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Vacuum erectile devices for managing erectile dysfunction for those receiving radical prostate radiotherapy and androgen deprivation therapy: a user evaluation

Isabel Wilson[1], Phil Reynolds[2] and Pete Bridge[1]

[1]School of Allied Health Professions and Nursing, University of Liverpool, Liverpool, UK and [2]Clatterbridge Cancer Centre, Liverpool, UK

Original Article

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Corresponding author:
Pete Bridge; Email: pete.bridge@liverpool.acuk

Abstract

Introduction: Radiotherapy with androgen deprivation therapy (ADT) is the standard of care for locally advanced prostate cancer but causes erectile dysfunction (ED). Vacuum erectile devices (VED)s are a first-line treatment for ED along with phosphodiesterase-5 inhibitors (PDE5-Is), yet all evidence supporting their use arises from post-surgical ED. This study aimed to assess effectiveness of VEDs for patients with ED resulting from radiotherapy and ADT.
Methods: This service evaluation utilised a longitudinal survey method to gather ED scores at baseline, after commencing ADT and after receiving a VED. Patients who were undergoing ADT for prostate cancer either before or alongside radical radiotherapy and who had been referred to receive a VED were invited to participate. Data including how patients used the VED, psychosexual counselling and PDE5-Is were also collected. Thematic analysis was used to identify men's perceptions of the VEDs.
Results: Data from the 15 participants demonstrated statistically significant treatment-related ED but failed to determine impact of VED on this. Qualitative data identified that participants found the VEDs to be unhelpful, too clinical, unappealing, emasculating and frustrating to use. Limited data suggested that VEDs are more effective at treating ED when used in combination with PDE5-Is.
Conclusion: Patients in this small sample generally reported dissatisfaction with VED usage. Limited engagement with the study frustrated attempts to draw conclusions regarding the effectiveness of VEDs for radiotherapy patients suffering from ED during ADT and a larger national study should be conducted to establish this. Improvements to the care pathway and access to psychosexual counselling are recommended.

Introduction

External beam radiotherapy with androgen deprivation therapy (ADT) is the international standard of care[1] for locally advanced prostate cancer yet has a significant impact on erectile function (EF). Radiotherapy directly impacts vascular structures, which can reduce EF, but this is a late effect and, for these patients, the addition of ADT causes immediate loss of EF due to the blocking of interactions between androgens and the prostate and therefore a decrease in the production of testosterone.[2] The duration of these side effects may extend 3–6 months beyond completion of ADT.[3] Erectile dysfunction (ED) following treatment has an extensive impact psychologically on men and can lead to depression, anxiety, a lack of sexual confidence and potential avoidance of sexual activity.[2,3] Previously, treatment success for prostate cancer has been measured almost exclusively by survival rates. A paradigm shift has altered this perspective, and the significance of preservation of sexual function and the treatment of and recovery from ED is rightly being recognised as a factor central to survivorship care for men with prostate cancer, as well as their partners.[3]

Erectile dysfunction (ED) is the most commonly reported health-related quality of life (QoL) outcome following prostate cancer treatment.[3] According to national guidance,[3] the first-line treatment for ED for men who have had radiotherapy and ADT for PCa is early initiation of phosphodiesterase-5 inhibitors (PDE5-I), combined with optional use of a vacuum erectile device (VED) 10 min daily and psychosexual counselling.[4] VEDs mechanically engorge the corpora and glans with venous blood, producing an erection using a vacuum seal independent of the autonomic and sensory neuronal control often damaged following radiotherapy. The vacuum seal is placed on the base of the penis, and an electric or manual pump produces a negative pressure within the cylinder, pulling blood into the phallus. A constriction ring can be placed at the penile base to maintain the erection throughout sexual intercourse for up to 30 min.[5] An associated benefit of VEDs, compared to PDE5-Is, is reducing further penile

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shortening and shrinkage of the testicles caused by reduced EF and long-term damage from radiation.[6] VEDs can significantly improve peak flow velocity and vascular diameter of the cavernous arteries of patients with organic ED and can prevent fibrosis of the corpus cavernosum.[6]

Early guidance[4] related to VED use was derived from a review and UK-wide consensus survey and stated recommended early initiation of PDE5-Is with an option to include use of a VED for 10 min daily and psychosexual counselling. More recent international guidelines.[3] have been developed to engage patients in taking ownership of their sexual recovery and to provide a framework to facilitate shared decision-making between clinicians, patients and partners around such an important survivorship goal. Whilst this guidance supports use of VEDs, it states that patients should be informed about the lack of direct evidence demonstrating consistent benefit of VEDs for these patients.

There is good evidence related to the efficacy of VEDS with evidence for the benefits of early VED intervention reported in a 2010 study[7] which compared early intervention of VEDs (<6 months following radical prostatectomy) with delayed intervention (>6 months). The study reported significant improvement in EF for the early intervention cohort, along with an increase in the proportion of men experiencing unassisted erections and PDE5-I assisted erections (58% vs 30%). This research, however, focused on men who suffered from ED following surgery and may not be generalisable to the population of men who have radiotherapy and ADT. A 2016 study[5] assessed the efficacy of VEDs and patient satisfaction of a dedicated VED clinic in 65 men attending a dedicated VED clinic where 40 (76·3%) purchased a VED. They reported significant differences between 3-month postoperative and the post-VED use EF scores, with all participants reporting the VED to be helpful. Despite the unavoidable consequence of a reduction in EF after surgery, successful erections were attained with the assistance of a VED. Again, however, this study focuses on post-surgical patients and not those treated with radiotherapy and ADT. In fact, all evidence supporting use of VEDs relates to their use as a post-surgical intervention. The radiotherapy and ADT-induced causes of ED are different, however, and this evidence may not apply to them. Since no studies have thus far evaluated the use of VEDs for men with ED following radiotherapy and ADT, this service evaluation aimed to gather new data related to the lived experience of these VED users.

Methods

A longitudinal descriptive survey method was adopted to identify the impact of VEDs on ED and the patient's lived experience. The survey adopted a multi-methods approach to gather mostly quantitative data providing objective, measurable results with some additional qualitative data providing more detailed information on men's lived experiences using the VED. A survey method was utilised to ensure that sensitive information could still be collected whilst minimising the discomfort of participants sharing their experiences and thus increasing response rate[8] The project gained approval as a quality improvement project by the local clinical governance committee. All participants provided written informed consent and were advised that responses were voluntary and anonymous.

Participant recruitment

Patients who were undergoing ADT for prostate cancer either before or alongside radical radiotherapy were referred to a specialist VED clinic at a hospital, informed verbally during their appointment about the study and invited to take part in the evaluation. A convenience sample was utilised based on a specific timeframe for the study. Potential participants were excluded if they could not speak English sufficiently well to understand the questionnaires and if they were not prescribed external beam radiotherapy combined with ADT for radical treatment. This group included patients with local and advanced diseases due to small projected participation rates.

Data collection

An anonymous online baseline questionnaire (SurveyMonkey) was emailed to participants in June of 2023, prior to commencement of ADT; a second anonymous online questionnaire in September 2023 prior to receipt of the VED and a final anonymous online follow-up questionnaire was sent in December 2023 after participants had been offered/received the VED. All three questionnaires sought demographic data and utilised the International Index of Erectile Function (IIEF-5) questionnaire, a multi-dimensional self-report tool that evaluates male sexual function. The IIEF-5 is considered the gold standard measure for efficacy assessment in clinical trials of ED[9] and was used to calculate a score representative of ED severity. Additional questions related to the care pathway included how long they had to wait, whether they had chosen to receive a VED and whether they had received psychosexual counselling and/or PDE5-Is. The final questionnaire given to participants included an open question asking if they were still using the VED, and if they were not, asking them to explain why they were unwilling to continue using the VED. In May 2024, a further follow-up questionnaire was sent out, which collected data on whether participants were still using the VED with/without PDE5-Is and assessed their erectile function.

Data analysis

The quantitative data from the questionnaires were subject to statistical analysis. Data were subjected to the Shapiro-Wilks test to determine normality. Data were then subjected to the Mann-Whitney U test for the comparison of two paired samples of the non-normally distributed, ordinally scaled parameters. This was done to establish whether there was a statistically significant difference in EF between the surveys 1, 2 and 3, and hence evaluate the effectiveness of VEDs in improving and preserving EF, with the null hypothesis being that EF remained unchanged. Part of the quantitative data collected related to adherence to the recommended care pathway, and these were utilised to conduct a simple clinical audit against national and international guidelines.[3,4] Descriptive statistics were used to compare timings and percentage compliance.

Responses to the open question were subject to thematic analysis. The focus was on identifying and describing both implicit and explicit themes within the data. The Giorgi method was implemented to perform thematic analysis, as in phenomenological research, it is the participant's feelings and lived experiences that are paramount.[10]

Results

Cohort demographics

A total of 15 men who had radiotherapy and ADT for prostate cancer participated in the study. All 15 responded to both the baseline survey and the survey after commencing hormones, but only 11 responded to the survey after receiving the pump. Only

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four responded to the survey at the final time point. The ages of participants ranged from 59 to 83, with a mean age of 70·5 and a wide range of clinical features. The Cambridge Prognostic Group (CPG) system[11] was used to classify men into five categories based on information about the clinical features of their disease. This is commonly utilised to inform management decisions for prostate cancer and takes into account a wide range of combinations of Gleason biopsy score, pre-treatment prostate-specific antigen and clinical stage. CPG scores for the cohort are shown in Table 1. Timing for receipt of the VED varied considerably between the participants; this was due to differences in response times between clinics.

There was a range of variables within the study relating to the inhomogeneity of the sample group and the low engagement rates. The participants had received a variety of radiotherapy doses and techniques; some to the prostate and some including nodes. Doses were in accordance with National Institute for Health and Care Excellence (NICE) guidance although one participant in a trial was allocated to receive 67Gy/20#/4 weeks. None of the participants were in same-sex relationships. Before commencing radiotherapy and ADT, six participants had no ED; six had mild ED; one had moderate ED and two had severe ED, which was calculated using the IIEF-5 questionnaire. Two participants were on PDEI-5s before commencing treatment.

Of the 11 participants that responded to the final survey, six were on PDE5-Is and eight had received the VED. Only four of these responded to the question asking how long after commencing hormones they received the VED. Two participants received the VED after three months, one received it around the same time as commencing hormones and one participant received it after two and a half years. Out of 15 participants, only one received psychosexual counselling.

Impact of VEDs on EF

Figures 1–4 demonstrate the change in EF determined by IIEF-5 scores at each time point.

The Shapiro-Wilks test identified that the IIEF-5 scores for Surveys 1 and 2 were not normally distributed, although the Survey 3 responses were. The Mann-Whitney U test demonstrated a statistically significant difference ($p < 0{\cdot}00016$) in EF scores between surveys 1 and 2 but failed to identify any between EF scores in surveys 2 and 3. The final survey determined that the 2 participants that used the VED in combination with PDE5-Is had improved erectile function, with no erectile dysfunction and mild erectile dysfunction; compared to 2 participants who used VEDs alone who had moderate erectile dysfunction and severe erectile dysfunction.

Thematic analysis

The 11 respondents to survey 3 were asked whether they had received a VED, and whether they were still using it, shown in Fig. 5.

The participants who did not receive the VED or were no longer using it were asked why; five main themes were identified from their responses, as seen in Table 2. These formed the basis for the main discussion section following.

Discussion

The aim of this study was to identify the impact of VEDs on ED and the patient's lived experience arising from use of these. The study was thwarted by low response rates, but some key themes were identified and are discussed below.

Table 1. Numbers of participants per Cambridge Prognostic Group (CPG) group

CPG	Participants (n(%))
1	1 (6·7%)
2	1 (6·7%)
3	3 (20%)
4	6 (40%)
5	4 (26·7%)

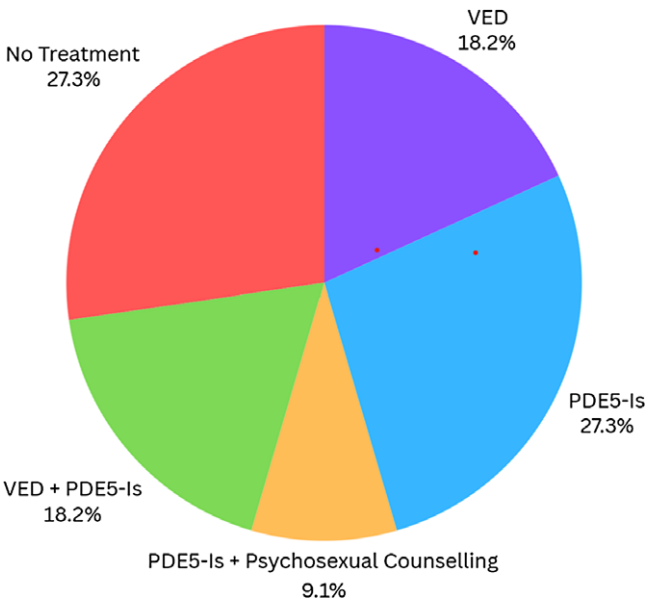

Figure 1. Interventions chosen by participants.

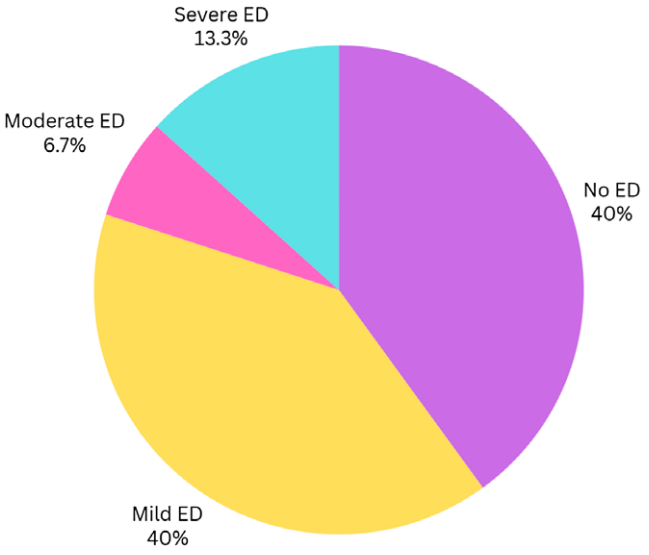

Figure 2. Erectile dysfunction among participants in survey 1 — baseline.

Cohort characteristics

The average age of the cohort is slightly younger than the age group of 75–79 with the highest rates of prostate cancer.

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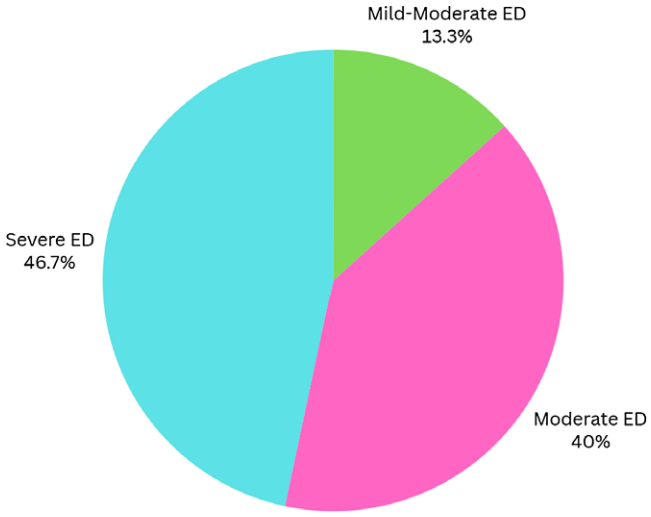

Figure 3. Erectile dysfunction among participants in survey 2 — after commencing androgen deprivation therapy.

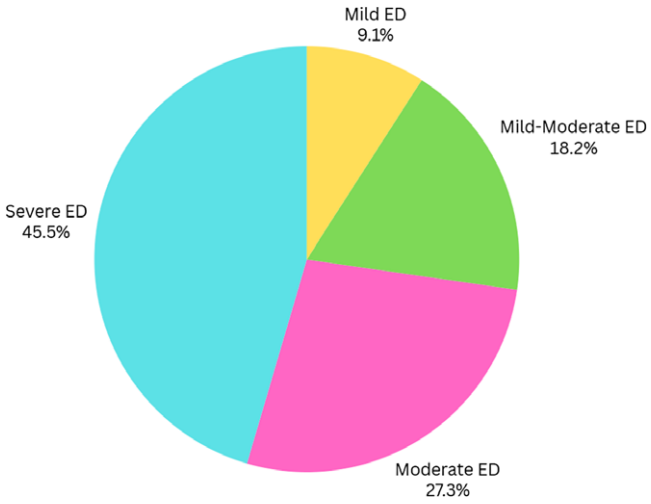

Figure 4. ED among participants in survey 3 — after receiving vacuum erectile device.

Nonetheless, the age range of 70–74 had the highest average number of cases per year between 2016–2018, with 11,153 new cases and an incidence rate of 759·8 per 100,000 male population.[12] Our sample included men with localised and locally advanced cancer, so this did mean that length of ADT varied from 6 months to 3 years. The majority of participants were CPG 4 and 5 (highest risk group); this suggests that the sample is not representative of the general population, which exhibits equal distribution among the classifications. Our data match that of Parry et al.,[13] who reported a proportion of men receiving radical treatment increasing from 11·3% in CPG1 to 78·8% in CPG4, and 73·3% in CPG5.

A further limitation of the study is that none of the participants were in same-sex relationships. Men in same-sex relationships are disproportionately affected by prostate cancer despite not being at an increased risk of developing the disease. This is because both partners have a prostate gland — this translates to a one in four chance of being directly or indirectly affected by the disease.[14]

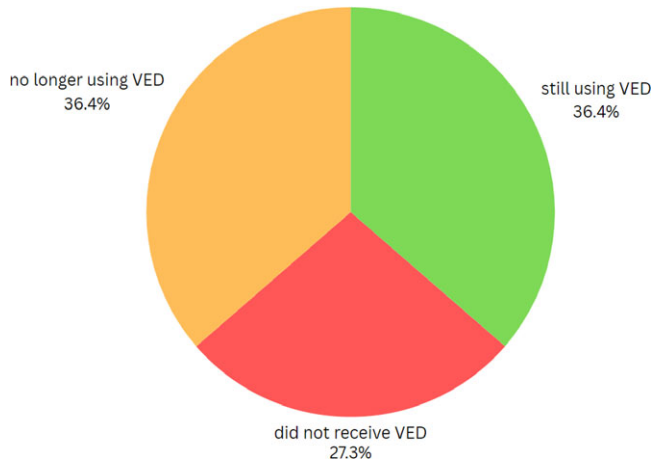

Figure 5. Percentage of participants who are still using/not using the vacuum erectile device.

Impact on EF

Unsurprising statistically significant results demonstrated that participants' EF decreased following commencement of ADT. Before commencing treatment, 80% of the men were suffering from either no ED or mild ED. After commencing ADT, 100% of participants were suffering from mild-moderate ED, moderate ED or severe ED.

No statistically significant data were found to support the effectiveness of VEDs as a treatment for radiotherapy and ADT-induced ED, which contrasts with evidence from past studies demonstrating the effectiveness of VEDs for men who have had surgery for prostate cancer.[2,5,15] However, out of the 11 participants that completed the final survey, only 4 continued using the VED, so it is not possible to conclude from this data that VEDs are ineffective.

The lack of psychosexual counselling may have impacted the potential of VED efficacy in improving erectile function. A randomised controlled trial of 45 patients suffering from ED selected 25 couples to have psychosexual counselling along with the VED. In this study, 95% of participants who continued using the pump had an improved outcome as assessed by the therapist compared to 60% of the participants who did not have this combination therapy.[16] This demonstrates how addressing both the physical, psychological and social components holistically can aid in improving ED. However, this evidence is again based on men who have ED for a variety of reasons, not solely as a consequence of radiotherapy and ADT to treat prostate cancer.

Very limited data from the final survey align with reported data[4] that men who used the VED in combination with PDE5-Is had improved outcomes than those who used it alone; however, it is not possible to conclude this with such a limited sample size.

Clinical audit

Of the 11 participants that responded to the final survey, six were on PDE5-Is and eight had received the VED. Only four of these responded to the question asking how long after commencing hormones they received the VED. Two participants received it after three months, one received it around the same time as commencing hormones and one participant received it after two and a half years. For the most part, this was good adherence to

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Table 2. All responses and identified themes

Theme	VED Status	Response
Not helpful	No longer using	'Too difficult to use, can't get it to work'
Not helpful	No longer using	'No benefit with pump or medication'
Not helpful	No longer using	'Not helpful'
Not appealing	Not received	'Didn't fancy getting it after meeting (VED demonstrator)'
Emasculation	No longer using	'Stopped using it as do not feel like a man'
Too clinical	Not received	'Did not collect, didn't fancy it. Too clinical'
Frustration with service	Not received	'Who knows? Have you sent it?'

guidance that treatment should be initiated soon after commencing ADT, no later than 3–6 months.[4] This is important because as identified in the literature review, there is evidence for the benefits of early intervention.[3,7]

One participant, however, did not receive the VED until 2 and a half years after commencing ADT. This could be for a variety of reasons. The patient's primary focus throughout treatment may have been on his disease, and it was not until 2 and a half years later that he paid attention to his ED. Alternatively, radiation-induced ED has been shown to increase between one- and two-years post radiotherapy,[17] which may have been the case for this patient. It is impossible to deduce from the experience of one participant whether quality improvement is required in this area.

Out of 15 participants, only one received psychosexual counselling. This is against guidance from both Prostate Cancer UK[4] and Movember[3], which place emphasis on the importance of psychosexual counselling in improving the effectiveness of sexual rehabilitation programmes. It improves compliance and acceptance of treatments and reduces loss of sexual interest. It is essential in strengthening relationships and helping couples overcome distress. Clinicians should provide support for couples coping with the sexual side-effects of PCa therapy both directly and through referral for psychosexual treatment.

Qualitative Themes

Theme: feelings about the device

The comments relating to 'not helpful', 'not appealing' and 'too clinical' indicate poor acceptance from participants despite the evidence that VEDs improve erectile function in 84–95% of patients post-surgery.[5,17] This reinforces the need for more research into the effectiveness of VEDs for patients who have had radiotherapy and ADT[2] and, in particular, about how best to engage users with them. These comments may reflect how VEDs are uncomfortable, clumsy and mechanical; a skilled instructor is needed and they are not always acceptable to partners.[4] These themes are supported by a study which investigated the efficacy of two types of VEDs and identified only 46% continued treatment after 1 month, 23% of those who discontinued stated ineffectiveness and 6% lacked acceptance of patient and partner.[18]

Theme: emasculation

The sentiment of emasculation may be due to the perception of VEDs as awkward and their interference with foreplay and sexual cadence. The erection induced by VEDs is not a natural feeling and must be sustained with a tension ring which can result in altered penile sensations during intercourse.[19] This is consolidated by the extensive psychological impact ED can have on men following prostate cancer therapies which can lead to depression, anxiety and a sense of loss of masculinity.[3]

ADT often results in metabolic syndrome and body changes towards sarcopenic obesity, genital shrinkage and gynaecomastia. Many men experience negative changes to their body image as a result.[20] Manhood is commonly defined societally by athleticism, sexual readiness and stoicism. ED makes patients feel less capable of meeting their culture's model of what it means to be manly, and men may experience a reduction in their sense of masculinity as a result.[21]

Theme: frustration with service

One of the participants did express frustration with the service provided, having failed to receive the VED. A UK-wide cross-sectional survey of men with ED following prostate cancer treatment[22] supports this feeling, revealing inadequate management of ED in primary care. Twenty-one percentage of participants were not offered any ED management and 23% were unsatisfied with the way healthcare professionals addressed ED. There was poor communication and HCPs failed to initiate conversations about ED or involve partners, while 12% were not informed that ED was a probable side effect. These results contrast with guidance from Movember 2022[3] which states that it is the responsibility of the clinician to initiate discussions about ED and involve the partner. Confusion about how the participant is supposed to receive the VED could be a result of this poor communication, resulting in dissatisfaction with the service provided.

Study Limitations

A key limitation of this study is the small sample size of 15 participants, which was reduced to 11 at point of completion of the final survey. In this case, it is possible that the participants who suffered from the worst ED dropped out of the study, resulting in attrition bias. The study is unable to differentiate between different factors that influenced the participants' EF including other comorbidities, smoking status, BMI, age, pre-existing ED, testosterone levels and time it takes for testosterone levels to return to normal after ADT.[4] Finally, the uncontrolled nature of the study meant that participants utilised a range of interventions, making it difficult to identify VEDs as an effective means of treating ED after combined radiotherapy and ADT for prostate cancer.

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Conclusion

The aim of this research was to evaluate the effectiveness of VEDs in treating ED arising from radiotherapy and ADT as a treatment for prostate cancer. There was a significant difference in EF between surveys one and two, reinforcing the impact of radiotherapy and ADT on ED; the small sample size should be acknowledged here. No statistically significant difference in EF was detected arising from use of VEDs. In order to establish the effectiveness of VEDs for this patient cohort, a larger multi-centre study would be required. It would also be interesting to perform long-term evaluations to identify any lasting effects of VEDs and, in particular, in relation to late effects of radiotherapy.

The study also revealed data concerning the patient cohort adherence to the pathway recommended by guidance. It was identified that patients often find VEDs unhelpful and emasculating. Furthermore, many centres still lack resources to provide these patients with the supportive care they deserve. In particular, only one participant had access to psychosexual counselling, which is an important component of any successful sexual rehabilitation programme, and key to treating not only the physical causes of ED but also the psychological and social aspects.

Acknowledgements. None.

Competing Interests. There are no conflicts of interest.

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