Review Article

Adjustable continence therapy (ProACT/ACT™) with periurethral balloons for treatment of stress urinary incontinence: a narrative review

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Background and Objective: First-line surgical management of stress urinary incontinence (SUI) currently involves implantation of an artificial urinary sphincter (AUS) in male patients and midurethral sling in female patients. Still, there is demand for a less invasive treatment option without the need to use a device during voiding. Since its first description in 2005, many clinics have implemented adjustable continence therapy balloons in male (ProACT™) and female patients (ACT™).

Methods: Publications on the use of ProACT/ACT™ were reviewed from 2002 until September 2022, focusing on functional and safety outcomes, including predictors of treatment failure and complications.

Key Content and Findings: Most publications report the use of ProACT™ in patients after prostate surgery, with approximately 60% experiencing a cure rate and 82% achieving over 50% improvement. Consistent functional outcome assessment in female and neurogenic lower urinary tract dysfunction (NLUTD) patients lacks. Few predictors of treatment failure were described, resulting in an advise to not use the balloons after male pelvic radiation therapy. High revision rates were observed in all patient groups, with balloon defects as one of the most common causes for revision.

Conclusions: Based on the current literature, ProACT™ is safe and effective in male patients after prostate surgery, but the role of ProACT/ACT™ in female and NLUTD patients is still unclear. There is need for research of higher level of evidence with uniform outcome assessments. Preferably, ProACT™ is prospectively compared with AUS in a randomized setting. In addition, development of better-quality balloons should reduce mechanical failure and revision surgeries, resulting in improved functional and patient satisfaction outcomes.

Keywords: Stress urinary incontinence (SUI); mixed urinary incontinence; minimally invasive surgery; functional outcome; spinal cord injury

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Introduction

Urinary incontinence (UI) severely impacts quality of life and is associated with considerable healthcare costs (1,2). The most common subtype of UI in women is stress urinary incontinence (SUI), defined by the International Continence Society as "*the complaint of involuntary leakage on effort or physical exertion or on sneezing or coughing*" (3). Depending on age, SUI occurs as primary symptom in approximately 50% of women with UI (4) and is typically caused by weakened pelvic floor musculature and innervation, including that of the external urethral sphincter, which is usually associated with pelvic floor damage due to vaginal delivery. SUI in male patients is less common and typically occurs after prostate surgery, with a radical prostatectomy (RP) as the most common cause (5). Other etiologies include transurethral resection of the prostate (TURP), internal urethrotomy, radiation therapy (RT) for treatment of prostate cancer or neurogenic lower urinary tract dysfunction (NLUTD).

First-line management of non-NLUTD SUI patients consists of conservative treatment, primarily pelvic floor rehabilitation. When conservative treatment fails, surgical treatment options can be offered. These include various types of slings, bulking agents, artificial urinary sphincters (AUS) and adjustable continence therapy balloons, abbreviated ProACT™ for male and ACT™ for female patients (Uromedica, Inc., Plymouth, MN, USA). The AUS is considered the highest evidence-based treatment of SUI; however, it is prone to revisions and infections due to its invasive nature and the lack of adjustability possibilities after surgery. Furthermore, not all patients are comfortable with an AUS or capable to use the scrotal pump. First described in 2005 by Hübner *et al.* (6), the ProACT™ and ACT™ offer a minimally invasive surgical procedure with two volume-adjustable continence balloons with the aim to achieve continence in SUI patients. Since then, ProACT™ was approved for male patients (7) and many clinics have implemented the ProACT/ACT™ to treat SUI in male and female patients.

This narrative review aims to provide an overview of the current implementation of the ProACT/ACT™, including its functional outcomes, safety and predictors of treatment failure or complications in different patient populations. We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-807/rc).

Procedure

Preoperative assessment

Prior to ProACT/ACT™ implantation, thorough patient assessment should be conducted, including full medical history, physical examination and additional diagnostics. To assess UI severity, subjective pad usage per day or provocative pad weight testing is recommended. Pad weight testing have been considered of higher value to rate UI severity (8), but this method is more time-consuming and complex for patient and healthcare provider. In addition to pad testing, it is recommended to obtain a voiding diary and a validated and appropriate questionnaire to capture a broad overview of the patient's urinary situation, i.e., Urogenital Distress Inventory (UDI-6) or International Consultation of Incontinence Questionnaire-Short Form (ICIQ-SF) (9,10). Preoperative urodynamic testing and cystoscopy is recommended by the European Association of Urology (EAU) guidelines for non-neurogenic male lower urinary tract symptoms (11) and should therefore be considered to confirm the primary SUI diagnosis and assess the bladder function during filling and micturition. Furthermore, it may identify a possible obstruction, low compliance and detrusor over- and underactivity, which may lead to postoperative complications.

Clinicians should inform patients preoperatively that they are usually not continent directly after implantation. Although swollen tissues around the urethra following device placement could cause temporary continence, the majority needs several balloon volume adjustments to reach the desired treatment effect. The risk of complications and revisions should be anticipated by the patient as well, although device removal can take place under local anesthesia. Especially in female and NLUTD patients, less information is available on functional and safety outcomes after ProACT/ACT™ implantation. This should be taken into account as well. *Table 1* presents indications and relative contraindications for use of slings, AUS and ProACT™ in non-NLUTD male patients. It is advised to not use ProACT™ after pelvic RT (11).

Surgical technique

In our clinic at the Erasmus Medical Center of Rotterdam, implementation of adjustable continence therapy is currently only performed in male patients. ProACT™ balloons are generally implanted under general anesthesia

Table 1 Indications for male urethral sling, artificial urinary sphincter or adjustable continence therapy balloons[1]

Indications	Slings	AUS	ProACT™
Cognitive impairment or reduced dexterity	x		x
Mild SUI	x		x
Severe SUI		x	x
Previous prostate radiation therapy		x	
TURP	x	x	x

[1], an "x" illustrates that the treatment modality could be offered to a patient with the specified indication. AUS, artificial urinary sphincter; SUI, stress urinary incontinence; TURP, transurethral resection of the prostate.

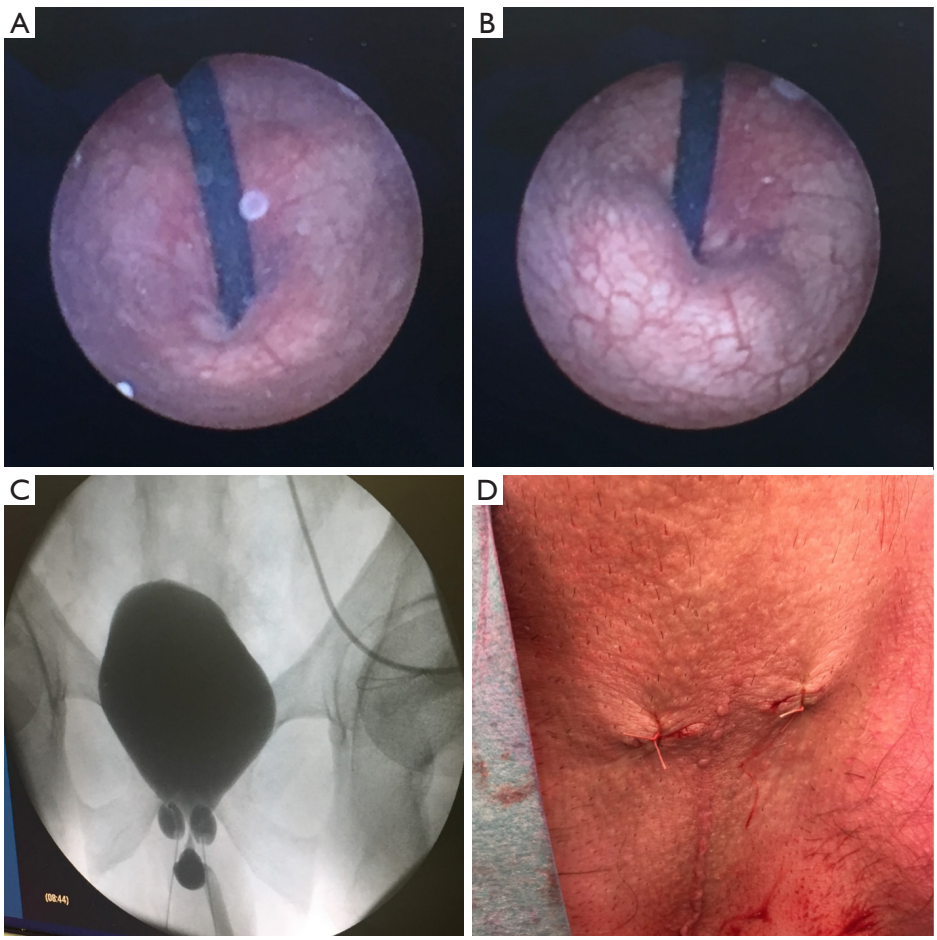

Figure 1 Retrovision of the bladder neck using flexible cystoscopy in a post-prostatectomy incontinent patient before ProACT™ balloon implantation (A) and after implantation of two balloons (B); anterolateral fluoroscopic view of the bladder, urethra and ProACT™ balloons *in situ* (C); postoperative result at the perineum after the minimally invasive ProACT™ implantation (D).

with fluoroscopic control and retrovision of the bladder neck using a flexible cystoscope in patients with post-prostatectomy incontinence (PPI) (*Figure 1A-1C*). In patients with post-TURP incontinence (PTI), we use a rigid cystoscope Ch19. In male patients, two ProACT™ balloons are implanted with a sharp trocar at either side of the urethra just distal to the bladder neck in PPI or to the prostate in PTI, in both cases cranial to the pelvic floor

Table 2 The search strategy summary

Items	Specification
Date of search	1 September 2022
Databases and other sources searched	PubMed/Medline
Search terms used	Incontinence, balloons, adjustable, Uromedica, ACT, ProACT
Timeframe	2002 to 2022
Inclusion criteria	English and Dutch language original articles and reviews
Selection process	S.d.H.

via a perineal approach (*Figure 1D*). In female patients, a similar approach is performed (12), where two incisions are made between the labia majora and minora and ACT™ balloons implanted at the same location as in male patients. The position of the trocar and balloons are controlled with fluoroscopy. After positioning, the titanium ports connected to the balloons are placed subcutaneously at the scrotum lateral to the testes or in the labia majora. Through these ports, balloons are initially filled with a mixture of 1mL of sterile saline and iodinated contrast agent.

Postoperative management

A transurethral urinary catheter is placed after ProACT™ implantation. The catheter is removed approximately two hours later, and a micturition trial is conducted to ensure there is no significant post-void residue. Our clinic considers an accepted post-void residue as a maximum of one third of the functional bladder capacity. Once this is achieved, the patient is discharged. The patient is asked to avoid physical exercise such as lifting more than ten kilograms, cycling, jogging or being sexually active prior to the first outpatient visit 4 to 6 weeks after implantation. At this visit and every 2 weeks after, the balloons are inflated with a mixture of saline and contrast medium, adding 1 mL per visit until continence was almost reached, post-void residual increased or a subjectively weaker stream. A hypodermic needle is used to reach the desired effect, with a maximum of 8 mL. Validated questionnaires conducted at baseline and pad testing could be repeated postoperatively to objectively obtain treatment effects.

Methods

Publications on the use of adjustable continence balloons in SUI patients were collected and reviewed in September 2022 in the PubMed database using a combination of the following search terms: urinary incontinence, ProACT, ACT, adjustable continence (balloons) and Uromedica. As this intervention involves a relatively new surgical technique, the literature search was limited to articles published within the past 20 years. Studies citing included articles were reviewed for inclusion as well. Case reports, conference abstracts and editorials were not included. No further exclusion criteria were applied, since we intended to describe the wider application of the ProACT/ACT™ in SUI patients. *Table 2* provides an overview of the literature search method.

Discussion

Implantation methodology

Although implantation methodologies appeared similar across different studies, variations in placement guidance were described (*Tables 3*,*4*).

The use of transrectal ultrasound guidance (TRUS) instead of fluoroscopic control was reported in some earlier (17,20-22,24) and one recent study (18), mostly in studies from Italy. While fluoroscopy provides two-dimensional planes to guide device placement, TRUS provides a three-dimensional visualization of anatomical structures, the device and the inserted urinary catheter. In theory, intraoperative complications such as bladder and urethral perforation may be avoided considerably and balloons can be placed more accurately when using TRUS over fluoroscopic guidance without concomitant control with a flexible cystoscope. The significance of accurate balloon placement was previously expressed by Giammò *et al.* (55). In patients with poor functional outcomes after treatment, it was found that placement of balloons was not optimal.

Table 3 Characteristics for studies on ProACT™ for patients after prostate surgery

Author	Year	Design	N	Patient population (n)	Age (years)	Follow-up (months)	Methodology	Remarks
Al-Najar (13)	2011	NR	40	RP: 40	Mean: 68	8+6 after implantation	NR	After sling failure, 15/40 patients treated with ProACT™
Bada (14)	2023	Retrospective	42	RP: 42	Median: 68	Median: 102.5	Fluoroscopy + rigid cystoscopy	–
Baron (15)	2017	Retrospective	14	RP: 13; Ablatherm®: 1	Median: 69	Median: 34	Fluoroscopy + rigid cystoscopy	After sling failure
Crivellaro (16)	2008	Prospective	84	RP: 84	Mean: 67 *vs.* 65	Median: 19 *vs.* 33	Fluoroscopy + rigid cystoscopy	N=46 ProACT™ *vs.* n=38 BAMS
Crivellaro (17)	2012	Prospective	42	RP: 42	Mean: 65.2	Mean: 12	TRUS	–
Finazzi (18)	2019	Retrospective	240	RP: 218; BPO treatment: 22	Mean: 68.3	Mean: 44.8	Fluoroscopy + rigid cystoscopy: n=179; TRUS: n=61	–
Gilling (19)	2008	Prospective	37	RP: 30; HoLEP: 7; SRT: 4	Mean: 69.9	Mean: 51.5	Fluoroscopy + rigid cystoscopy	–
Gregori (20)	2006	Prospective	7	RP: 7	Mean: 68.4	Median: 5	TRUS	–
Gregori (21)	2008	Prospective	11	RP: 11	Mean: 69.9	Mean: 51.5	TRUS	–
Gregori (22)	2010	Retrospective	79	RP: 79	Mean: 67.9	Mean: 25	TRUS	–
Hübner (6)	2005	Prospective	117	RP: 110; TURP: 6; cystectomy: 1	Median: 70	Mean: 13	Fluoroscopy + rigid cystoscopy	–
Hübner (23)	2007	Prospective	100	NR	Mean: group 1, 72; group 2, 69	Mean: group 1, 23; group 2, 20	Fluoroscopy + rigid cystoscopy	First 50 patients (group 1) *vs.* most recent 50 patients (group 2)
Kjær (24)	2012	Retrospective	114	RP: 67; palliative TURP: 7; BPO treatment: 34; NLUTD: 5; bladder cancer: 1	Median: 68	Median: 58	TRUS + fluoroscopy	Combination of TRUS and fluoroscopy in most patients
Kocjanic (25)	2007	NR	64	RP: 60; TURP: 3; cystectomy: 1	Mean: 65.4	Mean: 19.51	Fluoroscopy + rigid cystoscopy	–
Lebret (26)	2008	Prospective	62	RP: 57; TURP: 4; HIFU: 1	Mean: 71.1	12	Fluoroscopy + rigid cystoscopy	–
Martens (27)	2009	Retrospective	29	RP: 29	Mean: 65	NR	Fluoroscopy + rigid cystoscopy	–
Munier (28)	2020	Retrospective	27	RP: 27	Mean: 72	Mean: 36	Fluoroscopy	After sling failure, no information about cystoscopy use
Nash (29)	2018	Prospective	124	RP: 117; TURP: 12; laser ablation: 3	Mean: 69.7	18	Fluoroscopy	No information about cystoscopy use
Nash (30)	2019	Prospective	68	RP: 66; TURP: 6; laser ablation: 1	Mean: 69.2	48	Fluoroscopy	No information about cystoscopy use

Table 3 *(continued)*

Table 3 *(continued)*

Author	Year	Design	N	Patient population (n)	Age (years)	Follow-up (months)	Methodology	Remarks
Nestler (31)	2019	Retrospective	134	RP: 102; TURP: 28; unknown: 4	Median: 71	Median: 118	Fluoroscopy	No information about cystoscopy use
Noordhoff (32)	2018	Retrospective	143	RP: 143	Median: 69	Median: 46	Fluoroscopy + rigid/flexible cystoscopy	>2014 flexible cystoscopy
Noordhoff (33)	2019	Retrospective	29	TURP: 29	Median: 70.5	Median: 21	Fluoroscopy + rigid/flexible cystoscopy	>2014 flexible cystoscopy
Reuvers (34)	2016	Retrospective	27	RP: 27	Median: 65	Median: 7	Fluoroscopy + rigid/flexible cystoscopy	>2014 flexible cystoscopy
Ricard (35)	2022	Retrospective	200	RP: 200	Median: 68	Median: 43	Fluoroscopy + rigid (n=31)/ flexible (n=169) cystoscopy	–
Rouprêt (36)	2011	Prospective	128	RP: 120; TURP: 8	Mean: 71	Mean: 56.3	Fluoroscopy	No information about type of cystoscopy used
Trigo-Rocha (37)	2006	Prospective	25	RP: 25	Mean: 68.62	Mean: 22.4	Fluoroscopy + rigid cystoscopy	–
Utomo (38)	2013	Retrospective	49	RP: 49	Median: success, 68; nonsuccess: 75.5	Median: 9	Fluoroscopy + rigid cystoscopy	Success *vs.* nonsuccess patients
Venturino (39)	2015	Retrospective	22	RP: 18; TURP: 4	Mean: 70.2	Median: 57	Fluoroscopy + rigid cystoscopy	–
Yiou (40)	2015	Prospective	22	RP: 22	Mean: 68.6	12	Fluoroscopy + flexible cystoscopy	After sling failure
Yiou (41)	2015	Prospective	10	RP: 10	Mean: 66.8	Mean: 22.7	Fluoroscopy + flexible cystoscopy	Combined implantation erectile prosthesis + ProACT™

BAMS, bone-anchored male sling; BPO, benign prostate obstruction; HIFU, high-intensity focused ultrasound; HoLEP, holmium laser prostate surgery; NR, not reported; NLUTD, neurogenic lower urinary tract dysfunction; RP, radical prostatectomy; TURP, transurethral resection of the prostate; TRUS, transrectal ultrasound; SRT, salvage radiation therapy.

This emphasizes the role of accurate balloon placement in outcomes after ProACT™ implantation.

TRUS was compared with fluoroscopy in a retrospective series published by Finazzi *et al.* in 2019 (18), with 61 patients receiving TRUS and 179 fluoroscopic guidance. All 16 intraoperative complications occurred with fluoroscopic guidance, however no statistically significant differences in success (16.4% *vs.* 34.8%) and improvement rates (67.2% *vs.* 67.8%) were found between TRUS and fluoroscopy after 24 months. The author noted that the TRUS technique was primarily used by experienced ProACT™ surgeons, which should be taken into account when drawing conclusions from these data.

Few studies used flexible cystoscopy instead of conventional rigid cystoscopy. Ricard *et al.* retrospectively compared outcomes between these techniques during

Table 4 Characteristics of studies on ProACT/ACT™ for female and NLUTD patients

Author	Year	Design	N	Patient population (n)	Age (years)	Follow-up (months)	Methodology	Remarks
Aboseif (42)	2009	Prospective	162	Non-NLUTD: 162 F	Mean: 67.4	12	Fluoroscopy	–
Aboseif (43)	2011	Prospective	89	Non-NLUTD: 89 F	Mean: 67.9	12	Fluoroscopy	After failed surgical SUI treatment
Ammirati (44)	2017	Retrospective	16	NLUTD: 13 M, 3 F	Mean: 47.5	Mean: 37	Fluoroscopy	–
Billault (45)	2015	Retrospective	52	Non-NLUTD: 52 F	Median: 83	Median: 10.5	Fluoroscopy + rigid cystoscopy	Patients aged >80 years
de Guerry (12)	2023	Retrospective	281	Non-NLUTD: 229 F; NLUTD: 52 F	Median: 71	12	Fluoroscopy + flexible cystoscopy	–
De Meestere (46)	2022	Retrospective	277	Non-NLUTD: 226 F; NLUTD: 51 F	Mean: Non-NLUTD, 69.1; NLUTD, 65.9	12	Fluoroscopy + flexible cystoscopy	Non-NLUTD *vs.* NLUTD
Freton (47)	2018	Retrospective	25	Non-NLUTD: 24 F; NLUTD: 1 F	Mean: 70.4	Mean: 22.3	Fluoroscopy + flexible cystoscopy	N=25 ACT™ *vs.* n=36 AUS
Galloway (48)	2013	Prospective	162	Non-NLUTD: 162 F	Mean: 67.4	Mean: 29.7	Fluoroscopy	–
Kocjanic (49)	2008	NR	49	49 F	NR	Mean: 40.1	Fluoroscopy	–
Kocjanic (50)	2010	Prospective	57	57 F	Mean: 62.59	Mean: 72	Fluoroscopy	–
Mehnert (51)	2012	Retrospective	37	NLUTD: 13 M, 24 F	46.2	48	Fluoroscopy + rigid cystoscopy	–
Ronzi (52)	2019	Retrospective	102	NLUTD: 55 M, 47 F	Mean: 48.4	Mean: 32.4	Fluoroscopy + rigid or flexible cystoscopy or TRUS	–
Stecco (53)	2006	Prospective	25	NR	NR	12	Fluoroscopy	–
Wachter (54)	2008	Retrospective	41	Non-NLUTD: 41 F	Mean: 72.9	Mean: 25	Fluoroscopy	–

AUS, artificial urinary sphincter; F, female; M, male; NR, not reported; NLUTD, neurogenic lower urinary tract dysfunction; TRUS, transrectal ultrasound; SUI, stress urinary incontinence.

ProACT™ implantation in male non-NLUTD patients and found no differences in efficacy or complications between both techniques (35). The author noted that these findings are in contrast to Vayleux's findings in female patients, where a higher success rate and lower complication rate were found in patients operated with flexible cystoscopy guidance (56). A more complex and challenging implantation of adjustable balloons through a scarred pelvic floor in male patients compared to female patients could be the explanation for this difference in outcomes.

A flexible cystoscope has several potential advantages over a conventional rigid cystoscope. Retrovision of the bladder neck is possible with flexible cystoscopy and provides additional guidance for trocar and balloon localization besides fluoroscopy. This may result in less bladder or urethral perforation during surgery. In patients that underwent RP, scar tissue is formed around the proximal urethra, forming a bladder-urethra anastomosis. Inducing friction at the anastomosis with a rigid cystoscope could increase SUI severity postoperatively, which is avoided when a flexible cystoscope is used.

Working mechanism

The working mechanism of ProACT/ACT™ differentiates it from other surgical options for treating SUI, as it applies non-circumferential compression at two opposite sites around the urethra. In contrast with AUS or slings, where

circumferential and compressive elevation are applied respectively relatively distal from the bladder neck, the ProACT/ACT™ is placed at either side of the urethra close to the bladder neck.

To date, few studies attempted to identify the exact working mechanism of ProACT™ using urodynamic studies (34,38), however none were conducted in female patients with ACT™ implantation. These studies were performed in PPI patients and urodynamic parameters were compared between baseline and follow-up in successfully and non-successfully treated patients. The first to report outcomes on the working mechanism were Utomo *et al.* (38), indicating that an increase in urethral pressure seems to be one of the factors associated with a better continence function after ProACT™ implantation. A more recent study by Reuvers *et al.* (34) found that in successfully treated PPI patients, the maximum urethral close pressure (MUCP) significantly increased, while in non-successfully treated PPI patients MUCP did not increase significantly. However, the author noted that an increase in MUCP was not observed in all successfully treated patients. The exact working mechanism is not yet fully understood, but the effort by these studies helps identifying how implantation of ProACT™ balloons results in regaining continence, why treatment fails in certain patients and how we can predict which patients will benefit from ProACT™ implantation.

Functional outcomes

The implementation of ProACT/ACT™ for management of SUI is most frequently described in male non-NLUTD patients, mostly for treatment of PPI or PTI. All reporting literature was of observational nature, predominantly with a retrospective approach. Studies on postoperative functional outcomes were reviewed and presented in *Table 5* for male non-NLUTD SUI patients and *Table 6* for female and NLUTD patients, as some studies included both NLUTD and non-NLUTD female patients.

Studies most often used urinary pad data for primary functional outcomes, defining treatment 'success' as postoperative continence or a maximum of one pad per day and treatment 'improvement' as a reduction of at least 50% in daily pad count or weight with respect to baseline values. Studies including female or NLUTD patients were less consistent with assessing functional outcomes. Pooling results of individual studies is challenging, especially because of varying outcome measures on pad weight or number of pads. A recent systematic review attempted to combine the results of ProACT™ outcomes in non-NLUTD male SUI patients and reported a pooled proportion of 81.9% [95% confidence interval (CI): 74–87.8%] as improved after ProACT™ implantation, including 60.2% (95% CI: 54.2–65.9%) of patients that were successfully treated. More recent studies that were published following this review reported similar results, with success rates ranging between 29.6% and 66.7% (14,18,28,30,35). One of the recent studies with the lowest success rate was conducted by Finazzi *et al.*, with a success rate of 29.6% after a 24-month follow-up period (18).

The majority of non-NLUTD male ProACT™ studies included patients with PPI. In some studies, a minority of patients had other prostate surgeries, with TURP as most frequently described. Noordhoff *et al.* (33) studied functional outcomes in 29 PTI patients only and found a 45% success and 76% improvement rate with a median follow-up time of 28 months. Subjective improvement in health was also assessed with the patient global impression scale of improvement (PGI-I). All but one patient reported at least slight improvement, with 69% describing their condition as "much better" since ProACT™ implantation, concluding that the majority of PTI patients are satisfied with ProACT™ balloons.

As ProACT™ treatment is not always implemented as first surgical treatment, there are patients eligible for ProACT™ balloons with a failed male urethral sling (MUS) *in situ* for treatment of PPI. Al-Najar was the first to our knowledge to report outcomes with ProACT™ placement after failed MUS treatment (13). Forty patients implanted with MUS were prospectively followed for 8 months, with fifteen patients not improved at follow-up. Ten of these fifteen patients received ProACT™ placement and were fully continent within 6 months after subsequent ProACT™ treatment. Another two patients were already implanted with ProACT™ balloons before MUS implantation, and were fully continent after additional ProACT™ fillings following MUS failure. This suggests that there is a possible synergic effect with MUS and ProACT™ implantation, especially because of their distinctive mechanisms of action. In two other small case series by Baron *et al.* (15) and Yiou *et al.* (40), fourteen and twelve patients with ProACT™ implantation after failed MUS were included respectively. Baron observed a continence rate of 28%, with five of nine patients reporting their condition to be much better or very much better after ProACT™ placement (15). Yiou found similar continence rate as in patients without failed MUS, with 66% of patients dry 1 year after ProACT™

Table 5 Definitions and outcomes of cure and improvement rates in studies on ProACT™ for patients after prostate surgery

Author	Year	Success definition	Success (%)	Improvement definition	Improvement (%)
Al-Najar (13)	2011	Dry or 1 security PPD	100	>50% reduction in PPD	100
Bada (14)	2023	Dry [1] or 1 security PPD [2]	[1] 59.5; [2] 85.7	>50% reduction in PPD	90.5
Baron (15)	2017	24-h pad weight <8 grams [1] or <1 PPD [2]	[1] 29; [2] 57	NR	NR
Crivellaro (16)	2008	Dry or 1 security PPD	68	>50% reduction in PPD	84
Crivellaro (17)	2012	Dry or 1 security PPD	70	>50% reduction in PPD	90
Finazzi (18)	2019	24-h pad weight <8 grams	29.6	>50% reduction in 24-h pad weight	67.1
Gilling (19)	2008	Dry [1] or 1 security PPD [2]	[1] 62; [2] 81	NR	NR
Gregori (20)	2006	0 PPD	75	Subjective improvement	100
Gregori (21)	2008	24-h pad weight <8 grams [1] or ≤1 PPD [2]	[1] 63.6; [2] 63.6	>50% reduction in PPD	100
Gregori (22)	2010	24-h pad weight <8 grams or <1 PPD	66.1	>50% reduction in PPD	91.9
Hübner (6)	2005	Dry or 1 security PPD	67	>50% reduction in PPD	80
Hübner (23)	2007	Dry or 1 security PPD	First 50 pts: 52; last 50 pts: 60	>50% reduction in PPD	First 50 pts: 60; last 50 pts: 82
Kjær (24)	2012	24-h pad weight <8 grams or ≤1 PPD	50	>50% reduction in 24-h pad weight or PPD	72
Kocjanic (25)	2007	Dry or 1 security PPD	67	>50% reduction in PPD	83
Lebret (26)	2008	Dry or 1 security PPD	21	>50% reduction in PPD	72.6
Martens (27)	2009	Dry [1] or 1 security PPD [2]	[1] 20; [2] 36	NR	NR
Munier (28)	2020	0 PPD	66.7	>50% reduction in PPD	96.3
Nash (29)	2018	90–100% reduction in 24-h pad weight	41	>50% reduction in 24-h pad weight	61
Nash (30)	2019	90–100% reduction in 24-h pad weight	42.6	>50% reduction in 24-h pad weight	80.9
Nestler (31)	2019	NR	NR	>50% reduction in PPD and ≤2 PPD	83.6
Noordhoff (32)	2018	Dry or 1 security PPD	51	>50% reduction in PPD	64
Noordhoff (33)	2019	Dry or 1 security PPD	44.8	>50% reduction in PPD	75.8
Reuvers (34)	2016	Dry or 1 security PPD	85.2	NR	NR
Ricard (35)	2022	Dry or 1 security PPD and PII ≥80%	40.1	>50% reduction in PPD and PII ≥50%	78
Rouprêt (36)	2011	Dry or 1 security PPD	66	Subjective improvement	75
Trigo-Rocha (37)	2006	Dry or 1 security PPD	65.2	NR	NR
Utomo (38)	2013	Dry or 1 security PPD	75.5	NR	NR
Venturino (39)	2015	0 PPD	4.5	>50% reduction in PPD or <2 PPD	45
Yiou (40)	2015	Dry [1] or 1 security PPD [2]	[1] 44.4; [2] 66.7	>50% reduction in PPD	94.4
Yiou (41)	2015	0 PPD	60	>50% reduction in PPD	100

NR, not reported; PPD, pads per day; PII, patient's impression of improvement; pts, patients.

Table 6 Definitions and outcomes of cure and improvement rates in studies on ProACT/ACT™ for female and NLUTD patients

Author	Year	Success definition	Success (%)	Improvement definition	Improvement (%)
Aboseif (42)	2009	<2 grams of provocative pad weight test	52	>50% reduction of provocative pad weight test	80
Aboseif (43)	2011	<2 grams of provocative pad weight test	47	>50% reduction of provocative pad weight test	92
Ammirati (44)	2017	0 PPD	43.8	>50% reduction in PPD	62.5
Billault (45)	2015	Subjective: fully continent	13.5	Subjective: >80% improvement	38.5
de Guerry (12)	2023	Dry or 1 security PPD + NRS ≥8/10	37.0	Decrease in PPD + NRS ≥5/10	70.5
De Meestere (46)	2022	Dry or 1 security PPD + NRS ≥8/10	NLUTD: 39.2; Non-NLUTD: 36.3	Decrease in PPD + NRS ≥5/10	NLUTD: 70.6; Non-NLUTD: 69.9
Freton (47)	2018	NR	NR	NR	NR
Galloway (48)	2013	<2 grams of provocative pad weight test	12 months: 51; 60 months: 76	>50% reduction of provocative pad weight test	12 months: 83; 60 months: 93
Kocjanic (49)	2008	Subjective: dry	68	Subjective: improvement	84
Kocjanic (50)	2010	Subjective: dry	62	Subjective: improvement >50%	92
Mehnert (51)	2012	Subjective: fully continent	38.9	Subjective: improvement >50%	54.5
Ronzi (52)	2019	Numeric scale on incontinence (0–100): complete continence (100/100)	4.9	Subjective: improvement >50%	51.2
Stecco (53)	2006	0 PPD	64	Dry or 1 security PPD	84
Wachter (54)	2008	0 PPD	44	>50% reduction in PPD	59

NR, not reported; NRS, numeral rating scale; NLUTD, neurogenic lower urinary tract dysfunction; PPD, pads per day.

implantation (40).

In a separate study, Yiou described the feasibility of ProACT™ placement in patients with erectile prosthesis *in situ* (41). In terms of urinary functional outcomes, all patients showed improvement, with six of ten patients reaching full continence. Significant improvement on subjective sexual and urinary functions were observed as well, concluding that ProACT™ is feasible in combination with an erectile prosthesis, with no differences in outcomes between asynchronous or synchronous implantations.

Outcomes for female ACT™ implantations were less frequently described. A systematic review on ACT™ balloons was published in 2014 (57), which noted that literature up till 2014 had reported a continence rate of 15–44% and a subjective improvement rate of 66–78.4% at the end of follow-up. At least six English language studies were published after this review (12,44-47,52), including a large retrospective series with 281 patients (12). This study by de Guerry *et al.* followed patients implanted with ACT™ for 12 months and reported continence and improvement rates of 37% and 70.5% respectively. These outcomes are in line with outcomes of a previously published systematic review, but continence rates remain lower than in male non-NLUTD ProACT™ patients. ACT™ is usually offered as secondary option in female patients when other surgical SUI treatments fail, such as synthetic midurethral sling failure, possibly explaining in part why success rates are lower compared to outcomes in male non-NLUTD SUI patients.

Few studies investigated ProACT/ACT™ implantation in NLUTD patients (12,44,46,47,51,52). Most of these studies had overlapping patient populations or only had a small percentage of NLUTD patients in their patient population. A recent systematic review observed a pooled continence and improvement rate of 12% and 17% respectively after a mean follow-up of 1.4 to 3.16 years. Ronzi *et al.* presented the largest cohort of NLUTD SUI patients implanted with ProACT/ACT™ (52). Patients

included in this retrospective multicenter study were on average younger (mean: 48.4 years) than non-NLUTD male patients (mean: 67.5 years) (5) and female patients (mean: 62 to 73 years) (57) in other studies. Only 4.9% of patients were completely continent after a mean follow-up of 32 months. 51.2% of patients were improved, of whom 14.6% improved at least 90%.

Complications

Despite ProACT/ACT™ device placement being a minimally invasive procedure, generally performed within a short surgical time, some intraoperative and postoperative complications are possible. Complications were usually well-described in the literature, with bladder or urethral perforation as the most common intraoperative complication during device implantation. Urethral or bladder perforations were estimated to occur in 5.3% (5) and 3.7–4.5% (57) of male patients in post-prostate surgery SUI and female SUI patients respectively. In the event of mild urethral perforation, the ProACT/ACT™ balloon can still be implanted at the side of the perforation followed by an indwelling catheter during 1 week with antibiotic prophylaxis. In some cases, the balloon must be implanted several weeks later, usually without postoperative consequences.

Relatively common early complications include hematoma, acute urinary retention and infection. The incidence of the latter two were estimated in a recent meta-analysis as respectively 2.2% (95% CI: 1.1–4.3%) and 1.5% (95% CI: 0.7–3.4%) in male patients after prostate surgery. Management of acute urinary retention after ProACT™ implantation varied between studies, but generally an indwelling catheter is placed for several days in combination with antibiotic prophylaxis. Alternatively, deflating the balloon can be sufficient to solve urinary retention. If the infection cannot be cured with antibiotics, device removal or replacement is necessary. Other late postoperative complications such as device migration, rupture or urethral erosion could result in a revision surgery as well.

Postoperative urethral erosion is another complication which frequently leads to explantation with reimplantation of the device. Pooled analysis showed that urethral/bladder erosion occurs in 3.8% (95% CI: 2.3–6.2%) of non-NLUTD male ProACT™ patients after a mean follow-up of 102.5 months (5). The incidence of urethral erosion development was high especially in previously irradiated patients (22,35,36). For non-NLUTD female and NLUTD patients, incidence rates of erosion varied profoundly across studies, reporting rates of 0.4% to 9% and 18.75% to 20.6% respectively. As the incidence of erosion could increase over time and very long-term data (>10 years) is not available for ProACT/ACT™ data yet, we do not know what the long-term risk is of this complication. Long-term data is available in male non-NLUTD SUI patients implanted with an AUS device, with reported urethral erosion rates of 8.5%, usually occurring within 1 to 2 years after implantation (58).

Predictors of treatment failure and complications

Many studies made an effort to identify predictors of treatment failure and complications in non-NLUTD male ProACT™ treatment (6,14,16-18,22-26,28-31,35,36,38), with previous RT in the pelvic region as the most frequently presented risk factor for treatment failure. In Rouprêt's prospective series (36), 30 of 128 included patients were treated with RT for prostate cancer before ProACT™ implantation. Failure rate among these patients was 54%, while failure rate was 27% in non-irradiated patients (P=0.02). Similar results in favor of non-irradiated patients were found in other studies (6,17,22,24-26,35,36), which resulted in general consensus that clinicians should be cautious with implantation of ProACT™ balloons in irradiated patients.

Success rates in severe, moderate and mild SUI patients after prostate surgery were described by numerous studies. In the literature, there seems to be no consensus whether patients with severe SUI have lower continence rates than those with mild or moderate SUI. Robust evidence supporting this claim is currently lacking. A comparable number of studies observed lower continence rates in severe patients (22,35,36,38) as studies reporting similar results between mild/moderate and severe patients (14,16,18,29,30). In addition to the severity of SUI, variations in the presence of pre-existent concurrent overactive bladder may partly account for the differences in functional outcomes observed across studies. Most studies, however, excluded patients with overactive bladder or other pre-existent voiding dysfunction, which makes it challenging to understand its role in causing treatment failure.

Except for Utomo *et al.* (38), studies solely used univariable analyses or independent tests between subgroups to test for significance. To illustrate the consequence of this, Ricard *et al.* observed a higher proportion of patients with a history of pelvic RT in severe patients compared with moderate or mild SUI patients, possibly influencing the functional outcomes between severity groups. This

Table 7 Possible risk factors for ProACT™ failure in patients after prostate surgery

Risk factor	Studies reporting
Pelvic RT	(6,17,22,24-26,35,36)
Severe SUI	(22,35,36,38)
Pre-existent overactive bladder	NR
Longer period between SUI diagnosis and ProACT™ implantation	(38)
Less experienced surgeon	(23)
Rigid instead of flexible cystoscope	(32)

NR, not reported; RT, radiation therapy; SUI, stress urinary incontinence.

example is further illustrated by outcomes of Nash *et al.* (30), where severe SUI patients experienced similar success rates as moderate SUI patients (50.0% *vs.* 56.6%) and higher rates than mild patients (27.6%). In this prospective series with a 4-year follow-up duration, irradiated patients were excluded. In our clinic, irradiated patients are not offered ProACT™, but AUS. We have observed that severe SUI patients have comparable outcomes to those with moderate or mild SUI. Therefore, previous pelvic RT could be the confounder missed in the analysis of studies reporting lower success rates in severe SUI non-NLUTD male patients.

The duration of SUI after RP seems to play a role in success rates as well. In a retrospective series of Utomo *et al.* (38), 37 successfully treated patients were compared with twelve non-successfully treated patients. They found that after adjusting for confounders, a longer duration of SUI increased the odds of treatment failure (odds ratio: 1.83; 95% CI: 1.17–2.83), indicating that therapy for SUI should therefore be implemented sooner than later after diagnosis to increase the probability of treatment success.

To date, four studies (12,46,52,54) attempted to identify predictors for treatment success or adverse events for female and NLUTD patients eligible for ProACT/ACT™ implantation. Although female NLUTD and non-NLUTD patients are generally offered ACT™ implantation for different indications, one study directly compared efficacy and safety outcomes between these patients (46). Outcomes were evaluated in a retrospective cohort design with a 1-year follow-up period, observing no differences between NLUTD and non-NLUTD female SUI patients for treatment success (39.2% *vs.* 36.3%, P=0.69) or improvement (70.6% *vs.* 69.9%, P=0.92). However, the author noted there was a trend towards lower complication rates in NLUTD patients than in non-NLUTD patients (24% *vs.* 34.5%, P=0.15).

de Guerry *et al.* attempted to find additional risk factors for treatment failure, including previous pelvic surgery or RT and urodynamic parameters such as MUCP and detrusor over activity, but found none (12). These outcomes are in contrast with outcomes in male ProACT™ patients, where RT for prostate disease in particular is identified as predictor for treatment failure and often extrapolated to female treatment assessment. The location of pelvic RT is a possible explanation for the observed difference between male and female patients, as RT for prostate cancer is located more proximal at the location of balloon placement than RT for cervical or endometrial malignancies. In addition, outcomes described by de Guerry do not agree with studies reporting urodynamic parameters prior to midurethral sling surgery for predicting treatment failure (59). Baseline mixed UI, previous SUI surgery and detrusor overactivity were all associated with unfavorable outcomes after midurethral sling placement. Similar future studies for ProACT/ACT™ placement could help predict which patients are at risk for unfavorable outcomes and complications.

Ronzi *et al.* (52) reported improvement and complications rates between male and female NLUTD patients, but found no statistically significant differences between the two groups. However, a trend was observed towards higher improvement (65.9% *vs.* 34.2%) and lower complications rates (64.2% *vs.* 87.8%) in male patients. Still, improvement rates are generally lower in NLUTD patients than in non-neurological patients. The author hypothesized that these lower continence and improvement rates in NLUTD compared to non-NLUTD patients can be attributed to the complexity of urological management in NLUTD patients. This is relevant especially in patients with a progressive disease, such as multiple sclerosis, where both type and severity of lower urinary tract dysfunction can change over time (60,61). Underlying worsening or new-onset NLUTD detrusor overactivity in NLUTD SUI patients could negatively impact the success and improvement rates compared to non-NLUTD patients as well. ProACT/ACT™ balloons have a potential advantage over urethral slings, as they can be adjusted in volume over time, allowing for greater flexibility and control over treatment outcomes.

An overview of potential predictors of ProACT™ failure or complications in patients after prostate surgery are presented in *Table* 7. Studies supporting these predictors with their findings are included in *Table* 7 as well. Only

predictors for ProACT™ treatment are presented, as none were described for patients treated with ACT™ balloons.

Revision surgery

The overall risk of ProACT™ revision surgery for any reason was estimated at 22.2% (95% CI: 15.2–31.2%) with a mean follow-up of 43.2 months (5). Some recent studies not included in this estimate reported lower revision rates, with Finazzi *et al.* (18) reporting 12.5% and Bada *et al.* (14) reporting 14% revision rate with a 24 to 120 months and mean 102.5 months follow-up respectively. Ricard's large retrospective series observed a larger revision rate than previously reported in the meta-analysis, reporting a revision rate of 47.5% during a median follow-up period of 43 months. This outcome is remarkable, as 80% of devices were implanted with flexible cystoscopy guidance with retrovision of the bladder neck. It is hypothesized that this method is superior over rigid cystoscopy guidance as balloons can be placed more accurately. This difference with the meta-analysis outcome could be explained by the inclusion of RT patients in Ricard's study, as some studies in the meta-analysis excluded patients that received RT in the pelvic region before ProACT™ implantation.

In the early days of ProACT™ implementation for treatment of SUI after prostate surgery, Hübner *et al.* (23) already described that more experience with the surgical technique decreased the incidence of complications and revisions greatly. These outcomes were extrapolated to the EAU guidelines on ProACT™ placement in non-NLUTD male patients, which recommends that ProACT™ placement should only take place in expert centers (11).

One of the leading causes for revision are balloon migration or defects, the latter often reported as balloon deflation, rupture leakage or mechanical failure. Large studies (>100 patients) reported balloon failure rates ranging between 4.7% and 31.1% (18,23,24,31,33,35,36,52). We experience this phenomenon frequently as well, which makes us believe that there is still room for product improvement in order to reduce the high balloon failure rates.

Comparison with other surgical SUI treatment modalities

The general recommendation by the EAU guidelines for surgical treatment of both NLUTD and non-NLUTD SUI in female patients is placing a mid-urethral sling (62). For male NLUTD and non-NLUTD SUI patients, implantation of an AUS device is considered as an adequate surgical treatment for SUI (11,63). For most male patients who did not receive pelvic RT, ProACT™ implantation could be offered as a minimally invasive first choice treatment when conservative treatment fails (11,62,63). However, to date, no studies were published comparing a standard treatment with ProACT/ACT™ in any patient population.

In 2016, a systematic review evaluated various surgical treatment modalities for PPI patients, including AUS. The review found that the efficacy of AUS and ProACT™ were comparable (20–89% *vs.* 62–68%). However, overall complication rates were higher in patients implanted with an AUS compared to ProACT™ (19.4% *vs.* 12.3%) (64). Still, revision surgery is not uncommon after ProACT™ implantation. While explantation or reimplantation is typically performed quickly and sometimes in an ambulatory setting, this is something patients and clinicians should take into account when considering ProACT™ as a treatment option for SUI after prostate surgery. It could also take more time to experience improvement after ProACT™ placement, as balloon inflations have intervals of several weeks to a month. Some confounding by indication is warranted when interpreting these numbers, as patients with a history of pelvic RT are usually offered AUS.

In female patients, ACT™ implantation for treatment of SUI is not routinely used. Considering subjective short- and long-term success rates of 62% to 98% and 43% to 92% respectively are reached with mid-urethral slings (65), outcomes of ACT™ do not look promising. Still, female patients are usually only offered ACT after one or more failed previous surgical treatments, mostly after sling implantation. Taking this in consideration, improvement rates of 38.5% to 92% (*Table 6*) seem reasonable, especially because functional outcomes seem to be stable or even improve over time (48).

The efficacy and safety of various surgical procedures for treatment of NLUTD SUI have recently been systematically reviewed by Musco *et al.* (66), including AUS, ProACT/ACT™, bulking agents and various types of slings. AUS seems to have the highest efficacy in NLUTD patients; however, a high frequency of complications and revision surgeries should be addressed with eligible patients. ProACT/ACT™ could be offered to patients not capable to use AUS device or when invasive surgery is not desired, but lower efficacy results and high revision rates (30–65%) were observed.

Future directions

Similar to our observations in this review, Musco *et al.*

noticed that studies on surgical treatment for SUI are generally of poor quality due to the observational study designs, most frequently with a retrospective approach (66). Comparing studies that report on difference surgical modalities can therefore be challenging, considering the high risk of confounding by indication. Discussed by many authors on surgical management for treatment of SUI, prospective trials with sufficient power are required, preferably in a randomized design comparing AUS or midurethral sling with ProACT/ACT™.

Fortunately, there are several prospective trials registered, including one non-randomized prospective post-approval study for ProACT™ placement in male patients diagnosed with SUI after prostate surgery (67) and one in female patients for ACT™ placement with a similar study design (68). One on-going randomized clinical trial is comparing the AMS 800™ AUS device with ACT™ in female patients with SUI due to intrinsic sphincter deficiency (69). The outcomes of this study will aid clinicians in offering a suitable surgical treatment for female SUI patients when urethral sling is unsuccessful or not feasible, especially because AUS and ACT™ are currently positioned on the same level of recommendation by the EAU guidelines (62).

Most importantly, future research should assess why ProACT/ACT™ balloons fail over time, especially because balloon leakage is highly incident and one of the main reasons for revision surgery. Development of improved quality devices will decrease the number of revision surgeries and improve functional and patient satisfaction outcomes. Furthermore, flexible cystoscopy to guide the trocar movement towards the bladder neck using retrovision should be implemented and evaluated more frequently, as less intraoperative complications and more accurate balloon placement are expected when using this technique. We look forward to seeing the results of these type of studies.

Limitations

With respect to systematic reviews, narrative reviews are inherently associated with specific limitations. In this review, studies were not critically assessed for potential biases, nor was a comprehensive systematic search method used. Most importantly, there is always the risk of selection bias of studies supporting our expert opinions. For this specific review, we were not able to include French or Italian language studies on this subject. In addition, due to the observational design of included studies with heterogeneous outcome assessments, comparing and weighing studies against each other could have resulted in invalid conclusions. We attempted to minimize the aforementioned risks by carefully evaluating studies in favor and disfavor of a certain belief or outcome.

Conclusions

Over the last two decades, there has been considerable interest in an alternative surgical treatment for SUI using adjustable continence therapy balloons. The minimally invasive ProACT/ACT™ procedure have been described and implemented in many studies for different patient populations. For patients with SUI after prostate in particular, ProACT™ implantation can be considered to avoid more invasive surgical treatment such as placement of an AUS. Still, progress can be made regarding functional outcome assessment, especially in female and NLUTD patient populations. Future research should consistently use functional outcome assessments recommended by guidelines. This is necessary to demonstrate which role ProACT/ACT™ will have in the future for these patients with respect to urethral slings and AUS.

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