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ORIGINAL ARTICLE

Early use of vacuum constriction device following radical prostatectomy facilitates early sexual activity and potentially earlier return of erectile function

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To assess the efficacy of vacuum constriction devices (VCD) following radical prostatectomy (RP) and determine whether early use of VCD facilitates early sexual activity and potentially earlier return of erectile function. This prospective study consisted of 109 patients who underwent nerve-sparing (NS) or non-nerve-sparing (NNS) RP between August 1999 and October 2001 and developed erectile dysfunction following surgery. The patients were randomized to VCD use daily for 9 months (Group 1, $N = 74$) or observation without any erectogenic treatment (Group 2, $N = 35$). Treatment efficacy was analyzed by responses to the Sexual Health Inventory of Men (SHIM) (abridged 5-item International Index of Erectile Function (IIEF-5)), which were stratified by the NS status. Patient outcome regarding compliance, change in penile length, return of natural erection, and ability for vaginal intercourse were also assessed. The mean patient age was 58.2 years, and the minimum follow-up was 9 months. Use of VCD began at an average of 3.9 weeks after RP. In Group 1, 80% (60/74) successfully used their VCD with a constriction ring for vaginal intercourse at a frequency of twice/week with an overall spousal satisfaction rate of 55% (33/60). In all, 19 of these 60 patients (32%) reported return of natural erections at 9 months, with 10/60 (17%) having erections sufficient for vaginal intercourse. The abridged IIEF-5 score significantly increased after VCD use in both the NS and NNS groups. After a mean use of 3 months, 14/74 (18%) discontinued treatment. In Group 2, 37% (13/35) of patients regained spontaneous erections at a minimum follow-up of 9 months after surgery. However, only four of these patients (29%) had erections sufficient for successful vaginal intercourse and rest of patients (71%) sought adjuvant treatment. Of the 60 successful users, 14 (23%) reported a decrease in penile length and circumference at 9 months (range, 4–8 months) compared to 12/14 (85%) among the nonresponders. However, in control group 22/35 reported decrease in penile length and circumference. Early use of VCD following RP facilitates early sexual intercourse, early patient/spousal sexual satisfaction, and potentially an earlier return of natural erections sufficient for vaginal penetration.
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Introduction

Patients who undergo nerve-sparing (NS) and non-nerve-sparing (NNS) radical prostatectomy (RP) usually report the absence of spontaneous erection (both nocturnal and at awakening) during the early postoperative period.[1–4] The cause of this erectile dysfunction (ED) is mainly neurogenic – in the case of NNS-RP, it stems from a failure to preserve the cavernous nerves, whereas in a NS procedure, the nerves are preserved but are sometimes physiologically injured despite the best efforts of the surgeon. The latter often results in a period of neuropraxia.[5]

A number of standard, nonoral treatments are available for ED, but they produce erections via artificial means. Oral therapy can help salvage

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erectile function but only in men who have undergone NS RP.

Fraiman *et al*.[6] assessed penile morphometrics following RP and found that denervation muscular atrophy is most apparent between the first 4–8 months after RP. This research has encouraged clinicians' to use 'early penile rehabilitation' to maintain the vascular and cellular integrity of the penis after RP. With this approach, the integrity of the cavernous tissues may be maintained, which can potentially prevent cavernous tissue fibrosis from precluding the return of spontaneous erections or decreasing the response to erectile aids.[7–9]

Vacuum constriction devices (VCD) have been successfully used in a variety of patients with organic ED.[10] Its use included those patients treated for prostate carcinoma with either RP or radiation therapy.[7,8,10,11] Colombo *et al*.[12] found that their patients who practiced early application of VCD without the constrictive band to produce 'stretching' for the smooth muscle fibers showed significant improvement of spontaneous erectile ability.

In an attempt to encourage early sexual activity and prevention of post-RP veno-occlusive dysfunction, we prospectively studied the effect of early intervention clinical protocols using VCD in men who underwent NS and NNS RP at our institution. We specifically set out to determine whether early use of VCD facilitates early sexual activity and potentially earlier return of erectile function.

Materials and methods

Patient selection

The Cleveland Clinic Institutional Review Board approved this study, and all patients granted their written informed consent. The study consisted of all consecutive patients who underwent NS (unilateral or bilateral) or NNS RP as a treatment for prostate cancer between August 1999 and October 2001. To be eligible, patients must have been sexually active before surgery and free of any comorbid conditions. Patients were excluded if they received preoperative or postoperative hormonal therapy or monotherapy.

All eligible patients were initially evaluated with a comprehensive sexual history, physical examination, and pertinent laboratory testing. They were then randomized to the VCD group (Group 1) or to no erectogenic treatment (Group 2). Patients in Group 1 were instructed to begin using the VCD daily after catheter removal (2 weeks after surgery). An experienced nurse practitioner (AS) conducted a training session to teach the patients how to select and use a VCD. Patients were instructed to apply the constriction ring only when attempting sexual intercourse.

Patients were asked to complete the International Index of Erectile Function-15 (IIEF-15) questionnaire[13] before undergoing RP (presurgery) and then after RP but before VCD therapy (postsurgery); this was carried ut as part of their routine care. To assess the efficacy of the treatment, data from the IIEF-15 questionnaire were condensed into the IIEF-5 questionnaire, which is an abridged 5-item version of the IIEF-15 questionnaire referred to as the Sexual Health Inventory of Men (SHIM).[13,14] The SHIM is a validated, multidimensional, self-administered questionnaire that is a sensitive indicator of changes in erectile function. It is scored from 1 to 5: 1 = never/occasionally; 2 = less than half of the time; 3 = sometimes/half of the time; 4 = more than half of the time; and 5 = almost always. The total IIEF-5 score was calculated by totaling the response to all five questions.

A second questionnaire developed at our institute (Post Prostatectomy Questionnaire (PPQ)) was used to determine the sexual satisfaction of the patients' spouses/partners. The spouses/partners were specifically asked how often they were satisfied with intercourse and how often the patient was able to achieve and maintain an erection. This questionnaire was scored from 1 to 5: 1 = never/occasionally; 2 = less than half of the time; 3 = sometimes/half of the time; 4 = more than half of the time; and 5 = almost always. Total spousal satisfaction was calculated from these questions and expressed as a percentage.

Both surveys were also mailed to all patients in the VCD group and their spouses/partners 9 months after VCD therapy was started. We also mailed the other 35 patients (Group 2) the IIEF-15 and spousal questionnaires 9 months after RP to assess prospectively long-term potency and attrition in sexual function. Data from the IIEF-15 at 9 months was also condensed into the IIEF-5 (SHIM). At this time, we also performed a chart review to collect data on mean duration of intercourse, number of patient attempts at intercourse, number of successful attempts (vaginal penetration), change in VCD efficacy and frequency of use, compliance, return of natural erections, and new side effects. All patients were followed at 2- to 3-month intervals for 9 months. We also assessed the penile length before and after surgery.

Statistical analysis

The baseline scores of SHIM were compared before and after treatment with VCD to determine the change in response using Wilcoxon's signed-rank tests. The use of VCD for vaginal intercourse, return of natural erections, and return of erection sufficient for vaginal intercourse, quality of erections, and reason for discontinuation were also assessed. The responses were stratified by type of surgery (NS or NNS) and were compared with Wilcoxon's rank-sum tests.

An algorithm for determining potency was devised such that the patients' pretreatment status was assessed. Then, for each patient, the last potency

status was recorded based upon the time that follow-up visit. The data are presented as means and percentages as summary statistics. The methods consist of comparison of scores of the patients before and after VCD treatment using mean values. The number of patients discontinuing treatment for multiple reasons was calculated as a percentage of the total. In addition to the Wilcoxon tests, χ^2 tests were used to compare categories.

Statistical significance was assessed with two-tailed test at $P<0.05$. Computations utilized SAS version 8.1 software (SAS Institute Inc., Cary, NC, USA). Summary statistics for the continuous variables are expressed as mean $\pm$ s.d.

Results

During the study, 450 patients underwent RP at our institution. Of those patients, 109 (31.7%) were eligible (PSA <10, G's $\leqslant 6$, stage T1–T2, and baseline total IIEF-5 $\geqslant 16$); 74 were randomized into Group 1 and 35 were randomized into Group 2.

All 109 patients completed the IIEF-15 questionnaire at all three designated times (presurgery, postsurgery, and 9 months post-therapy), and all spouses/partners responded to the PPQ questionnaire. The minimum follow-up for all 109 patients was 9 months. The average age of the men at follow-up was 58.6 years (range, 50–71 years).

Group 1 (VCD): efficacy of early VCD use and compliance

An NS RP was carried out in 53 patients and an NNS RP was carried out in 21 patients. Use of the VCD began an average 3.9 weeks after surgery (range, 2–8 weeks). All of the 74 patients who initiated early VCD for treatment of ED following RP had attempted to use their VCD, and 60 (80%) successfully used VCD with a constriction ring for vaginal intercourse (50 had used manual devices, six had used battery-operated devices, and four had tried both). These 60 patients used their VCD for sexual intercourse on an average of twice a week, and their spousal satisfaction rate was 55% (33/60) (Table 1).

Patients reported an improved erectile function after using VCD (Table 2) with significant improvements in the mean IIEF-5 score to 16 ± 7.33 from a baseline pretreatment score of 4.8 ± 3.62 ($P\leqslant 0.05$). There was no statistical difference in the total IIEF-5 score or response to individual questions between the NS and NNS groups ($P\geqslant 0.05$). Of the 60 men, 19 (32%) who successfully used a VCD for sexual intercourse reported a return of natural erections at mean interval of 9 months; for 10 of these 19 patients (52%), erections were sufficient for vaginal intercourse. Overall in the early VCD group, 17% (10/60) had return of natural erections sufficient for vaginal intercourse.

Of the 14 patients who discontinued treatment (18%), 55% did so because of discomfort, 8% were unable to get an airtight seal, 17% reported that VCD use was socially inconvenient, and 20% quit because of penile bruising. The mean time interval at which the patients discontinued VCD was 2.5 months after starting the therapy. The patients who tried both battery and manual VCD did not seem to prefer any one to the other.

When patients were asked about the length of the penis while using VCD, 65% (39/60) were satisfied

Table 1 Comparison between patients with NS and NNS prostatectomies in response to early use of VCD

Variable	*Bilateral NS* (n = *31*)	*Unilateral NS* (n = *22*)	*NNS* (n = *21*)
Using VCD for sexual intercourse	80.6% (25/31)	86% (19/22)	76% (16/21)
Return of natural erection with VCD at 9 months	36% (9/25)	37% (7/19)	19% (3/16)
Natural, erection sufficient, for intercourse at 9 months	55% (5/9)	57% (4/7)	33% (1/3)
Spouse satisfaction	52% (13/25)	57% (11/19)	57% (9/16)

P-value is not significant between the three group.

Table 2 Response to abridged 5-item version of IIEF questionnaire following early use of VCD

IIEF-5 questionnaire		*Presurgery*	*Postsurgery*	*After VCD use*
IIEF Q-5	Maintenance ability	4.10 ± 0.86	0.99 ± 0.72	3.61 ± 1.47*
IIEF Q-15	Erection confidence	4.33 ± 0.96	0.86 ± 0.75	3.24 ± 1.43*
IIEF Q-4	Maintenance frequency	4.76 ± 0.86	0.91 ± 0.65	2.64 ± 1.46
IIEF Q-2	Erection firmness	4.81 ± 0.74	0.91 ± 0.75	3.14 ± 1.40*
IIEF Q-7	Intercourse satisfaction	4.46 ± 0.80	1.11 ± 0.75	3.12 ± 1.57*
	Total IIEF-5 score	22.5 ± 4.22	4.8 ± 3.62	16 ± 7.33*

Values are represented in mean $\pm$ s.d.
*$P<0.05$, considered statistically significant between baseline and after the use of VCD.

(NS; 75% (33/44) vs NNS; 37% (6/16)). Concerning the circumference of the penis with VCD use, 85% (51/60) of the patients were satisfied (NS; 92% (41/44) vs NNS; 62% (10/16)). Of the 60 successful users, 14 (23%) reported a decrease in penile length and circumference at 6 months (range, 4–8 months) compared to 12/14 (85%) among the nonresponders.

Group 2 (observation): long-term sexual potency and attrition in sexual function after RP

Of total 35 patients, 29 underwent NS RP and six NNS RP. Although 37% (13/35) of patients in this group regained spontaneous erections at a minimum follow-up of 9 months from surgery, in 71% (9/13) of these patients penile erections were not sufficient for successful vaginal intercourse and sought adjuvant treatment. In these 13 patients, the total mean IIEF-5 score was 15.76 ± 1.13, with a spousal satisfaction rate of 54%. Overall, these 35 patients had a total mean IIEF-5 score of 11.17 ± 1.76; this is significantly lower than early VCD group ($P < 0.05$). Overall, 11% (4/35) had return of natural erections sufficient for vaginal intercourse.

When asked about the penile length and circumference, 22/35 reported a decrease in the parameters.

Discussion

ED commonly occurs after NS and NNS RP. Most standard treatments make erectile function possible through artificial means, or they work only in men who have undergone an NS procedure. Early penile rehabilitation using erectile aids have been proposed to enhance recovery of natural, spontaneous erections earlier than what are normally anticipated.[15] Moreover, it can be used after NS and NNS procedures.

In the current study, our patients were asked to use a VCD as part of an early penile rehabilitation program. Our results suggest that early use of VCD resulted in a normal erection recovery rate (erections sufficient for vaginal intercourse) that was higher than the rate among nontreated controls (17 vs 11%). No significant difference was present in the response rate in patients undergoing NS or NNS RP. When patients were asked about the length of the penis while using VCD, 65% were satisfied. Concerning the circumference of the penis with VCD use, 85% (51/60) of the patients were satisfied. In all, 14 of 60 (23%) responders reported decrease in penile length and circumference at 6 months (average 4–8 months) compared to 12/14 (85%) among the nonresponders.

A study by Cookson and Nadig[10] reported long-term results of post-RP patients who used a VCD. They found that the their subgroup of impotent patients had a 100% satisfaction rate compared with 83% in the other patient groups. They reported long-term efficacy and patient satisfaction rates of more than 80% with statistically significant increase in the frequency of successful intercourse attempts in 79% of the patients using the device for 1 year, which were maintained in 77% beyond the first year.

Parallel to these findings, Derouet *et al*.[16] reported that VCD was most preferred by their patients with radical pelvic surgery. However, despite this excellent satisfaction in this subset of patients, various authors reported overall dropout rate was 30–70%.[16,17] The primary reasons for discontinuation were bruising and petechiae (5%), pivoting at the base of the penis (6%), coldness and numbness around the penis (5%) and pain related to VCD or the constriction band (10%), and decreased ability to achieve orgasm with device (10%). Sidi *et al*.[18] reported similar high degree of satisfaction.

To date, most urologists performing NS RP have suggested that patient should wait until completion of postoperative year 1 before evaluating the actual recovery of spontaneous erectile function. We believe therapeutic intervention postsurgically with VCD may restore nocturnal erections (both frequency and duration), may facilitate vascular perfusion of the corpus cavernosum, and can subsequently inhibit corporeal hypoxia and fibrosis. Initial data with intracavernous (IC) agents have been very encouraging and lend support to this hypothesis.[15] However, alternative mechanisms of action cannot be excluded, such as a direct effect on collagen synthesis. Numerous physiological insults lead to the production of TGF-beta and subsequent tissue fibrosis. It is possible that erectogenic agents like VCD, IC injections, or transurethral alprostadil (MUSE) may modulate the expression of TGF-beta, or other factors, independently of tissue oxygenation. Moreover, Althof[19] stated that one of the most important causes of failure of therapy of ED and the high dropout rates is the long asexual period of time the couple spends before the onset of therapy.

Besides VCD, other nonsurgical ED treatments are available, including IC pharmacotherapy and MUSE.[7,8,10] In our early penile rehabilitation program, the VCD was the preferred erectile aid. The advantage of VCD is that the erections produced are independent of endogenous vasoactive substance such as nitric oxide (NO) production, which is impaired by nerve damage. However, the degree of smooth muscle relaxation may be more complete with pharmacologically induced erections so that patient with a mild venous leak still may veno-occlude to the point of functional erection.

IC pharmacotherapy has high efficacy (up to 80%), and it produces natural erections of good rigidity. However, it has many side effects, including painful erections, penile fibrotic changes, and priapism. These side effects together with later loss of effectiveness may explain the high incidence of dropout among its users.[20–23] MUSE has the dis-

advantages of penile and urethral pain and the most important is the low efficacy.

Although sildenafil has a high success rate in RP patients, it early use in patients who undergo NNS is theoretically ineffective. However, some authors found it justifiable to use sildenafil in such patients depending on its effect mediated through non-neuronal-NO pathway to produce tumescence enough to maintain integrity of cavernous tissue, encourage patients of early regaining sexual interest, and activity thus enhancing chances of spontaneous recovery of erections and/or successful long-term therapy. Recently, Padma-Nathan *et al.*[9] reported that early daily sildenafil following RP appears to increase the recovery of spontaneous erections by seven time compare to the placebo (no treatment). Mc Auley *et al.*[23] demonstrated experimentally that IC sildenafil has an erectogenic effect independent of the classical NO/cGMP pathway. Furthermore, Medina *et al.*[24] found that the relaxant effect of sildenafil on penile vessels involves in addition to the NO-mediated relaxation an inhibitory effect on the noradrenergic contractions and on the smooth muscle contractions.

Although our study was based on a limited number of the patients assessed at a short-term follow-up. We still believe early intervention with VCD after RP may be able to restore nocturnal erection (both frequency and duration) and can facilitate early sexual activity.

Early use of VCD following RP facilitates early sexual intercourse, early patient/spousal sexual satisfaction, and maintenance of penile length/girth and, potentially, an earlier return of natural erections. Sexual activity that occurs during the first 9 months after surgery helps maintain the sexual interest and comfort between the couples that existed preoperatively. Patients who are motivated and sexually potent preoperatively, and interested in maintaining preoperative potency should be encouraged for early prophylactic treatment options.

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