

# #72 EFFICACY AND SAFETY OF PROACT™ FOR THE TREATMENT OF MALE POST-SURGICAL STRESS URINARY INCONTINENCE: A SYSTEMATIC REVIEW OF LITERATURE

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## BACKGROUND AND OBJECTIVE

Stress Urinary Incontinence (SUI) is one of the most clinically significant complications following prostate surgery, with rates varying between 3%-74% for post-prostatectomy incontinence<sup>1</sup> and 0%-0.5% for post-TURP incontinence.<sup>2</sup> When conservative management fails to re-establish continence, the recommended treatment is implantation of a urinary incontinence device. The aim of this study is to perform a systematic review of the evidence regarding the male Adjustable Continence Therapy (ProACT™) device, with focus on its functional outcomes and complications in the treatment of SUI.

## METHODS

A computerised systematic search of papers published from 1998 in English language was independently conducted by two of the authors on three databases [MEDLINE (Via Pubmed), Scopus and ISI Web of Science] in January 2018. Search terms included: "Adjustable Continence Therapy", "Adjustable Continence Balloons", "ProACT" and "Periurethral Balloons". 814 records were identified through the database search. Abstract-only publications, conference papers and reviews were deemed not eligible. To be eligible, studies had to have minimum follow-up of 12 months, cohort size of more than 20 consecutive patients, complete reporting of both outcomes and complications with the device, and no other urinary incontinence device implanted at the time of ProACT™ implantation. After removing duplicate results and assessing eligibility based on outlined requirements, 11 articles were included in the qualitative synthesis (Fig.1). Systematic review and data extraction were conducted independently and then cross-checked by two authors using data extraction forms. No disagreement during the inclusion process occurred.

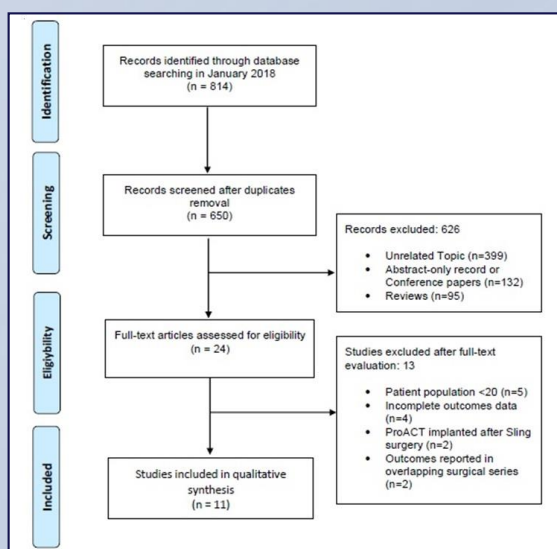


Fig.1 PRISMA Flow Diagram

## RESULTS

(Fig.2) Of the 11 studies selected for review, 9 were prospective single centre studies, 1 was a prospective multicentre study, and 1 was a retrospective single centre study. These studies involved 833 patients in total, with a mean/median time of follow-up up to 58 months. Most patients had the ProACT™ device implanted to treat post-prostatectomy SUI (59%-100%). In all studies, the primary outcome assessed was reduction in pad per day usage. Most of the studies also assessed changes in the I-QoL score after implantation. All studies reported perioperative and long-term complications with the device. Success rates varied between 45%-71% (definition of success: 0 pad or 1 pad per day postoperatively, 8 studies) and 4.5%-68% (definition of success: 0 pad per day postoperatively, 3 studies). The mean number of pads per day ranged from 2.8 to 5.9 preoperatively and 0.75 to 3.9 postoperatively (10 studies). The mean I-QoL score ranged from 31.7 to 61.0 preoperatively and 66.3 to 84.3 postoperatively (10 studies). The main perioperative complications recorded were: urethral perforation (up to 11.9%), bladder neck perforation (up to 9%), and acute urinary retention (up to 5%), No study reported significant perioperative bleeding. The main postoperative complications recorded were: migration/dislocation of the device (up to 14%), urethral erosion (up to 11.1%), infection (up to 8%) and balloon rupture/loss of volume (up to 15.4%). Overall the rate of revisional surgical procedures ranged from 6.3% to 34.3% (9 studies). Complications and failure rates were higher in sub-groups of patients who received radiotherapy after the prostatectomy. Postoperative complications were ranked according to the Clavien-Dindo Classification in 2 studies: one reported 3 (2.1%) grade IIIb complications in the first 30 postoperative days, the other reported 29 grade IIIb complications in 22 patients. In 3 studies, reported data allowed to assess that no grade IIIb or higher complication occurred, whereas grade IIIa complications occurred in 7.1% to 20.2% of the patients. None of the included studies reported complications rankable as grade IV or higher. The reported mean operative time ranged from 19 to 69 minutes (7 studies).

## CONCLUSIONS

The studies selected include mixed patient populations in terms of etiology of the SUI, severity of the incontinence and history of adjuvant radiotherapy. However the functional outcomes of ProACT™ and AUS are similar and seem to be superior to the ones of the male slings. Even though the AUS remains the gold-standard treatment, its complication rates are higher when compared to ProACT™. Randomised trials should be conducted to compare the different SUI treatments in terms of efficacy, long-term safety and durability. ProACT™ has low complication rates and high success rates when compared to other urinary incontinence devices. Thanks to its adjustability, minimally invasive design and short operative times, it may have the potential to be the first-line treatment of choice for males with any degree of post-surgical SUI.

Study	Study Design	Patients No.	Mean/median Follow-up (mo)	PPSUI Patients (%)	Success (%)	Definition of success	Improved (%)	Mean No. Of Pre-Operative PPD	Mean No. Of Post-Operative PPD	Surgical Revisional Procedures
Hübner e Schlarp (2005)	PSC	117	13	94	67	0 pad or 1 security PPD	25	5.6 (1-24)	1.2 (0-6)	79 procedures in 54 patients
Kocjancic et Al. (2006)	PSC	64	19.5	91	68	0 pad	15	5.2	1.54	17%
Trigo-Rocha et Al. (2006)	PSC	25	22.4	100	65	0-1 pad	13	4.76±1.71	1.83±1.58	17.3%
Lebret et Al. (2008)	PMC	62	12	100	71	0 pad or 1 security PPD	89*	4.6 (1-10)	1.06 (0-6)	30.6%
Gilling et Al. (2008)	PSC	37	24	81	62	0 pad	19	2.81 (1-12)	0.75 (0-4)	11%
Gregori et Al. (2009)	PSC	79	25	100	66,1 (75*)	0 pad or 1 security PPD, <8g/24h	25.8	3.7 (1-10)	3.5 (1-10)	6.3%
Rouprêt et Al. (2011)	PSC	128	56.3	94	68	0 pad or 1 security PPD	75 <sup>1</sup>	4.2 (1-20)	1.46	18%
Kjær et Al. (2012)	PSC	114	58	59	50	0 pad or 1 security PPD, <8g/24h	30	4.75 (1-26)	2.25 (0-26)	27%
Crivellaro et Al. (2012)	PSC	42	12	100	71	0 pad or 1 security PPD	21	NR	NR	7.1%
Venturino et Al. (2015)	PSC	22	57	82	4.5	0 pad	55	5.9 (3-12)	3.9 (0-10)	24 procedures
Noordhoff et Al. (2017)	RSC	143	46	100	45	0 pad or 1 security PPD	19	3.5 (IQR 2.0-5.0)	1.0 (IQR 0.0-2.9)	34.3%

Fig. 2 Table of results. PPSUI= Post-Prostatectomy Stress Urinary Incontinence, PSC = Prospective Single Centre, PMC = Prospective Multicentre, RSC = Retrospective Single Centre, "\*" = Non-radiotherapy subgroup, "f" = Patient subjective evaluation

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