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A STUDY ASSESSING THE SAFETY, EFFICACY, COMFORT, AND PATIENT SATISFACTION WITH THREE COMMONLY USED PENILE COMPRESSION DEVICES FOR INCONTINENCE AFTER PROSTATECTOMY.

Aims of Study

After radical prostatectomy (RP) some men experience annoying or continuous incontinence. If pelvic floor muscle exercises are not effective, there are 3 nonsurgical choices: pads, condom drainage, or penile compression devices. To date there have been no published reports on the clinical use of penile compression devices despite their availability for many years in shops and over the internet.

In this study we assessed the safety, efficacy, comfort, and patient satisfaction with 3 penile compression devices: the Cunningham Clamp (Bard Urological; Covington, Georgia), C3 (Timms Medical Technologies, White Bear Lake, MN), and U-Tex devices (marketed by Laborie). Outcome measures were: 1) gm of urine lost on 4 hour pad test, 2) Circulatory impedance measured by penile doppler ultrasound (10 cm/s or more safe level) and 3) Patient satisfaction assessed by a patient completed questionnaire. Ethical approval was received from the Health Research Institutional Board.

Methods

Penile compression devices were tested in random order in a multiple period crossover design using a Latin squares configuration. Eligible men were at least 6 months post RP with no neurological or cognitive impairment (Mini Mental State Exam > 27) and who had not undergone radiotherapy. Subjects were instructed on the use of each device, applying the device only tightly enough to stop leak with a gentle cough and then provided a return demonstration of the use, repeating the instructions aloud. They then underwent a baseline penile doppler ultrasound followed by an ultrasound with each device in place, tested in random order. Devices were applied at a comfortable pressure sufficient to stop urine flow with gentle cough. Right and left systolic velocities and resistance indices of penile blood flow were calculated. A baseline 4 hour pad test was conducted to assess urine loss followed by a 4 hour pad test using each device and questionnaire completion at the same time on subsequent days. Subjects were asked to adhere to the same activity and fluid intake for each of the four measurements. A four hour pad test was chosen as four hours is the maximum length of time we recommended that a penile compression device be worn at any one time.

Results

12 men completed the study. Mini mental state exam score was mean 29.6, sd 1.2 (27-30). Mean urine loss at baseline (without device) was 122.8 gm (sd: 130.8) in the 4 hour pad test; mean urine loss was significantly decreased for the three compression devices compared to baseline: U-Tex 53.3 gm (sd:65.7); C3 32.3 gm (sd:24.3); Cunningham 17.1 g (sd:21.3) (Table 1). For all subjects there were some subjective and objective improvements in continence with at least one of the devices tried. Highest satisfaction was noted for the Cunningham clamp and was linked to ease of application, comfort, and efficacy. The U-Tex device was consistently ranked lower than the other two because it was difficult to apply, did not stay on with activity, and did not control urine leakage satisfactorily. None of the three devices had a significant impact on the resistive index; the C 3 and U-Tex allowed good distal penile blood flow; the Cunningham clamp significantly lowered distal blood flow velocity (from 12.5 cm/s to 7.3 (left systolic velocity) to 9.5 cm/s (right systolic velocity) even at the loosest setting (see Table 2). Despite its slightly reduced blood flow, the Cunningham clamp was the only device ranked positively by all 12 men; 2 of 12 men rated the C3 positively; no men rated the U-Tex positively (Table 3).

Conclusions

The use of urethral compression device is probably a safe and efficacious alternative available to some men who wish to pursue improved continence following radical prostatectomy. Individualized instruction to cognitively capable men is necessary to ensure appropriate use, comfort, and fit. The Cunningham device was the most efficacious and the most acceptable to users but also contributed to reduced systolic velocity in all men. Clinically, we would recommend that men who are at risk for circulatory impedance such as those with diabetics, not use the Cunningham device.

Table 1

Mean Pad Weights for Various Devices

Device	Mean Pad Weight (SD)
None	122.8(130.8)
Cunningham Clamp	17.1(21.2)*
C3	32.3(24.3)*
U-Tex	53.3(65.7)*

*Compared to baseline ($p<.05$)

Table 2

Device	Mean Rt Systolic Velocity (SD)	Mean Lt Systolic Velocity (SD)	Mean Rt resistance index (SD)	Mean Lt Resistance Index (SD)
No Device	12.4 (2.8)	12.3 (3.0)	0.90 (0.10)	0.87 (0.10)
Cunningham	9.5 (2.3)*	7.3 (3.0)*	0.92 (0.13)	0.86 (0.29)
C3	12.4 (5.5)	11.7 (4.7)	0.92 (0.10)	0.92 (0.11)
U-Tex	11.9 (4.4)	13.8 (7.3)	0.93 (0.08)	0.91 (0.11)

*$p< 0.05$ compared to baseline

Table 3

Mean Overall Satisfaction (1= good, 2 = acceptable, 3 = unacceptable)

Device	Satisfaction Score (SD)
Cunningham Clamp	1.6(0.5)
C3	2.1(0.8)
U-Tex	2.3(0.5)*

*$p>.05$ U-Tex compared to Cunningham