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ORIGINAL RESEARCH ARTICLE

Patients experience with the use of a penile clamp in post-prostatectomy incontinence – a prospective pilot study

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ABSTRACT

Objectives: The aim of this study was to assess the efficacy of a penile clamp in managing urinary incontinence (UI) and its impact on perceived quality of life (QoL) amongst post-prostatectomy patients.

Material and methods: A prospective pilot study was conducted including patients with post-prostatectomy UI treated with a penile clamp. Inclusion criteria consisted of UI after radical prostatectomy, good hand function, full cognitive function and a minimum penile length of 3 cm and a circumference of 5 cm. An appropriately sized penile clamp was selected during the first visit, and patients were given instructions on how to use it. The first follow-up was a scheduled phone call 1 week after the initial visit. Formal evaluations were performed prior to use of the penile clamp and again after 3 months of usage. These consisted of weighing pads during the daytime with evaluation of leakage, International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), incontinence-QoL (I-QoL) and a questionnaire specific for the penile clamp.

Results: There were 22 patients included, and two were excluded due to reduced hand function and surgery before the study endpoint. The results showed a significant median reduction of urinary leakage of 57% at rest and 58% during physical activity. One complication was observed, as one patient developed a pinching ulcer, after extensive usage. ICIQ-SF showed an increase of 6% for the included patients ($n = 20$). Ten patients were satisfied with the clamp, and 15 would recommend the clamp to others.

Conclusion: The penile clamp shows promising results in reducing leakage with minimal risks of complications. It can be used as a treatment for patients awaiting surgery. However, patient selection is important regarding hand function, cognitive function and the penile anatomy.

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Urine incontinence; radical prostatectomy; conservative treatment; quality of life (QoL); new devices; penile clamp

Introduction

With an incidence of 1.4 million new cases of prostate cancer worldwide, the complication of urinary incontinence (UI) after radical prostatectomy is increasing [1] and has been reported in 4%–69% [2, 3]. Conservative management includes pelvic floor muscle training with or without biofeedback, electrical stimulation, extracorporeal magnetic innervation (ExMI), compression devices (penile clamps), lifestyle changes or a combination of methods [4]. In addition, different surgical approaches are available, such as the artificial urinary sphincter (AUS), which is considered the gold standard, with continence rates of approximately 80% [5]. Also other surgical options that have shown variable efficacy, in mild to moderate cases, include urethral bulking agents, fixed male slings, adjustable male slings and, occasionally, the adjustable continence balloon known as ProACT [5]. Not all patients are suitable for surgical treatment, and therefore, after radiation therapy, initially and following prostate-specific antigen (PSA) relapse, incontinence is difficult to treat due to a high complication rate. The waiting time for incontinence surgery can sometimes be long. The aim of this study was to evaluate the efficacy of using the penile clamp, before and after 3 months of usage, for urine incontinence after radical prostatectomy as well as the effect on quality of life (QoL) in a small patient cohort consisting of men awaiting incontinence surgery.

Methods and material

This is a prospective pilot study that includes patients with urinary leakage after radical prostatectomy due to prostate cancer. The majority of the patients were on a waiting list for surgical intervention due to UI. The inclusion criteria are as follows: the patients needed good hand function, full cognitive function and a minimum penile length of 3 cm and a circumference of 5 cm. Due to the long waiting times, we considered testing a penile clamp device (PaceyCuff™) for a period of 3 months. This penile clamp comes in three specific sizes: circumference 4–6 cm (small), 7–9 cm (medium) and >10 cm (large).

At the first visit, the patient signed an informed consent and received information regarding the usage of the penile cuff. The evaluation consisted of measuring body mass index,

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measuring the size of the penis and collection of incontinence pads. The pads were weighed during daytime, after 4 h of rest and after 4 h of physical activity. The patient received accurate instructions on how to use the cuff, which was fitted directly on the patient under clinician guidance. In addition, patients were given written instructions containing pictures, and a film was shown regarding the use of the cuff. Patients were also instructed to use the cuff in 2-h intervals initially and avoid use during the night, to prevent possible injury.

The patients were contacted by phone a week later by the research nurse for the first follow-up. The final follow-up visit was after 3 months. Evaluation consisted of weighing a pad during the daytime, after 4 h of rest and after 4 h of physical activity with the penile clamp in place. The QoL was evaluated by two validated questionnaires, using the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and incontinence-QoL (I-QoL) [6, 7].

The ICIQ-SF is a questionnaire for evaluating the frequency, severity and impact on QoL of UI in men and women in research and clinical practice across the world. This questionnaire is also of use to general practitioners and clinicians to screen for incontinence, to obtain the impact and perceived cause of symptoms of incontinence pertained to the handling of the penile clamp after 3 months (Table 2).

The University of Gothenburg regional ethical review board (2019-05460) approved the protocol.

Statistical analysis

Normality was assessed using the Shapiro-Wilk test before deciding on appropriate variation testing. Using the Wilcoxon rank test, statistical analysis was performed with Jamovi (2022, Version 2.3) based on RStudio for Mac (version 1.2.5033). The results were considered significant where p-values were less than 0.05.

Table 1. Population characteristics (n = 20).

	Median (Range)
Age, years	75 (54–82)
Body Mass Index	26 (22–31)
Penile length, cm	7.8 (5.5–10)
Penile circumference, cm	9.5 (8.5–11)

Results

The study included 22 patients with UI following radical prostatectomy for the treatment of prostate cancer. The characteristics of the study population are described in Table 1. One patient was excluded due to difficulties handling the clamp, and one underwent surgery with AUS before the study endpoint. The results are based on the remaining 20 patients' leakage test before and after 3 months, and 21 patients for the pacey cuff questionnaire.

Urinary leakage test showed significant reduction, both during rest and during activity (Table 2). The ICIQ-SF questionnaire has three sections (A, B and C) plus a total score, which showed no significant difference between the scores before using the clamp and after 3 months of usage (Table 2).

I-QOL has three different sections: Avoidance and limiting behaviour (ALB), Psychosocial Impact (PI), Social Embarrassment (SE) and total overall score. I-QoL total score showed an insignificant decrease in score (Table 2).

Six (29%) patients found the cuff uncomfortable to use. Six (29%) patients also answered that they were uncomfortable with how safe the penile clamp was on reducing the leakage. Fifteen (71%) patients found the cuff superior when compared to pads. Ten (48%) patients reported that they were satisfied with the clamp. Fifteen (71%) patients in the study would probably or definitely recommend the clamp to others with a similar problem (Table 3).

Table 2. ICIQ-SF, I-QoL and leakage (weighing pads in g = gram) before and after using the penile clamp (n = 20).

	Pre-test 0 month	Post-test 3 month	P value
ICIQ-SF Total points (median, range)	17 (11–21)	18 (5–21)	0.339
I-QoL Total points (median, range)	61 (31–100)	55 (33–101)	0.340
Leakage whilst resting, g (median, range) (n = 17, 3 missing data)	60 (0–296)	26 (0–130)	0.004*
Leakage during exercise, g (median, range) (n = 19, one missing data)	144 (15–578)	60 (0–256)	<0.001*
Interquartile range (IQRr), resting, g	92	30	
Interquartile range (IQRe), exercise, g	237	67	

*P value < 0.05 is significant. The Wilcoxon rank test was used. g = gram

Pre-test = Before using the penile clamp

Post-test = After 3 months of clamp usage

ICIQ-SF A = How often do you leak urine? 0 – never; 1 – about once a week or less than often; 2 – two or three times a week; 3 – about once a day; 4 – several times a day; 5 – all the time.

ICIQ-SF B = We would like to know how much urine do you think leaks. How much urine do you usually leak (whether you wear protection or not)? 0 – none; 2 – a small amount; 4 – a moderate amount; 6 – a large amount.

ICIQ-SF C = Overall, how much does leaking urine interfere with your everyday life? 0 – 10: 0 is not at all and 10 is a great deal.

I-QOL: ALB = Avoidance and limiting behaviour; PI = Psychosocial Impact; SE = Social Embarrassment. g = grams

Discussion

This study analysed patients with UI after radical prostatectomy for prostate cancer, by using a penile cuff during rest and activity, to reduce UI and to explore if QoL improves.

The change in urinary leakage before and after usage of the cuff was measured in addition to patient-completed validated questionnaires. This study showed a significant difference in leakage before and after using the penile clamp. However, more than half of the patients had difficulty adjusting the clamp to a comfortable position on the penis, and 30% found it uncomfortable. Nevertheless, most patients would recommend the clamp to other patients. In addition, the patients' expectations to be continent are high before radical prostatectomy and/or radiation. When complications occur afterwards, such as urinary leakage, it makes the situation overwhelming. It is shown that UI has a negative impact on QoL in both physical and mental health domains [8].

With that in mind, leakage still persists during usage of the penile clamp. Using the clamp will improve life in a portion of patients; however, it will not cure the patient of incontinence. The patient will likely not be completely satisfied if he has incontinence with wet diapers, even if the leakage has diminished significantly. This was probably the reason why the QoL did not improve as much as we would expect, despite less leakage. This study did not show any difference in QoL before and after the patients had used the penile clamp. Two different QoL-questionnaires were used, and neither showed any significant improvement of QoL.

There are several conservative methods to deal with UI, such as behavioural modification, including fluid management,

Table 3. Pacey Cuff questionnaire answered after 3 months of usage penile clamp due to incontinence after radical prostatectomy.

Pacey Cuff questionnaire	Answer number	Answers per question				No answer	Total answers
		1	2	3	4		
Q1. How would you classify your incontinence?	1. Mild 2. Moderate 3. Severe	1	12	8	n/a		21
Q2. How easy is it to adjust the Pacey Cuff so that it is comfortable?	1. Simple 2. Relatively simple 3. Quite difficult 4. Difficult	1	7	11	2		21
Q3. How easy is it to find a good fit using the numbered fitting adjustment on the top side of the product? (Numbered 1–4)	1. Simple 2. Relatively simple 3. Quite difficult 4. Difficult	4	9	6	2		21
Q4. Do you (or with help from health personnel) use the adjustment on the underside of the product to make a good fit? (Numbered 1–4)	1. Yes 2. No	10	11	n/a	n/a		21
Q5. Does the device pinch when you tighten it?	1. Yes 2. No	13	8	n/a	n/a		21
Q6. How simple is it to adjust the pinching protector to avoid the problem?	1. Simple 2. Relatively simple 3. Quite difficult 4. Difficult	3	5	8	4	1	20
Q7. How comfortable is the device to use?	1. Uncomfortable 2. Slightly uncomfortable 3. Comfortable 4. Very comfortable	6	12	2	1		21
Q8. How secure do you feel with the effect on the reduction of leakage with Pacey Cuff?	1. Uncomfortable 2. Slightly uncomfortable 3. Comfortable 4. Very comfortable	6	7	8	0		21
Q9. What number on the top strap (1–4) do you use?	1,2,3,4	0	7	12	0	2	19
Q10. What number on the bottom compressor strap (1–4) do you use?	1,2,3,4	1	3	12	2	3	18
Q11. During how many hours per day have you in general been using Pacey Cuff?	1 >2 h 2. 2–6 h 3. 6–10 h 4. <10 h	1	11	6	2	1	20
Q12. How would you compare Pacey Cuff with the use of only pads?	1. Pads much better 2. Pads better 3. Pacey Cuff better 4. Pacey Cuff much better	1	5	11	4		21
Q13. How satisfied are you with the total experience of Pacey Cuff?	1. Very unsatisfied 2. Unsatisfied 3. Satisfied 4. Very satisfied	2	9	8	2		21
Q14. Would you recommend Pacey Cuff to others with the same condition?	1. No 2. Probably not 3. Probably 4. Yes, definitely	2	4	12	3		21

bladder retraining, pelvic floor physiotherapy, use of pads/diapers, condom catheters and penile clamps/penile compression devices [4]. Marchioni et al. showed that pelvic floor muscle training shortens the time for recovery, but the effect of solifenacin showed no striking advantages for the treatment of post-operative incontinence [9].

Another approach is using the medication duloxetine (Yentreve®), which diminishes incontinence by affecting the level of serotonin in the spinal cord [5, 10]. Most studies have been done on women with stress incontinence. Incontinence in men after radical prostatectomy is a pure stress incontinence in most cases and not treatable by any medication in most cases. There are no good options for the treatment of male UI besides surgery. The penile clamp may be a treatment option for the patient awaiting incontinence surgery.

The operative treatment of UI has excessive costs, and not all patients are suitable for surgery. When performing radical prostatectomy, there is a need to screen for different risk factors, both intraoperative and post-operative, that can affect the outcome of UI [11]. There are validated online tools available that may assist clinicians and their patients in adequate counselling of the incontinence risk after robotic assisted radical prostatectomy (RARP) [12].

According to Kurimura et al., one can use special preoperative pads to predict prolonged UI after robot-assisted radical prostatectomy [13]. If you predict a high risk for UI, then the penile clamp can be introduced preoperatively.

There are currently several clamp designs on the market and a few other studies that describe the safety and efficacy of penile compression devices [14, 15].

In a study by Lee et al., where amazon buyers reviewed the clamp, the overall attitude against penile clamps tended to be more positive than negative. It is, however, a study with obvious limitations and an amount of selection bias [16]

More studies are needed to establish the efficacy of the different types of clamps, to make them easier to use and to decide which penile clamp should be recommend for the patient.

This study was performed over a period of 3 months with only one report of an ulceration on the site of the clamp, which was superficial and healed completely after a few days without scarring. In this case, the patient did not adjust the penile clamp even when it was hurting, using it for several hours resulting in a small bruise on the penile shaft. That is why it is of importance in the first meeting to instruct the patient to adjust the clamp when it becomes painful. It can feel uncomfortable, but it should never feel painful.

We observed some limitations in the design of the penile

clamp. The penile clamp could fall off the penis when sitting down due to 'penile retraction', especially with shorter penises. Therefore, it is essential to inform the patient that this can happen, before handing out the penile clamp.

Some patients reported pain in the distal part of the penis after prolonged usage of the clamp, which disappeared when they opened and moved the clamp more distally or proximally on the shaft. More than half of the patients felt the device pinching whilst tightening it, even though it has a pinching protector to avoid that problem. Some patients asked for a broader pinching protector, to alleviate the pinching sensation, which can be adjusted by the producer of the clamp in the future. However, almost half of the patients were satisfied with the total experience of the penile clamp, and two-thirds would recommend it to another patient.

A limitation of this study is the small cohort size. A larger study can add enriched results. Another limitation is that the 12 questions concerning the penile clamp are not validated, and the total number of answers ranges from 18 to 21, which is shown in Table 3. As this is a preliminary pilot study, our intention was to present as many responses as possible; hence, no exclusions were made in the questionnaire.

These questions are important to understand and evaluate the efficacy and function of the penile clamp for the patient.

The ICIQ-SF and I-QoL are validated, but the results are not as relevant when using a penile compression device, since they are not directly designed for conservative treatment but more for the evaluation of the surgical treatment outcome. Yet, Bernard J et al. demonstrated that men who used penile compression devices reduced their incontinence impact questionnaires scores significantly [15].

One of the strengths of this study was that the same nurse and doctor performed all the consultation with the patients. This study confirmed the benefits of penile clamping in reducing urinary leakage in patients awaiting incontinence surgery. However, patient selection is important regarding hand and cognitive function as well as the penile anatomy and the patient's physique.

Conclusion

The use of the penile clamp has showed promising results in reducing UI following radical prostatectomy, with minimal risk of complications. We observed no significant improvement in QoL when using the penile clamp. Some men found the clamp uncomfortable to use, yet half of the patients expressed satisfaction with it. The penile clamp presents a viable treatment option instead of only using incontinence pads for patients either awaiting definitive incontinence surgery or those who are not candidates for surgical treatment.

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Disclosure statement

The authors declare that there are no conflicts of interest.

Ethics of approval statement

Approval for this study was obtained from the Swedish Ethical Review Authority. Diary number: 2019-05460. A signed informed consent was established.

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