Best practice guidelines on the use of vacuum constriction devices for erectile dysfunction following radical prostatectomy

Professor Michael Kirby

British Society for Sexual Medicine

Introduction

Prostate cancer is the most common cancer in men in the UK, accounting for 24% of all new male cancer diagnoses.[1] Despite the range of alternative treatment modalities, radical prostatectomy (RP) remains the standard treatment for men with clinically localised disease, with over 4000 patients in this country undergoing the procedure every year.[2]

In conjunction with early detection, RP has resulted in a 15-year overall actuarial cancer-specific survival rate of 90%.[3] However, even with significant advances in surgical technique, excellent results for cancer control and preservation of urinary function, erectile dysfunction (ED) remains a common consequence of this procedure. Erectile function may take between 6-24 months to return, even among men in whom bilateral nerve sparing is performed, and reported recovery rates vary from 16%-86%.[4,5] Sexual dysfunction is a common quality of life issue following primary treatment for prostate cancer.

With a growing number of sexually active patients undergoing radical prostatectomy, the restoration of sexual function has become increasingly important, and the concept of penile rehabilitation following this procedure is now widely accepted in clinical practice. Penile rehabilitation has been defined as the use of any drug or device at the time of or following RP to facilitate the restoration of erectile function.[6] Penile rehabilitation is aimed at improving oxygen delivery to the penile erectile tissues, preserving erectile tissue health, minimizing erectile tissue damage and promoting the early recovery of natural erections. Current penile rehabilitation methods include the use of phosphodiesterase type 5 (PDE5) inhibitors, vacuum constriction devices (VCD) intracavernosal injection, intraurethral alprostadil and combination therapy.

These best practice guidelines focus on the use of vacuum constriction devices for penile rehabilitation following RP and are based on a review of the available literature published within the last decade.

Background

ED following RP results from damage to the penile nerves, vasculature and/or smooth muscle. Neuropraxia as a result of trauma from thermal injury and/or traction on the cavernous nerves has numerous effects on erectile function and is almost impossible to avoid, even after meticulous surgical dissection and bilateral nerve sparing surgery. Even the most minor neural trauma can cause at least short-term erectile problems and the immediate effect is a loss of daily and nocturnal erections.[7]

Neuropraxia has several consequences and is associated with smooth muscle apoptosis, collagen accumulation and fibrosis. Cavernosal changes may also be attributed to hypoxia as a result of haemodynamic changes.[8] Smooth muscle apoptosis and constriction can lead to post-prostatectomy veno-occlusive dysfunction[9,10] and a prolonged loss of erectile function.[10] The accessory pudendal arteries are also vulnerable to injury at the time of RP and arterial insufficiency as a result of damage to these arteries during surgery has been shown to result in poorer recovery and a longer delay in recovery compared to patients in whom the integrity of these arteries was preserved.[11] In addition to a loss of erections, cavernous tissue damage following RP may result in significant reductions in penile length and circumference, and these changes have been shown to occur within the first few months of surgery.[12,13,14]

Men with normal erectile function have three to six erections each night during rapid eye movement sleep,[15] which exercises the penile tissues and keeps them healthy. Following damage sustained by RP, it appears that the longer a man goes without erections, the more tissue damage occurs and the more difficult erections are to restore.

The need for guidelines

The British Society for Sexual Medicine Guidelines of 2007[16] recommend vacuum erection devices as a first line treatment option for ED after RP.

NICE guidance of 2008[17] recommends that men who experience a loss of erectile function following RP should be offered PDE5 inhibitors to improve their chance of spontaneous erections. If these agents fail to restore erectile function, or are contraindicated, vacuum devices can be offered as an alternative.

Although vacuum constriction devices can be prescribed under Schedule 2, many GPs are unfamiliar with these products and there is currently a lack of guidance for clinicians regarding the use of these devices for ED following RP.

Evidence for the efficacy of vacuum constriction devices in the treatment of ED following RP

Although various studies have investigated the use of VCDs for erectile dysfunction, few have investigated the effectiveness of the VCD in artificially inducing erections after RP with the aim of preventing permanent damage.

Rupesh Raina and colleagues[18,19] investigated the early use of a vacuum constriction device for ED with treatment initiated within 2 months of nerve-sparing or non-nerve sparing RP. The study involved 109 men aged 50-71 years. The VCD was used daily and the constriction ring only applied when attempting sexual intercourse. Following 9 months of treatment, 80% of patients successfully used their VCD with a constriction ring for vaginal intercourse at a frequency of twice a week. 32% of patients using the device reported a return of natural erections at 9 months, with over 52% of those having erections sufficient for vaginal intercourse (this potency rate was significantly greater than that seen in the researchers' contemporary series (without VCD), which had a natural potency rate of 24% at 12 months). Overall, 17% of patients in the treatment group had a return of natural erections sufficient for vaginal intercourse compared to 11% of patients in the non-treatment group. Only 23% of successful VCD users reported a reduction in penile length and circumference at 6 months (range 4-8 months) compared to 85% of unsuccessful VCD users and 63% of the non-treatment group. Efficacy of the VCD was confirmed by a significant increase in Sexual Health Inventory of Men (SHIM) scores (abridged 5-item International Index of Erectile Function (IIEF-5), with total IIEF scores rising from 4.8 postsurgery to 16 after VCD use ($p \leq 0.05$). There was no statistical difference in the IIEF-5 scores or response to individual questions between the nerve-sparing or non-nerve sparing groups.

Tobias Kohler and colleagues[20] conducted a pilot study to evaluate the effect of early use of the VCD on ED after RP. 28 men who had undergone unilateral or bilateral nerve sparing surgery were randomised to either early intervention with VCD treatment initiated 1 month after RP, or a control group with treatment initiated 6 months after RP. Patients in the early intervention group used the VCD without the constriction ring for 10 minutes per day for 5 months. Follow-up continued for 6-12 months after surgery. IIEF scores were significantly higher in the early intervention group than the control group at both 3 (11.5 vs 1.8; $p=0.008$) and 6 months (12.4 vs 3.0; $p=0.012$) after RP. Although there were no differences between the groups in flaccid penile length or mid-shaft circumference, while stretched penile length was preserved in the early intervention group at all times, it was significantly reduced at both 3 and 6 months in the control group. However, patients in both groups were allowed to use PDE-5 inhibitors 6 months following RP, which means results obtained after this time are unlikely to have been entirely attributable to the VCD.

Rationale for the use of vacuum constriction devices for ED following RP

- Although oral agents are recommended as first line treatments for the treatment of ED after RP,[16,17] they have limited efficacy in patients who have undergone non-nerve sparing surgery.[21,22] VCDs are highly effective in inducing erections regardless of the cause of the ED.[23] These devices can therefore be used in the early stages of penile rehabilitation following RP until the nerves have healed sufficiently for drug treatments to work, they can also be combined with PDE5 inhibitors and intraurethral alprostadil, or used as an alternative to drug treatment when it is unsuccessful or unacceptable.
- Research suggests that early use of the of VCD after RP facilitates early sexual intercourse, early patient/spousal sexual satisfaction, maintenance of penile size and an earlier return of natural erections.[18,19,20]
- Satisfaction scores are generally high for both patients and their partners,[19] and most men who are satisfied with the VCD continue to use it long-term.[24]
- As compared to drug treatments for ED, a major advantage of the VCD is that it has a low risk of systemic side-effects and therefore the potential to be used in a greater number of patients.
- The VCD can be used to ensure multiple erections on a daily basis. Although it is not known how many erections are required in a given time to maintain the health of erectile tissue, it is plausible that if a man with normal erectile function has 3-6 erections every night, the VCD has the potential to more closely mimic natural physiology.
- Even though initial costs are significant, VCDs represent a very cost-effective way of treating ED over the long-term.[16]

Adverse effects of the VCD

Adverse effects of the VCD

- These include bruising, local pain and failure to ejaculate.[16] However, ejaculation is expected to be absent after RP and some of the other adverse effects may be reduced or eliminated with careful instruction on using the VCD.
- Urinary leakage can occur during use of the VCD if urinary control has not been achieved following RP.

Who should receive penile rehabilitation with a VCD for ED after RP?

- Patients who are motivated and sexually active preoperatively, who are interested in maintaining preoperative potency.[18]
- VCDs are most effective if the man and his partner have positive attitudes towards using them.[16]

Who should not be prescribed the VCD

- VCDs are contraindicated in men with bleeding disorders or those taking anticoagulant therapy.[16]
- Patients with severe Peyronie's disease are unlikely to be able to use the device.

Timing of penile rehabilitation with the VCD

- Clinical studies demonstrating efficacy of the VCD in restoring erections and maintaining penile size post RP initiated therapy at 1 month[20] or between 2-8 weeks (mean 3.9 weeks) after surgery.[18] 4-8 weeks may therefore be considered an appropriate recovery period, but this should be governed by the degree of healing and the patient's level of comfort.

The provision of information and support for patients

- Prior to performing RP in sexually active men, patients should be informed about the possible adverse effects surgery may have on their sexual function, the importance of concordance with early penile rehabilitation in restoring sexual function after RP, and the various therapeutic options that are available to them.
- VCDs are most effective if sufficient time has been spent demonstrating their use.[16] Clinicians prescribing VCDs will need to familiarise themselves with the devices and how they should be used.
- Some hospitals and clinics provide vacuum constriction devices on a short-term loan basis and provide technical support clinics for patients requiring advice or assistance with any devices.
- Individual product manufacturers may also provide a helpline for patients using their products and/or one-to-one instruction with a trained advisor.
- Following RP for prostate cancer, healthcare professionals should ensure that men and their partners have early and ongoing access to specialist erectile dysfunctions services.[18]
- Any patient requiring further explanation, extra support or specialist information should be referred to an appropriate health care professional.

An appropriate health care professional should possess:

- Experience, knowledge and understanding of the effects RP may have on erectile function.
- An awareness of the psychological impact ED after RP may have on the patient and their partner.
- Experience of the pharmacological and non-pharmacological options available for treating ED after RP.
- Familiarity with the working of the VCD and use of constriction rings.
- Excellent communication skills to provide empathy, support and guidance.
- Knowledge of the specialist services available for the sexual and relationship counselling of men and their partners.

Guidance on using VCDs

- Clinical trials demonstrating efficacy of the VCD for ED after RP involved daily use.[18,19,20] Because men with normal erectile function have multiple erections in a 24 hour period, when using the device for penile rehabilitation, patients should be advised to use the device at least once-daily. The aim is to achieve approximately 20 engorgements daily, which can be done in one 10 minute session, two 5 minute sessions or with multiple sessions throughout the day.
- Penile rehabilitation with the VCD can continue until natural erections are restored. The device can be used indefinitely if natural erections do not return.
- There are a number of different VCDs on the market, most of which use a similar technique but vary in their method of inducing a vacuum.
- The full system incorporates a plastic cylinder, vacuum pump, any necessary tubing and selection of constriction bands.
- Information on use is provided on paper or as a DVD.
- Because it reduces arterial inflow as well as venous outflow, the constriction ring should not be used for penile rehabilitation purposes.[15] However, it should be used for maintaining an erection for vaginal intercourse.

- When the VCD is used for penile rehabilitation the penis and cylindrical vacuum pump should be thoroughly lubricated with water soluble jelly. The cylinder is placed over the flaccid penis and pushed firmly against the pubis to create an airtight seal. The pump is then used to cause penile engorgement. Alternatively, the flaccid penis is drawn into the cylinder using the pump, the cylinder is pressed firmly against the body and the pumping then stopped to allow a full erection to develop. Pumping slowly appears to be more effective than pumping fast. Once an erection is achieved the vacuum pump can be released. This process can be repeated to achieve the recommended number of engorgements each day.
- To create an erection sufficient for vaginal intercourse, the penis, cylindrical vacuum pump and appropriate sized constriction ring should be thoroughly lubricated with water soluble jelly. The constriction ring is placed either directly onto the open end of the cylinder or slid over a transfer sleeve to the base of the cylinder. The cylinder is placed over the flaccid penis and pushed firmly against the pubis to create an airtight seal. The pump is then used to cause penile engorgement. Alternatively, the flaccid penis is drawn into the cylinder using the pump, the cylinder is pressed firmly against the body, and the pumping then stopped to allow a full erection to develop. Pumping slowly appears to be more effective than pumping fast. Once a full erection has developed, the constriction ring can be transferred onto the base of the penis and the vacuum pump removed. The constriction ring should not be worn for more than 30 minutes and a break of at least 60 minutes should be taken between uses to allow full restoration of the penile blood supply. If a condom is to be worn, is should not be used during the vacuum process, but put on as a last step.
- Always refer to individual manufacturers' instructions.

Research

There is an urgent need for randomised trials to evaluate the efficacy of daily PDE5 inhibitors in combination with VCD therapy for ED following RP.

Conclusions

VCDs have been in use for the past 3 decades and are a well established treatment for ED, being suitable for use in most patients with a low incidence of serious side-effects. They also appear to be an effective therapy for penile rehabilitation following RP when used without the constriction ring. The VCD offers patients and their partners the opportunity to play an active role in their rehabilitation and recuperation following RP. Careful and adequate education and instruction are important factors in gaining patient acceptance and maintaining concordance with these devices.

Thanks to all who assisted with these guidelines:

Professor Michael Kirby – Visiting Professor-The Prostate Centre, London & Faculty of Health & Human Sciences, University of Hertfordshire / Council member of the British Society for Sexual Medicine.

Thanks to the critical readers:

Dr David Edwards – GP, White House Surgery, Chipping Norton, Treasurer of the British Society for Sexual Medicine

Sarah M Hughes – Urology Nurse Specialist, Morriston Hospital, Swansea

Mr Neil Fenn – Consultant Urologist at Morriston Hospital, Swansea, Lead Clinician and programme director for urological training in Wales

Mr John McCoid – Independent Consultant in Sexual Medicine and former nurse practitioner in urology at Glasgow Royal Infirmary

Mr Ian Russel – Specialist practitioner in Andrology, Sexual Medicine, Royal Infirmary, Dumfries and Galloway

Patricia Allen MA – Clinical Nurse Specialist Andrology, Urology, Andrology Service, Urology Directorate, Royal Hallamshire Hospital

references

1. Cancer Research UK. UK Prostate Cancer Incidence Statistics. Available at: http://info.cancerresearchuk.org/cancerstats/types/prostate/incidence/ (Accessed 13/11/09).
2. Sethia KK. Open versus laparascopic radical prostatectomy. Ann R Coll Surg Engl 2007; 89: 109-112.
3. Han M, Partin AW, Pound CR *et al*. Long-term biochemical disease-free and cancer-specific survival following anatomic radical retropubic prostatectomy. The 15 years Johns Hopkins experience. Urol Clin North Am 2001; 28: 555-65 (Abstract).
4. Nandipati KC, Raina R, Argawal A et al. Erectile dysfunction following radical retropubic prostatectomy: epidemiology pathophysiology and pharmacological management. Drugs Aging 2006; 23: 101-17.
5. Mulhall JP, Mogentaler A. Penile rehabilitation should become the norm for radical prostatectomy patients. J Sex Med 2007; 4: 538-43.
6. Mulhall JP. Penile rehabilitation following radical prostatectomy. Curr Opin Urol 2008; 18: 613-620.
7. Magheli A, Burnett AL. Erectile dysfunction following prostatectomy: prevention and treatment. Nat Rev Urol 2009; 6: 415-427.
8. Hatzimouratidis K, Burnett AL, Hatzichristou D *et al*. Phosphodiesterase type 5 inhibitors in postprostatectomy erectile dysfunction: a critical analysis of the basic science rationale and clinical application. Eur Urol 2009; 55: 334-47.
9. Mullerad M, Donohoe JF, Li PS et al. Functional sequelae of cavernous nerve injury in the rat: is there model dependency? J Sex Med 2006; 3: 77-83.
10. Granchi S, Vannelli GB, Vignozzi L *et al*. Expression and regulation of endothelin-1 and its receptors in human penile smooth muscle cells. Mol Hum Reprod 2002; 8: 1053-64.
11. Rogers CG, Trock BP, Walsh PC. Preservation of accessory pudendal arteries during radical retropubic prostatectomy: surgical technique and results. Urology 2004; 64: 148-151.
12. Fraiman M, McCullogh A, Lepor H. changes in penile morphometrics in men with erectile dysfunction after nerve-sparing radical retropubic prostatectomy. Mol Urol 1999; 3: 109-15.
13. Munding M, Wessells H, Dalkin B. Pilot study of changes in stretched penile length 3 months after radical retropubic prostatectomy. Urology 2001; 58: 567-9.
14. Savoie M, Kim SS, Soloway M. A prospective study measuring penile length in men treated with radical prostatectomy for prostate cancer. J Urol 2003; 169: 1462-5.
15. Wang R. Penile rehabilitation after radical prostatectomy: where do we stand and where are we going? J Sex Med 2007; 4: 1085-1097.
16. British Society for Sexual Medicine Guidelines on the Management of Erectile Dysfunction. 2007. Available at: http://www.bssm.org.uk/downloads/BSSM_ED_Management_Guidelines_2007.pdf (Accessed 23/11/09).
17. NICE guideline 58. Prostate Cancer diagnosis and treatment. February 2008. Available at http://www.nice.org.uk/nicemedia/pdf/CG58FullGuideline.pdf (Accessed 23/11/09).
18. 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.
19. Raina R, Agarwal A, Zippe C. Management of erectile dysfunction after radical prostatectomy. Urology 2005; 66: 923-929.
20. Kohler TS, Pedro R, Hanlin K *et al*. A pilot study on the use of the vacuum erection device after radical retropubic prostatectomy. BJU 2007; 100: 858-862.
21. Raina R, Agarwal A, Shyam S *et al*. Sildenafil citrate and vacuum constriction device combination enhances sexual satisfaction in erectile dysfunction after radical prostatectomy. Urology 2005; 65: 360-364.
22. Raina R, Lakin MM, Agarwal A *et al*. Efficacy and factors associated with successful outcome of sildenafil citrate use for erectile dysfunction after radical prostatectomy. Urology 2004; 63: 960-966.
23. Levine LA, Dimitriou RJ. Vacuum constriction and external erection devices in erectile dysfunction. Urol Clin North Am 2001; 28: 335-341.
24. Dutta TC, Eid JF. Vacuum constriction devices for erectile dysfunction: a long-term, prospective study of patients with mild, moderate and severe dysfunction. Urology 1999; 54: 891-893.

British Society for Sexual Medicine

Produced and published by

Owen Mumford

Owen Mumford Ltd, Brook Hill, Woodstock, Oxon OX20 1TU
www.owenmumford.com

January 2011