The Use of Vacuum Erection Devices in Erectile Dysfunction After Radical Prostatectomy

Kimberley Hoyland, MBBS, Nikhil Vasdev, FRCS (Urol), James Adshead, MA, MD, FRCS (Urol) Hertfordshire and South Bedfordshire Robotic Cancer Centre, Department of Urology, Lister Hospital, Stevenage, UK

The risk of postoperative erectile dysfunction (ED) following radical prostatectomy (RP) is reported to be between 14% and 89%. With an increase in the detection of prostate cancer in younger men, there is a greater emphasis on the appropriate management of ED following RP. A number of options are available to manage ED after RP, including phosphodiesterase-5 inhibitors, intracorporeal injections, intraurethral alprostadil, and vacuum erection devices (VEDs). Penile rehabilitation programs are increasingly used to facilitate the return of natural postoperative erections; the VED is an ideal therapy given that it increases blood flow and oxygenation to the corpora to reverse the changes that result in ED after RP.

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KEY WORDS

Erectile dysfunction ● Radical prostatectomy ● Vacuum erection device ● Penile rehabilitation

rostate cancer is the most common cancer in men over the age of 50 years.¹ When patients undergo a radical prostatectomy (RP), there is a risk of postoperative erectile dysfunction (ED). The incidence of ED following RP has been reported to be between 14% and 89%.² With an increase in the detection of prostate cancer in younger men, there is a greater emphasis on the appropriate management of ED after RP. With an early diagnosis of prostate

cancer, there is an increase in the rate of RP in younger men and the importance of ED as a quality-of-life issue has subsequently increased.² There are a number of options available to manage ED after RP, including phosphodiesterase-5 (PDE-5) inhibitors, intracorporeal injections, intraurethral alprostadil, and vacuum erection devices (VEDs). Despite highly reported satisfaction and efficacy with VEDs, there is a move by some medical practitioners away

from VEDs due to cost. But what evidence is there for VED success after prostatectomy and what role do VEDs have in penile rehabilitation after ED? We present current evidence and provide our recommendations based on the latest literature.

Postprostatectomy Changes and Penile Rehabilitation

RP can be performed as either a nerve-sparing or non-nerve-sparing

prevention and reversal of some of the aforementioned changes. Although nerve recovery takes time, the fibrotic changes following RP can be prevented by increasing oxygenation of the corpora.⁴ Regular oxygenated blood flow to the corpora is required for smooth muscle maintenance, which has been found to atrophy 4 to 8 months after RP.⁶

At present, no set regimen has been determined for penile rehabilitation, but combinations of oral and non-oral therapies have been investigated. However, among and Drug Administration granted permission to market the VED as a prescription product.⁷ The work of Witherington and Nadig in the 1980s, and Lue in 1990, helped the device's usefulness gain recognition, and by 1991, it was prescribed more than any other treatment for ED.⁷

Mechanism of Action

The VED consists of a closed-ended clear plastic cylinder and a vacuum pump and can be hand- or battery-operated. Constriction rings may be used with the device to maintain an erection for penetration.⁷ An adequate erection can be achieved with a VED in 30 seconds to 7 minutes,³ but this does require manual dexterity by either the patient or his partner.⁷ The advantages and side effects of the VED are shown in Table 1.

The VED uses negative pressure in order to increase blood flow to the penis by distending the corporeal sinusoids.⁴ This negative pressure induces arterial inflow to the sinusoidal spaces, which aids oxygenation of the corpora.⁴ However, the constriction ring prevents venous outflow, which

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operation. However, despite which procedure is performed, there is almost inevitably some degree of nerve damage postoperatively due to the proximity of the nerves to the prostate. Nerve damage occurs due to stretching, cutting, or thermal injury during surgery.3 This neuropraxia has profound effects on erectile function. Although nerve regeneration occurs postoperatively, these nerves are slow to recover and can take up to 3 years to return to baseline function,4 which can result in either an absence or decrease in erectile function.5

In addition, there appears to be reduced arterial supply to the corpora as a result of injury to the accessory pudendal arteries.^{4,5} It has been found that 59% of patients have arterial insufficiency after RP, with a further 26% having venous leakage, which is associated with arterial insufficiency.³ This reduction in arterial inflow to the penis causes hypoxia and subsequently increased production of transforming growth factor- β , apoptosis, and collagen deposition, culminating in corporeal fibrosis.^{4,5}

The concept behind penile rehabilitation is the recovery of erectile function following RP by these, the VED seems ideally placed to form the basis of penile rehabilitation.

History of VEDs

The first clinical application for vacuum technology in the treatment of ED was in 1874 by Dr. John King.⁷ However, it was not until 1917 that Dr. Otto Lederer combined suction and compression to produce a surgical device for the treatment of ED.⁷ From 1917 to 1970 the device was barely altered, and it was Geddings Osbon who

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eventually designed and marketed the "youth equivalent device," with the help of Nu-Potent Inc. (Augusta, GA) in 1974.⁷ At first, the device was met with criticism and regarded as pornographic, until it was deemed a marital aid and supported by medical and educational literature, thanks to the efforts of Osbon.⁷ However, it was threatened once more in 1976 due to concerns about its safety and efficacy, and it was not until 1982 that the US Food reduces the percentage of oxygenated blood and results in ischemia after 30 minutes.⁴ Therefore, the VED used without the constriction ring is a prime therapy for use in penile rehabilitation as it is able to stimulate oxygenation of the corpora without the need for an intact nerve supply⁴; this increase in oxygenated blood flow may be able to reduce or even reverse some of the fibrotic changes occurring after RP.

TABLE 1

Advantages and Disadvantages of Vacuum Erection Devices (VEDs)

Advantages of VED

Disauvantages of V

Quick to use (erection in 2-3 min, on average), increased

spontaneity Reliable

Easy to use

Noninvasive

Can incorporate into foreplay

One time purchasing cost, affordable long term

Lasts > 5 y

Few contraindications (priapism, significant bleeding disorders)

Disadvantages of VED

Instability at base of penis causing pivoting

Bluish/cyanotic tinge, cool erection

Inability to ejaculate (12%-30%) due to urethral

constriction

Pain due to suction or constriction

Petechiae (25%-39%)

Bulky/indiscreet and messy with lubricant

Data from Raina R et al,² Lehrfeld and Lee,³ Oakley and Moore,⁷ and Albaugh JA.¹⁰

VED and PDE-5 Inhibitors

The British Society for Sexual Medicine guidelines on ED management recommend PDE-5 inhibitors as well as VED as first-line management of ED following RP.8 PDE-5 inhibitors are recommended due to their proven efficacy and cost effectiveness.9 In contrast, the limited evidence for VED effectiveness in large-scale trials has led to doubts over its use.9

PDE-5 inhibitors were originally used based on the premise that tissue damage is the result of poor corporeal oxygenation; thus, the early postoperative use of PDE-5 inhibitors helps address this.⁵ PDE-5 inhibitors act by increasing blood flow to the penis by smooth muscle relaxation of the blood vessels.9 However, patients with venous leakage and corporeal fibrosis tend to respond poorly to PDE-5 inhibitors,3 and it has been shown that PDE-5 inhibitors have a response rate of between only 15% to 80% following RP.5 Furthermore, following non-nerve-sparing RP, PDE-5 inhibitors are theoretically ineffective, as they rely on nerve formation

of nitric oxide.⁶ Therefore, overall, PDE-5 inhibitors alone may not be enough to succeed in penile rehabilitation; thus, a role for the VED emerges.

Despite a lack of large-scale trial evidence of VED success, there is evidence for high rates of satisfaction and efficacy, reported at rates exceeding 80%.¹⁰ VEDs used in penile rehabilitation without constriction rings following RP results

treatment; at 9 months after surgery, 17% of patients had a return of natural erections sufficient for penetration, compared with only 11% of those who did not receive treatment.⁶ In addition, daily use of the VED has been found to prevent loss of penile length, which occurs secondary to atrophy following prostatectomy.³

In combination, the VED used with a PDE-5 inhibitor has shown

In combination, the VED in addition to PDE-5 inhibitors has shown success. Studies have shown that a VED used for 5 to 10 minutes per day with tadalafil taken 3 times weekly has a success rate of 90%...

in a 60% improvement in spontaneous erections, as well as a significant improvement in International Index of Erectile Function (IIEF) scores when used early after surgery. The 2006 study by Raina and colleagues showed that early use of VEDs following RP resulted in 80% of patients successfully having intercourse, with a spousal satisfaction rate of 55%. Furthermore, the mean IIEF-5 score improved from 4.8 before treatment to 16 after

success. Studies have shown that a VED used for 5 to 10 minutes per day with tadalafil taken 3 times weekly has a success rate of 90% as measured by the IIEF-5 at 1 year, compared with 60% in those not using the VED.¹² Another study showed that VEDs combined with sildenafil postprostatectomy resulted in 30% of men reporting a return of spontaneous erections.¹⁰ Finally, use of the VED has also been found to reduce the

pain experienced with intracorporeal injections due to improved tissue health in the penile tissues. Overall, there is convincing evidence that VEDs are successful in the treatment of ED following RP, especially when used in combination with PDE-5 inhibitors, which appear to work synergistically to overcome postoperative changes and aid penile rehabilitation.

Discussion

Over time, there continues to be skepticism with regard to the use of VEDs, most likely arising from the lack of large-scale trial data on their efficacy. The existing trials are predominantly small and subjective in nature, with questionnaire-based feedback. In addition to this, there is a lack of universally defined terms, making these measures difficult to compare between existing trials.

Another resistance to VED use is the initial cost, and whether it should be the responsibility of primary or secondary care. The approximate cost to the UK National Health Service for a VED and constriction rings for approximately 5 years is £228 (\$349 USD).¹³ Given that there is no limitation to usage of the VED, it is by far the

cheapest long-term option among all ED treatments on the market today.

Equally, the cost of PDE-5 inhibitors is comparably low; 4 tablets of sildenafil cost between £16.59 (\$25 USD) and £19.34 (\$30 USD).9 With the recommendation that PDE-5 inhibitors be used at least once weekly, the cost is approximately £200 to £250 (\$307-\$383 USD) per year.

Even in combination, PDE-5 inhibitors and VEDs cost considerably less than intracorporeal injections alone; injectable alprostadil can cost up to £1000 per year (\$1533 USD) for a low-dose injection.¹³

When combined with the high compliance rates that have been demonstrated with VED use (as high as 80%), compared with only 40% compliance for intracorporeal injections, 10 dual therapy with PDE-5 inhibitors and VEDs is economically a far more cost-effective choice. Furthermore, the noninvasive nature of the VED and its few contraindications increase its availability to a wide number of patient groups who are clearly also satisfied with it as a treatment for ED.

Given that robotic prostatectomies are being performed in increasingly younger men, less-invasive therapies for ED will become progressively more important as a long-term solution in this population. Penile rehabilitation programs are increasingly used to facilitate the return of natural postoperative erections; the VED is an ideal therapy given that it increases blood flow and oxygenation to the corpora to reverse the changes that result in ED in the first place. Therefore, the VED should not be underestimated in its ability to aid in penile rehabilitation after prostatectomy, especially in combination with PDE-5 inhibitors. Further trial evidence will help to increase its position as a valid treatment.

References

- Landis SH, Murray T, Bolden S, Wingo PA. Cancer statistics, 1999. CA Cancer J Clin. 1999;49:8-31, 1.
- Raina R, Pahlajani G, Agarwal A, et al. Longterm potency after early use of a vacuum erection device following radical prostatectomy. BJU Int. 2010;106:1719-1722.
- Lehrfeld T, Lee DI. The role of vacuum erection devices in penile rehabilitation after radical prostatectomy. Int J Impot Res. 2009;21:158-164.
- Yuan J, Hoang AN, Romero CA, et al. Vacuum therapy in erectile dysfunction—science and clinical evidence. Int J Impot Res. 2010;22:211-219.
- Alivizatos G, Skolarikos A. Incontinence and erectile dysfunction following radical prostatectomy: a review. Scientific World Journal. 2005;5:747-758.
- Raina R, Agarwal A, Ausmundson S, et al. Early use of vacuum constriction device following radical prostatectomy facilitates early sexual activity and potentially earlier return of erectile function. *Int J Impot Res.* 2006; 18:77-81
- Oakley N, Moore KT. Vacuum devices in erectile dysfunction: indications and efficacy. Br J Urol. 1998; 82:673-681.

MAIN POINTS

- The risk of postoperative erectile dysfunction (ED) following radical prostatectomy (RP) is reported to be between 14% and 89%. The increase in the detection of prostate cancer in younger men has caused a subsequent emphasis on the appropriate management of ED after RP.
- A majority of patients have arterial insufficiency and venous leakage following RP, which is associated with arterial insufficiency. This causes hypoxia and subsequently increased production of transforming growth factor-β, apoptosis, and collagen deposition, culminating in corporeal fibrosis. The concept behind penile rehabilitation is the recovery of erectile function following RP by prevention and reversal of some of the aforementioned changes.
- There is convincing evidence that vacuum erection devices are successful in the treatment of ED following RP, especially when used in combination with phosphodiesterase-5 inhibitors, which appear to work synergistically to overcome postoperative changes and aid penile rehabilitation.

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- British Society for Sexual Medicine. Guidelines on the management of erectile dysfunction. British Society for Sexual Medicine Web site. http:// www.bssm.org.uk/downloads/BSSM_ED_Management_Guidelines_2009.pdf. Accessed June 3, 2013
- South Central Priorities Committee. Policy Recommendation 96a: Evaluation of treatments for erectile dysfunction. Solutions for Public Health Web site.
- http://www.sph.nhs.uk/ebc/sph-files/ship-policies/ship-policy-96a-evaluation-of-treatments-for-erectile-dysfunction/?searchterm=96a. Accessed June 3, 2013.
- Albaugh JA. Addressing and managing erectile dysfunction after prostatectomy for prostate cancer. *Urol Nurs*. 2010;30:167-177, 166.
- Köhler TS, Pedro R, Hendlin K, et al. A pilot study on the early use of the vacuum erection device after
- radical retropubic prostatectomy. BJU Int. 2007;100: 858-862
- Engel JD. Effect on sexual function of a vacuum erection device post-prostatectomy. Can J Urol. 2011;18:5721-5725.
- Tan HL. Economic cost of male erectile dysfunction using a decision analytic model: for a hypothetical managed-care plan of 100,000 members. *Pharmaco-economics*. 2000;17:77-107.