questionnaire (IIQ). The postoperative complications and the explantation rates were also recorded [9].

Results

Characteristics of Included Studies

The PRISMA flow chart of the systematic literature search process is shown in Figure 1. A total of 13 observational studies fulfilled the inclusion criteria. These studies were published between January 1, 2008, and June 1, 2022. They were from European and North American teams. Because no randomized controlled trials were available, a purely narrative analysis was undertaken without any pooled analysis [10].

Four studies were multicentre prospective series, one was a multicentre retrospective study, and the eight other studies were single-centre prospective or retrospective series. One study compared the clinical results and complications of ACT® balloons with the AUS [11]. Another study compared outcomes based on the presence or absence of neurological diseases [12]. Seven studies had a level of evidence of III according to the Oxford classification and six studies a level of evidence of IV. The Newcastle-Ottawa score (/9) ranged from 5 to 7, reflecting the "low quality" of the studies (Table 1).

Description of the Procedure

ACT® balloons are two silicone balloons, each connected to a titanium port by a conduct divided into

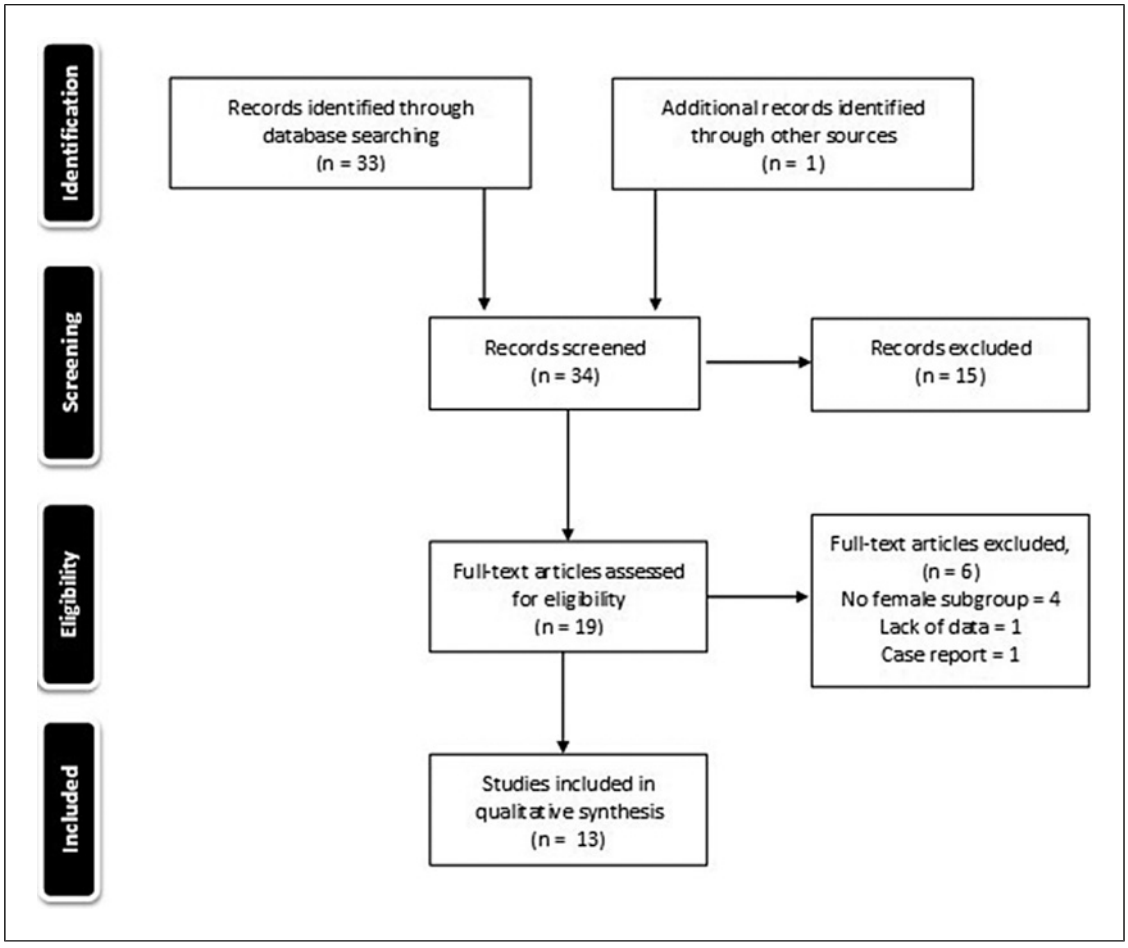

Fig. 1. PRISMA flowchart.

two lumens, one for filling the balloon and the other to insert the stylet needed for the positioning. A negative preoperative culture was requested before surgery. Intraoperative antibiotic prophylaxis was administered in accordance with the recommendations [24]. The patient was placed in standard lithotomy position. The bladder was filled with 50 [21] to 200 mL [22, 25] of medium contrast solution. The balloon of the Foley catheter was then filled with 10 mL of pure radio-opaque solution to locate the bladder neck. The skin was incised in the convexity of each labia majora on 0.5 [23] to 1 cm [22] at the level of the urethral meatus. The pelvic floor was then perforated laterally to the urethra until the bladder neck with a dedicated ancillary instrument under digital control. The positioning was checked by fluoroscopic +/− cystoscopic control. Some authors used a flexible cystoscope to facilitate balloon positioning and rule out bladder neck perforation in real-time using retrovision [12, 18]. The stylet was then removed, and the balloon was inserted after the ancillary has been lubricated. It could be dipped in antibiotic solution beforehand [21]. The positioning was checked thanks to a radio-opaque marker located on the balloon. Each balloon was then inflated with a radio-opaque solution with 0.3 [26] to 2 mL [23]. The procedure was repeated on the contralateral side. Finally, a subcutaneous space was created within each labium majora to place the injection port which allowed the adjustment of the balloons' volumes. The bladder catheter was left in place for 12 [11] to 24 h in most cases [19].

The first balloon inflation was performed between 4 and 6 weeks. Maximum injected volume at each session was 0.5–2 mL [21].

Patients' Characteristics

The population of included studies ranged from 18 to 277 patients. The baseline patients' characteristics

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Table 1. Bias of the selected articles assessed with Newcastle-Ottawa score

Study	Design	LE	Total Newcastle-Ottawa score (/9)	Selection (0–4)				Comparability (0–2)	Outcomes (0–3)		
				representativeness of the cohort	selection of the non-exposed cohort	ascertainment of exposure	demonstration that outcome of interest was not present at start of study	comparability	assessment of outcome	follow-up long enough for outcomes to occur?	adequacy of follow-up of cohorts
Demeestere et al. [12] 2022	Multicentric retrospective series	III	7	X	–	X	X	X	X	X	X
Guiffart et al. [13] 2018	Single-centre retrospective series	IV	5	X	–	X	X	–	–	X	X
Freton et al. [11] 2017	Single-centre retrospective series	IV	7	X	–	X	X	X	X	X	X
Billault et al. [14] 2015	Single-centre retrospective series	IV	5	X	–	X	X	–	X	–	X
Nacir et al. [15] 2013	Single-centre retrospective series	IV	6	X	–	X	X	–	X	X	X
Galloway et al. [16] 2013	Multicentre prospective series	III	6	X	–	X	X	–	X	X	X
Aboseif et al. [17] 2010	Multicentre prospective series	III	6	X	–	X	X	–	X	X	X
Vayleux et al. [18] 2010	Single-centre retrospective series	IV	6	X	–	X	X	–	X	X	X
Kocjancic et al. [19] 2010	Single-centre prospective series	III	6	X	–	X	X	–	X	X	X
Aboseif et al. [20] 2009	Multicentre prospective series	III	6	X	–	X	X	–	X	X	X
Wachter et al. [21] 2008	Single-centre retrospective series	III	5	X	–	X	X	–	–	X	X
Kocjancic et al. [22] 2008	Single-centre prospective series	IV	6	X	–	X	X	–	X	X	X
Chartier-Kastler et al. [23] 2007	Multicentre prospective series	III	6	X	–	X	X	–	X	X	X

LE, level of evidence.

Table 2. Characteristics of included studies and patients

Study	*N*	Mean age, years	History of anti-incontinence surgery	History of radiation therapy	Neurogenic bladder/ patients	Characteristics of the urinary incontinence	Maximal urethral closure pressure (cmH_20)
Demeestere et al. [12] 2022	277	N-N: 69.1 Neurogenic: 65.9	N-N: 65.9% Neurogenic: 58%	N-N: 8.8% Neurogenic: 4.1%	18.5%	N-N: pure SUI: 50.2%/mixed IU: 49.8% Neurogenic: pure SUI: 51%/mixed IU: 49%	N-N: 25.0 Neurogenic: 27.3
Guiffart et al. [13] 2018	18	70	100%	NR	28%	Pure SUI: 44% Mixed IU: 56% Stamey grade II: 56%/grade III: 44%	27
Freton et al. [11] 2017	25	70.4	Prior mid-urethral slings: 40%	20%	4%	NR	28.8
Billault et al. [14] 2015	52	83	67.3%	3.8%	Excluded	Bladder overactivity: 21.1%	20
Nacir et al. [15] 2013	67	68	58%	NR	NR	Pure SUI: 32% Mixed UI: 68%	30
Galloway et al. [16] 2013	162	67.6	83%	Excluded	Excluded	Recurrent SUI	NR
Aboseif et al. [17] 2010	89	68	100%	Excluded	NR	Recurrent moderate to severe SUI: 100%	NR
Vayleux et al. [18] 2010	67	70.3	Mid-urethral sling: 25.4% Burch procedures: 25.4% Sacral neuromodulation: 12% AUS: 12%	Excluded	19.4%	Pure SUI: 70% Mixed UI: 30%	26.1
Kocjancic et al. [19] 2010	57	62.6	100%	NR	NR	SUI related to ISD	47.4
Aboseif et al. [20] 2009	162	67.4	84%	Excluded	NR	Recurrent SUI (after surgical and medical treatment)	NR
Wachter et al. [21] 2008	41	73	38%	7.3%	NR	Pure SUI: 70% mixed stress/urge UI: 30%	NR
Kocjancic et al. [22] 2008	49	NR	100%	NR	NR	Recurrent SUI with severe ISD and normal bladder function	NR
Chartier-Kastler et al. [23] 2007	68	68.4	88%	NR	Excluded	SUI (mild: 31%, moderate: 16%, severe: 53%)	23

LE, level of evidence; *N*, number of patients; N-N, non-neurogenic group; SUI: stress urinary incontinence; UI, urinary incontinence; ISD, intrinsic sphincter deficiency.

are outlined in Table 2. The mean patients' age ranged from 62 to 83 years. Most patients had undergone at least one anti-incontinence surgery prior to ACT® balloon implantation and four studies exclusively focused of patients with a recurrent SUI [13, 17, 19, 22]. Pure SUI accounted for 32–70% of indications, mixed SUI for 30–68%, and neurogenic SUI for 0–28% of indications. Four studies included patients with

Table 3. Intraoperative parameters and complications

Study	Patients, *n*	Anaesthesia types	Outpatient procedure	Foley catheter time, hours	Mean operative time, min	Initial volume in balloons, mL	Intraoperative complications
Demeestere et al. [12] 2022	277	NR	NR	NR	NR	0.5–1	N-N: 2% of complication (1 vaginal perforation) Neurogenic: 5.1% of complications (5 vaginal perforations. 4 bladder perforations, 2 urethral perforations, and 1 other)
Guiffart et al. [13] 2018	18	General: 100%	Yes	NR	NR	0.5	Bladder perforation (*N* = 1) Bleeding hardly controlled (*N* = 1)
Freton et al. [11] 2017	25	NR	Yes	12	45.7	0.6	Bladder perforation (*N* = 1) Vaginal perforation (*N* = 1)
Billault et al. [14] 2015	52	General: 36.5% Spinal: 0 Local: 63.5%	86.5%	NR	NR	NR	After the 1st implantation: Bladder perforations (*N* = 2) Urethral perforations (*N* = 3)
Nacir et al. [15] 2013	67	General: 98.5% Local: 1.5%	NR	12	NR	1–1.6	Bladder injuries (*N* = 2) Vaginal injuries (*N* = 5) Bleeding hardly controlled (*N* = 1)
Galloway et al. [16] 2013	162	NR	NR	NR	NR	1.5	Bladder perforation (*N* = 38, 25%)
Aboseif et al. [17] 2010	89	NR	NR	NR	40.6	1.5	Perforation (*N* = 4, 4.5%)
Vayleux et al. [18] 2010	67	NR	NR	NR	NR	1.6 reduced to 1	Perforation (4.5%): - bladder perforation (*N* = 1) - urethral perforation (*N* = 1) - vaginal perforation (*N* = 1)
Kocjancic et al. [19] 2010	57	General: 10.5% Spinal: 64.9% Local: 24.6%	100% discharged within 24 h of surgery	12	20.3	1–1.5	Bladder perforation (*N* = 2)
Aboseif et al. [20] 2009	162	General: 100%	NR	NR	NR	1.5	Bladder perforation (3.8%)
Wachter et al. [21] 2008	41	General or spinal	NR	24	35	1	NR
Kocjancic et al. [22] 2008	49	General: 12% Spinal: 57% Local: 30.6%	100% discharged within 24 h of surgery	24	20.3	1–1.5	Bladder perforation (*N* = 2)
Chartier-Kastler et al. [23] 2007	68	General: 50% Spinal: 35% Local: 15%	NR	6–12	32	2 +/−0.5	Perforation (16%)

N-N, non-neurogenic group.

neurological diseases [11–13, 18], while three studies excluded them [14, 16, 23]; data were unavailable for other studies. The proportion of patients with a history of pelvic radiation therapy ranged from 0% to 20%.

Perioperative Outcomes

The perioperative outcomes are summarized in Table 3. The procedure was performed under general anaesthesia in 10.5–100% of cases but could also be made under spinal anaesthesia (0–64.9%) and local anaesthesia

Table 4. Modalities of balloon adjustments and functional outcomes of ACT balloons®

Study	*N*	Follow-up, months	Modalities of balloons adjustments			Functional results			
			no balloon adjustment, %	mean total number of adjustments	mean volume in each balloon, mL	mixed subjective and objective results	subjective results	objective results	
							patient declaration	use of pads (number per day or provocative pad test)	scores
Demeestere et al. [12] 2022	277	12	NR	N-N: 3 Neurogenic: 2	N-N: 3.5 Neurogenic: 3.1	Success: ≤1 pad per day and an NRS ≥8/10 N-N: 36.3% Neurogenic: 39.2% Improvement: decrease of daily pad use and/or NRS ≥5/10 N-N: 33.6% Neurogenic: 31.4% Failure N-N: 30.1% Neurogenic: 29.4%	NR	Number of pad/d: 1 in the two groups	Median NRS N-N: 7/10 Neurogenic: 7/10
Guiffart et al. [13] 2018	18	24	NR	4	3.8	Success = patients with 0 or 1 pads and with an NRS ≥9: 6 months: 17%/12 months: 33%/24 months: 33% Improvement = decrease in the number of pads or a NRS ≥5/10 6 months: 61%/12 months: 39%/24 months: 17% Failure 6 months: 22%/12 months: 33%/24 months: 33%	NR	NR	NR
Freton et al. [11] 2017	25	11	NR	2.9	3.4	NR		Number of pads/d: 2.2 Patients with no pads at 6 months: 21.7%	PGII (very much improved): 12% Mean USP stress incontinence sub-score: 4.8 (−3.2)

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Table 4 (continued)

Study	*N*	Follow-up, months	Modalities of balloons adjustments			Functional results			
			no balloon adjustment, %	mean total number of adjustments	mean volume in each balloon, mL	mixed subjective and objective results	subjective results	objective results	
							patient declaration	use of pads (number per day or provocative pad test)	scores
Billault et al. [14] 2015	52	10.5	NR	3 (2–5)	3.5 (2.4–6)	NR	At the end of the follow-up Continence: 13.5% Improvement rate >80%: 25% Failure rate: 42.3%	Number of pads/d: 0.5	NR
Nacir et al. [15] 2013	67	22	25%	2	3	NR	Continence: 25% Very much improvement: 33% Improvement: 6% Failure: 19%	NR	USP SUI sub-score: 4.08 (−37%) OAB SUI sub-score: 9.67 (−15%) PGII -very much improved: 32% of patients -much improved: 24%
Galloway et al. [16] 2013	162	60	NR	2.1 at 1 year	4	NR	Improvement >50% at 1 year: 83%, at 5 years: 93.1%	<2 g on provocative pad weight testing: at 1 year: 51%, at 5 year: 76%	IQOL score at 1 year: 71.1/at 5 years: 74.3 UDI score at 1 year: 37/at 5 years: 51
Aboseif et al. [17] 2010	89	12	22.1%	2.03	NR	NR	NR	Number of pad/d: 1.9 < 2 g on provocative pad weight testing: 39.3% > 50% reduction on provocative pad weight testing: 77.5% Mean pad weight: 25.7 g versus 77.3 g	Stamey score: 0.94 IQOL: 71.6 UDI: 33.3 IIQ: 21.6
Vayleux et al. [18] 2010	67	24.8	27%	2	1.9	NR	Improvement: 60% Failure: 40%	Number of pads/d: 1.2 Patient with 0 or 1 pad/d: 55%	USP SUI sub-score: 4.16 (−39%)
Kocjancic et al. [19] 2010	57	72	31.6%	3.8	NR	NR	At the end of the follow-up Continence: 62% Improvement >50%: 30% Failure: 8%	Number of pads/d at 72 months: 0.41	At 72 months Mean IQOL: 78.6 PGII very much improved: 64%±0.94 much improved: 23% minimally improved or unchanged: 13%

Table 4 (continued)

Study	*N*	Follow-up, months	Modalities of balloons adjustments			Functional results			
			no balloon adjustment, %	mean total number of adjustments	mean volume in each balloon, mL	mixed subjective and objective results	subjective results	objective results	
							patient declaration	use of pads (number per day or provocative pad test)	scores
Aboseif et al. [20] 2009	162	12	NR	2.3	3.45	NR	NR	< 2 g on provocative pad weight testing: 52% > 50% reduction on provocative pad weight testing: 80%	Stamey score improved by at least 1 grade: 76.4% of patients IQOL: 71.1 (+84.4%) UDI: 32 (−82.5%) IIQ: 23.3 (−78.3%)
Wachter et al. [21] 2008	41	25	31%	NR	NR	NR	Continent and improved: 59% Fully continent: 44% No change: 12%	NR	NR
Kocjancic et al. [22] 2008	49	40.1	38%	NR	NR	NR	Dry: 68% Improved: 16% No change: 16%	Number of pads/d: at 1 year: 1.2 at 4 years: 0.5	IQOL score at 1 year: 69.9 at 4 years: 93.8
Chartier-Kastler et al. [23] 2007	68	24	NR	1.4	NR	NR	Dry: 21% Improved: 66% No change: 14%	NR	IQOL score: 75

N-N, non-neurogenic; NRS, numeral rating scale; pads/d, postoperative number of pad per day; PGII, Patient Global Impression of Improvement; USP, Urinary Symptom Profile; OAB, overactive bladder; IQOL, Improved Quality of Life/100; UDI, Urogenital Distress Inventory/100; IIQ, Incontinence Impact Questionnaire/100.

Table 5. Complications of ACT balloons®

Study	Year	Patients, *n*	Complications rate, %	Postoperative complications details	Explantation rate, %	Reimplantation rate, %
Demeester et al. [12] 2022	2022	277	32.5	Early (13.1%): infection (3%), haematoma (5.2%), vaginal perforation (0.7%), bladder perforation (0.4%), others (6%) Late: vaginal perforation (7.2%), bladder perforation (1.5%), urethra perforation (3%), others (15.3%)	27	NR
Guiffart et al. [13] 2018	2018	18	11	Skin erosion (6%), majora labia haematoma (6%)	6	NR
Freton et al. [11] 2017	2017	25	40	UR (20%)	20	NR
Billault et al. [14] 2015	2015	52	NR	After the 1st implantation Early postoperative complications: 2 UR, 1 haematoma Late postoperative complications: 5 balloon migrations, 7 balloon erosions, 2 infections device	42	64
Nacir et al. [15] 2013	2013	67	NR	6 UR, 13 balloon erosions causing explant procedure, 4 labia majora haematoma, 4 infections, and 3 worsening of symptoms	28	NR
Aboseif et al. [17] 2010	2010	89	30	Port erosion (10.1%), balloon migration (7.9%), balloon erosion (4.5%), worsening incontinence or no change (4.3%), procedure failure (2.2%), pain/ discomfort (1.1%), device failure (1.1%), and device infection (1.1%)	21.7	50
Vayleux et al. [18] 2010	2010	67	37.3	4 UR, 5 balloon migrations, 6 infections device, 10 bladder or urethral erosions, 1 dyspareunia 1 chronic pelvic pain, 1 balloon perforation	28	63
Kocjancic et al. [19] 2010	2010	57	NR	Balloon migration (17.5%), balloon erosion (3.5%), skin erosion (3.5%), labia majora haematoma (5.3%), de novo urgency (10.5%)	21.1	NR
Aboseif et al. [20] 2009	2009	162	24.4	UR (6.2%), balloon migration (5.5%), balloon erosion (5.6%), skin erosion (7.5%), device infection (0.5%), worsening of symptoms (2.5%), urinary infection (1.9%), pain (0.5%), device failure (0.5%)	18.3	50
Wachter et al. [21] 2008	2008	41	39	4 UR, 5 balloon erosions	NR	NR
Kocjancic et al. [22] 2008	2008	38	NR	Balloon migration (12%), urethral or portal erosion (4%)	22	NR
Chartier-Kastler et al. [23] 2007	2007	68	56	4 UR, 10 balloon migrations, 10 balloon erosions, 6 device infections	38	33
Galloway et al. [16] 2013	2013	162	25	NR	NR	NR

UR, urinary retention.

(0–63.5%). The type of anaesthesia was not mentioned for five studies. The mean operating time ranged from 20 to 45.7 min. The operating procedure was considered easy for 48–62% of the operators, moderately difficult for 30–39%, and very difficult for 9–13% of them [16, 20, 23]. Outpatient procedures were reported in five studies [11, 13, 14, 19, 22].

The rate of intraoperative complications ranged from 3.5 to 25%. Bladder perforations were the most common complications, reported in 12 of 13 studies and ranging from 0 to 25%. The other complications were vaginal perforations (0–7.4%), urethral perforations (0–5.8%), and major bleedings (2 patients overall). Twenty-two to 38% of patients did not require any balloon inflation. The mean number of inflation sessions varied from 2 to 4, and the final volume was between 1.9 mL and 4 mL.

Postoperative complications rates are reported in Table 4. The rate of postoperative complications widely ranged from 11 to 56%. The main complications were urinary retention (5.8–20%), balloons or port migrations (3–20%), balloons or port erosions (4–14%), and haematoma of the labia majora (5%). Few other complications have been described: device infection in 0.5–9% of patients, pain, dyspareunia, device failure, worsening of symptoms, and chronic urinary retention. Only Kocjancic et al. [19] reported a rate of 10.5% of de novo urgency.

Between 6 and 42% of the ACT balloons had to be explanted. The removals were mostly performed under local anaesthesia. ACT® balloons were reimplanted in 13.8–63% of cases.

Functional Outcomes

The functional outcomes are presented in Table 5. After a mean follow-up period ranging from 10.5 to 72 months, continence rate ranged from 13.5% to 68%. The continence definitions were very heterogeneous (patient's declaration, pad test <2 g, no pad, 0 to 1 pad ± numeral scale score). Between 16% and 83% of patients declared themselves improved. The procedure was considered a failure for 8–42.3% of patients. The mean number of pads per day varied from 0.41 to 2.2, and 39.1–52% of patients had less than 2 g on provocative pad weight testing. Based on the PGII questionnaire, when available, 12–64% of the patients declared to be very much improved. The postoperative IQOL index ranged from 69.9 to 93.8.

Three studies assessed long-term functional outcomes (≥4 years) [16, 19, 22]. The mean IQOL ranged from 70 to 75 2 years after implantation and from 74.3 to 78.6 5 years after implantation for a preoperative mean IQOL of 27.2–36.8. At 5 years, Kocjanvic et al. [19] observed a mean number of pads per day of 0.41 g versus 5.6 before surgery.

One study involved a population of women over 80 years old only [14]. Full continence was reported in 13.5% of patients and improvement of more than 80% in 25% of patients. At the last follow-up available, the failure rate was 42.3%. The patients were discharged the day after the procedure in 86.5% of cases.

One study compared patients with neurological disease to patients without neurological disease. No difference was observed between the two groups with a success rate of 39.2% and 36.3%, respectively [12]

Discussion

SUI related to ISD differs from UI due to urethral hypermobility in several aspects, including those related to severity of incontinence and history of previous anti-incontinence surgery [27, 28]. The management of female SUI underpinned by ISD is controversial and relies on multiple surgical procedures including ACT® balloon implantation. Forty-eight to 62% of surgeons declared the placement was easy and the mean operating time was short. ACT balloons can be easily adjusted in clinics to get the optimal result. They may thus be interesting for frail patients. However, the results of our review suggest that the functional outcomes are inconstant and the complications are frequent. The poor quality of the available studies and the small number of patients included are significant limitations to be taken into account.

The improvement of SUI was very heterogeneous ranging from 13.5 to 68%. First, this variation can be explained by the various definitions of success/continence used. When the endpoint was defined based on the patient's subjective impression of improvement, the success rate ranged from 25% [15] to 68% [19] in the general population. When a pad test was used, the success rate was about 50%. When a questionnaire was combined with the number of pads per day, the rate was reduced to 35%. Standardization of the definition of success for ACT balloon implantations would certainly improve the assessment of its efficacy [29]. The discrepancies observed could also be explained by the lack of standardization of the surgical procedure. Indeed, some teams initially injected 2 mL into the balloons and others only 0.5 mL. An urethro-cystoscopy was inconstantly performed, and sometimes, balloons' placement was slightly different [11]. Finally, the populations were different according to studies with different proportions of elderly people [14], patients

with neurological diseases, or patients with a history of one or more previous anti-incontinence surgery.

Regarding complications, they were frequent and estimated to be between 11 and 56%. Some of them may be underestimated because of the short follow-up and of the lack of data regarding worsening of post-operative lower urinary tract symptoms such as de novo urgency which were described by only one study. The explantation rate was 18.3% at 1 year in the series of Aboseif et al. and was as high as 42% in patients over 80 years old in the series of Billault et al. [12, 20]. The high rate of complication may be related to the learning curve and may dwindle with surgeons' experience as it has been shown with ProACT® balloons in male patients [30]. Indeed, Chartier et al. [23] observed a decrease of 25% in complications after the initial five cases in each centre. Simulation training programmes could therefore be useful in mastering the procedure.

Moreover, the management of complication is easy. Balloons can be deflated. The removal can be performed under topical anaesthesia in an office and does not contraindicate a second implantation or an AUS. Finally, when we compare the morbidity of the larger cohort to that of other implanted devices such as the AUS, it was not so different: 24.7% [18] of the patients with early complications for AUS versus 32.5% [12].

As a result, determining the place of ACT® balloons is challenging. All the surgical techniques to treat SUI related to ISD present strengths and weaknesses. AUS is considered as the gold standard treatment of SUI by ISD in several European countries, but it requires a good manual dexterity and revisions [31]. Only one study compared ACT® to AUS and reported better functional results in favour of SAU with a lower number of pads per 24 hours (0.6–2.2 pads) and a better patient satisfaction [11]. Mid-urethral sling is a privileged option by the American Urology Association because of its excellent success rates. According to a meta-analysis by Ford et al. [32], the median declared cure rate is 77.5% in the transobturator route and 82.5% in the retropubic route. However, they are hard to remove in case of complications, which is the contrary for ACT balloons [33, 34]. The pubovaginal sling is an autologous alternative that provides great satisfaction to patients but causes significant postoperative urge symptoms [35]. Finally, bulking agents are the least morbid technique with reported cure rates ranging from 24 to 36% [36]. ACT balloons are cited only by the European Association of Urology guidelines. They stated ACT® balloons might improve complicated SUI, but secondary synthetic sling, colposuspension, and autologous slings are the first options to be proposed to patients with complicated SUI [6].

Conclusion

The ACT® balloons technique is simple and results in symptomatic improvement in two-thirds of female patients with SUI related to ISD. However, the complications are frequent and only poor level of evidence studies are available to support their use. The relatively high rates of explantation may raise concern and long-term follow-up data, along with prospective well-designed studies, are needed to fully elucidate the role of ACT® balloons in the management of female SUI.

Statement of Ethics

An ethics statement is not applicable because this study is based exclusively on published literature.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

This research received no funding.

Author Contributions

Study concept and design and drafting of the manuscript: Guérin. Acquisition, analysis, and interpretation of data: Guérin, Khene, and Peyronnet. Critical revision of the manuscript for important intellectual content: Khene and Peyronnet. Supervision: Peyronnet.

Data Availability Statement

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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