

Efficacy of a penile variable tension loop for improving climacturia after radical prostatectomy

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Study Type – Therapy (case series)
Level of Evidence 4

OBJECTIVE

- To define the impact of the use of a penile variable tension loop on climacturia and on the distress level experienced by patients and their partners as a result of climacturia.

PATIENTS AND METHODS

- All patients presenting for sexual function assessment after radical prostatectomy (RP) were questioned regarding climacturia.
- The study population consisted of men who had undergone RP < 6 months before initial evaluation, had reported having climacturia on $\geq 25\%$ attempts where orgasm was achieved, had agreed to use the variable tension loop consistently, and continued to have climacturia when not using the loop at follow-up.
- Patients were interviewed regarding the frequency and degree of climacturia, and their own and their partner's distress levels secondary to climacturia, both with and without the use of the variable tension loop.

What's known on the subject? and What does the study add?

Climacturia is present in ~20–40% of men after radical prostatectomy, and adversely affects sexual satisfaction. Although several strategies have been proposed for the treatment of climacturia, none have been systematically studied to date.

This observational study shows that use of a penile variable tension loop can significantly reduce the degree and frequency of orgasm-associated incontinence, and the associated distress experienced by patients and partners. Climacturia resolves completely in half the patients, and occurs occasionally or rarely in the remainder.

RESULTS

- The study population comprised 124 men.
- At baseline, the degree of climacturia was small, moderate, and large in 16%, 72%, 12% of patients, respectively, and 28%, 26% and 0%, respectively, at follow-up (all $P < 0.01$).
- Climacturia occurred rarely, occasionally, most of the time, or always in 15%, 48%, 16% and 21% of cases, respectively, at baseline, and 48% of patients experienced no climacturia with use of the variable tension loop.
- Distress was experienced by 14% and 61% of patients and partners at baseline, and 2% and 11% of patients and partners at follow up ($P < 0.01$).

- Severity of distress was significantly lower at follow-up for both partners and patients ($P < 0.01$).

CONCLUSIONS

- Climacturia is a common complication of radical prostatectomy.
- Application of the variable tension loop can result in a significant decrease in the frequency and volume of climacturia.
- Use of the variable tension loop is a simple and non-invasive strategy for relieving the distress associated with climacturia in patients who have undergone RP and their partners.

KEYWORDS

orgasm, incontinence, climacturia, prostatectomy

INTRODUCTION

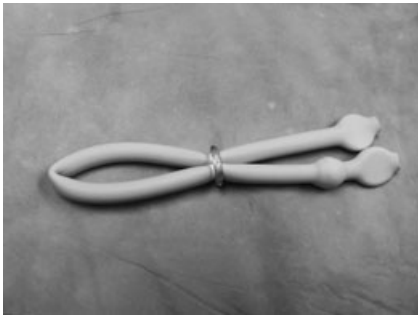
Climacturia, also referred to as orgasm-associated incontinence, is the involuntary loss of urine during orgasm, and has been recently described after radical prostatectomy (RP). While its persistent occurrence is uncommon, significant bother

has been reported in nearly half of all men who suffer from climacturia, leading to embarrassment, avoidance of sexual activity, and relationship problems between partners [1].

The optimum management of climacturia has not been systematically studied.

Non-invasive options include emptying of the bladder before intercourse, and the use of condoms or imipramine [1,2]. In addition, the use of pelvic floor rehabilitation has been recently reported as an alternative [3]. The use of a variable penile tension loop (Fig. 1) placed at the base of the penis for the management of incontinence

FIG. 1. Penile variable tension loop.



encountered during sexual activity has been reported [4].

The aim of the present independent, non-industry sponsored study was to define the impact of the use of a variable tension loop (ACTIS® band, Vivus, Mountainview, CA, USA) on climacturia after RP, and on the distress level experienced by patients and their partners as a result of climacturia.

PATIENTS AND METHODS

PATIENT POPULATION

Patients seen in our sexual medicine clinic are referred from a variety of institutions, including our own. All patients presenting for sexual function assessment after RP are routinely and specifically questioned about climacturia. The presence, severity and frequency of climacturia is assessed, along with associated patient and partner distress. A non-validated, institution-specific sexual health intake form is used for this purpose.

After institutional review board approval, patients were prospectively enrolled for inclusion in the present study between January 2004 and June 2006. Strict inclusion criteria were applied. Patients were required: to have undergone RP < 6 months before initial evaluation; to have climacturia during ≥25% of orgasms; and to have agreed to use the penile loop consistently. Only patients who continued to have climacturia when not using the penile loop at the time of follow-up, were included in the final analysis.

CLIMACTURIA ASSESSMENT

Each patient was interviewed regarding the frequency and degree of climacturia, and

TABLE 1 Patient characteristics

Mean (SD) patient age, years	68 (14)
Surgical approach, n (%)	
Open	35 (28)
Robot-assisted laparoscopic	89 (72)
Nerve-sparing status, n (%)	
Bilateral nerve sparing	92 (74)
Unilateral nerve sparing	17 (14)
Non-nerve sparing	15 (12)
Proportion of patients using PDE5-i for sexual activity, n (%)	30 (24)
Proportion of patients using ICI for sexual activity, n (%)	107 (86)

PDE5-I, phosphodiesterase type 5 inhibitor; ICI, intracavernosal injection.

FIG. 2. Degree of climacturia.

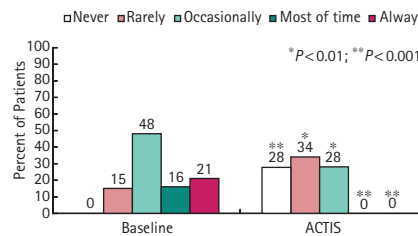
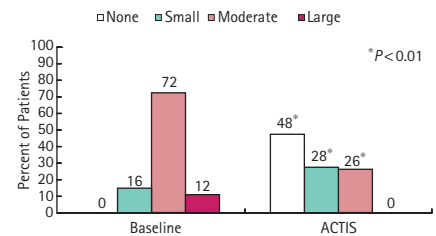


FIG. 3. Frequency of climacturia.



asked to grade it as follows: as small (drops), moderate (estimated by the patient as <30 mL of urine, or large (>30 mL of urine). Frequency was defined as: never, rarely (<50% of orgasms), occasionally (about half the time), most of the time (>50% of orgasms), or always. Each patient was also asked to provide an assessment of their own and their partner's distress resulting from the presence of climacturia. This was self-reported by the patients as low, moderate or high. All patients were instructed to apply the penile loop during sexual stimulation, once they had achieved the best quality erection achievable by them. They were encouraged to attempt sexual stimulation to orgasm regularly over the ensuing weeks. At the follow-up visit, patients were re-questioned regarding the frequency, degree of climacturia, and any associated distress.

STATISTICAL ANALYSIS

The expectation was that the application of the variable tension penile loop would lead to less climacturia and that this would be associated with less patient and partner distress. The mean values for climacturia frequency and severity as well as distress scores were recorded between baseline and

treatment phases and analysed using a repeated measures *t*-test.

RESULTS

PATIENT POPULATION

A total of 175 patients met the inclusion criteria, but only 124 continued to have climacturia without use of the variable tension loop at follow-up and constituted the study population. Patient demographics are shown in Table 1. The mean (SD) patient age was 68 (14) years, and the mean (SD) time from RP to initial evaluation was 3 (2.5) months, and to follow-up evaluation was 6 (2.4) months. A total of 85% of patients were evaluated within 12 weeks of starting penile loop use. The majority of patients had undergone robot-assisted laparoscopic prostatectomy, with complete or near-complete nerve-sparing bilaterally in 74% of patients. Oral phosphodiesterase inhibitors and intracavernosal injection therapy were used by 24% and 86% of patients, respectively, after RP.

CLIMACTURIA OUTCOMES

The degree and frequency of climacturia data are shown in Figs 2 and 3. At baseline,

FIG. 4. Patient distress levels.

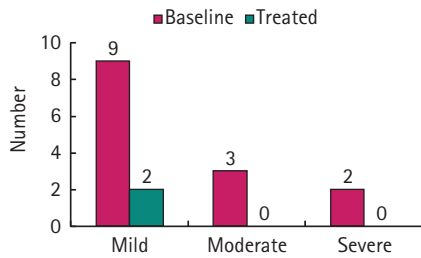
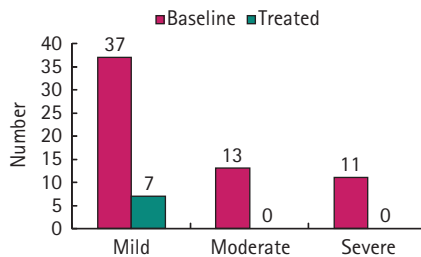


FIG. 5. Partner distress levels.



the degree of climacturia was small, moderate and large in 16%, 72%, 12% of patients, respectively, compared with 28%, 26% and 0% at follow-up ($P < 0.01$ for all comparisons). With regard to the frequency of climacturia, patients experienced it rarely, occasionally, most of the time, or always in 15%, 48%, 16% and 21% of cases, respectively, at baseline. By contrast, with the use of the penile loop, 48% of patients experienced no climacturia, with 34% and 28% of patients experiencing it rarely or occasionally, respectively ($P < 0.01$ for all comparisons). The patient and partner distress data are shown in Figs 4 and 5. Distress was experienced by 14% and 61% of patients and partners at baseline, and 2% and 11% of patients and partners at follow-up ($P < 0.01$ for both). At baseline, 33% of patient distress and 40% of partner distress was moderate to severe ($P < 0.01$).

DISCUSSION

Since the study by Koeman *et al.* [5] in 1996, awareness of post-prostatectomy orgasmic dysfunction in general, and climacturia in particular, has been increasing. Several authors have recommended that the postoperative evaluation of patients after RP should specifically include the assessment of climacturia, as this complication may otherwise be overlooked.

There is no validated questionnaire that specifically assesses post-RP orgasm function, which is a limitation for this or any other study addressing orgasm problems after RP. The most widely used questionnaire for the assessment of sexual function in general, the International Index of Erectile Function, contains only two of 15 questions in its orgasm domain, one of which actually addresses ejaculation and is, therefore, irrelevant to the post-RP population.

Nevertheless, orgasmic dysfunction is a relatively prevalent problem in men after RP. Barnas *et al.* [6] reported a complete absence of orgasm in 37% of 239 patients surveyed at a mean (SD) of 34 (21) months after RP. In their patient series, an additional 37% of men reported decreased orgasm intensity, while 14% reported dysorgasmia. Climacturia was present at some point in 93% of patients, and consistently in 16% of men. Climacturia occurred with every orgasm in 16%, occasionally in 44% and rarely in 33% of men surveyed.

The reported rate of climacturia in the literature varies between 16% and 93%, depending on the definition used, the patient population studied, and the timing of evaluation relative to surgery [1,5-9]. In a series of 475 men who underwent radical pelvic surgery, Choi *et al.* [9] found the prevalence of persistent climacturia to be 20%, it being significantly more common after RP than after cystoprostatectomy. Lee *et al.* [1] reported a comparatively higher prevalence rate of climacturia of 45% in a smaller cohort of men who had undergone RP. Most recently, Nilsson *et al.* [8] surveyed 1288 men after RP, and found the prevalence of sexual incontinence to be 20% in the overall cohort and 39% among men who reported being sexually active after surgery; however, it is unclear in their study how many of these men had climacturia or arousal incontinence. Based on the available data, therefore, climacturia appears to be present in ~20-40% of men after RP.

The mechanism of incontinence during sexual activity in men who undergo RP is not completely understood. In the normal male, incontinence during orgasm is prevented by a competent bladder neck, which is coapted during arousal and orgasm; meanwhile, the external urethral sphincter is relaxed, to allow antegrade ejaculation. Diurnal incontinence after RP is

thought to be attributable to external sphincter deficiency in the majority of patients [10]. Men who are continent after RP may, therefore, still experience climacturia, suggesting that deficiency in bladder neck coaptation during orgasm is the cause. While the prevalence of climacturia after RP is not associated with surgical approach (open vs laparoscopic prostatectomy), nerve-sparing status, continence status, or erectile function, climacturia is more commonly reported in men who experience loss of penile length or dysorgasmia [9]. Further study of the neurophysiology of orgasm is warranted to improve our understanding of the mechanism behind climacturia.

It is evident that climacturia adversely affects sexual satisfaction. In one study, 48% of prostate cancer survivors acknowledged that climacturia caused significant bother and had a negative effect on their quality of life [1]. Similar results have been reported by Abouassaly *et al.* [2], who reported that 47% of patients with climacturia after RP considered it a 'big problem', despite having minimal urinary incontinence during the day and night. Approximately one third of patients with climacturia in two separate studies reported avoiding any sexual contact with their partner because of embarrassment, fear of failure, and decreased orgasmic satisfaction [5,8]. The present results show that partner distress was higher than patient distress at all times during the study, but that the distress level for both patients and partners was significantly reduced or eliminated with consistent use of the penile variable tension loop. To our knowledge, this is the first study to report such a substantial degree of improvement in climacturia-related distress in such a large cohort of patients.

While several strategies for the management of climacturia have been reported in the literature, the majority have limited use or desirability. The use of condoms or pre-coital voiding to empty the bladder has not been shown to have any effect on the rate of climacturia or the bother associated with it. Furthermore, application of a condom may be challenging for men with early postoperative ED. Imipramine, used empirically in the patient with post-RP stress-associated urinary incontinence, because of its purported bladder relaxant and bladder neck contractile properties [11],

has also been used empirically in patients with climacturia, although no data exists on its efficacy or safety. Absence of data on its effectiveness and adverse event profile causes many men with climacturia to be hesitant to use this antidepressant. Lastly, although effective, the placement of a urethral sling or an artificial urinary sphincter involves a secondary surgical procedure and may be seen as a radical step in men who are otherwise continent and may be considered unnecessary in the long term if men are likely to experience resolution of the climacturia.

By comparison, the penile variable tension loop used in the present study (ACTIS® band) is an economical and non-invasive option for the management of climacturia, originally designed to augment the efficacy of the transurethral alprostadil suppository. As this device is no longer commercially available, we now use an almost identical device (Urostop®, Urosciences Inc, NY, USA) with similar results. These devices are termed 'variable tension loops' because they are constructed such that the patient can determine how much tension is applied, in contrast to a classic penile constriction band, thus enhancing patient comfort. When used for the purposes of climacturia control, the device is placed over the base of the penis and adjusted to securely encircle the girth of the penis, after the patient has achieved the best possible erection rigidity. The loop is re-usable and costs < \$20.

Our data clearly show the reduction in degree and frequency of climacturia with consistent use of a penile loop. In ~50% of the patients, climacturia resolved completely, and occurred occasionally or rarely in the remainder of the patients. To our knowledge, the present study also represents the first report of an effective and non-invasive treatment for this distressing problem.

As previously mentioned, a limitation of the present study is the absence of a validated

instrument to assess climacturia. Development of such a tool would greatly aid in the post-prostatectomy evaluation and treatment of men with orgasm disorders. Furthermore, this was not a randomized, controlled study and data on preoperative sexual health and continence status was not readily available for the study population. Given that patients were seen in our clinic for the first time only after RP, and that many had been referred from outside institutions, retrospective collection of such data would have introduced significant recall bias.

Strengths of the present study include the large size of the study population and the rigorous inclusion criteria, which allowed the focus to be placed on outcomes with use of the penile loop.

In conclusion, climacturia is a relatively common complication of RP. Application of a penile variable tension loop can result in a significant decrease in the frequency and severity of climacturia. Use of the penile loop is a simple and non-invasive strategy for relieving the distress associated with climacturia in patients and their partners after RP.

CONFLICT OF INTEREST

None declared.

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Abbreviation: RP, radical prostatectomy.