

ORIGINAL ARTICLE

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Is the daily use of vacuum erection device for a month before penile prosthesis implantation beneficial? a randomized controlled trial

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SUMMARY

Patient concerns about penile length after penile prosthesis (PP) implantation for erectile dysfunction (ED) have significant impact on patients and their partners. In addition, corporal fibrosis is associated with difficult PP implantation. The preoperative use of vacuum erectile devices (VED) is an uncommon physical treatment for such concerns. Therefore, the current randomized controlled study assessed two outcomes: whether pre-operative VED use for a month before surgery would significantly increase flaccid stretched penile length (SPL) on the day of surgery, and facilitate easier corporal dilatation intraoperatively. Fifty-one patients scheduled for PP implantation for ED were randomized to either intervention group (pre-operative VED use; 10–15 min/day for ≥ 30 days; Group A; $n = 25$), or control group (no intervention; Group B; $n = 26$). A research assistant (blinded to the treatment assignments) recorded SPL at baseline (initial consultation) and on day of surgery. The surgeons performing the PP implantation (also blinded to the treatment assignments) provided subjective assessments of the ease of corporal dilatation. Baseline patient characteristics, demographics, and comorbidities were the same in both groups. Baseline measurements (SPL-1) were 10.71 ± 1.28 and 10.87 ± 1.26 cm in Group A and Group B, respectively; and the day of surgery measurements (SPL-2) were 11.50 ± 1.33 and 11.06 ± 1.34 cm in Group A and Group B, respectively. In terms of outcomes: mean SPL increase in Group A was significantly more by a mean of 0.80 ± 0.38 cm ($p < 0.05$) compared to Group B; and surgeons' subjective report of surgical ease indicated smoother corporal dilatation for Group A compared to Group B. VED use (10–15 min/day during the month prior to PP implantation) was associated with significantly increased SPL on day of surgery, and facilitated easier corporal dilatation intraoperatively. Future studies should examine the long-term outcomes of penile prosthesis implantation after pre-operative use of vacuum erectile devices.

INTRODUCTION

Erectile dysfunction (ED) is the inability to achieve or maintain an erection sufficient for satisfactory sexual performance (Montague *et al.*, 2000). Surgical treatments are reserved for men with severe ED who cannot tolerate or fail to respond to first- (oral medications and lifestyle changes) and second-line treatments, for example, intracavernosal injections and vacuum erection device (VED) (Hassan *et al.*, 2008; Mulcahy *et al.*, 2014). The insertion of a penile prosthesis (PP) provides an acceptable, definitive solution for ED and has the highest patient satisfaction among other treatment choices (Falcone *et al.*, 2013; Mulcahy *et al.*, 2014).

As PP surgery is an elective procedure to re-establish sexual function and improve quality of life, patient-perceived satisfaction is the primary goal. The most bothersome problem to PP patients is penile shortening, and studies have shown that as much as one-third of patients with adequately functioning PP were dissatisfied because of penile shortening (Montorsi *et al.*,

2000). The decreased erect penile length is thought to be secondary to capsule development around the cylinder, which restricts circumferential and lengthwise expansion of the tunica albuginea (Borges *et al.*, 2006). In addition, infection rates have been dramatically reduced in PP surgery because of new antibiotic coatings (Mulcahy *et al.*, 2014).

Vacuum erection device is a common physical treatment modality for ED (Brison *et al.*, 2013). The VED mechanism depends on its ability to boost arterial inflow by the vacuum effect while decreasing venous outflow from the penis by applying a rubber constriction band after penile blood engorgement (Pahlajani *et al.*, 2012). Studies suggest that VED can assist in penile rehabilitation following radical prostatectomy and radiation, and also prevent penile shrinkage in length and girth in patients undergoing definite treatment for prostate cancer (Pahlajani *et al.*, 2012). Recently, there has been enthusiasm in using VED two to three months prior to the PP implantation surgery. In

addition, pre-operative VED usage has resulted in longer cylinder implantation at the time of surgery (Sellers *et al.*, 2009).

However, the literature shows many gaps. First, while research has shown that pre-operative VED usage can result in longer cylinder implantation at the time of surgery, for example, (Sellers *et al.*, 2009), to the best of our knowledge, no studies have actually assessed how 'easy' the surgery is rendered in terms of cavernotome usage and the effortless dilatation of corporal bodies when pre-operative VED is used. Secondly, no randomized controlled studies assessed VED usage before PP surgery, but rather, current knowledge is based on either case reports or non randomized uncontrolled studies (Moskovic *et al.*, 2011; Sellers *et al.*, 2013).

Aim of the study

Therefore, this study bridges the paucity of information and these gaps in the literature to assess, employing a randomized controlled research design across 51 male patients, the outcomes of using VED pre-operatively prior to PP implantation surgery. Specifically, we evaluated the following outcomes: (i) changes in penile length between baseline (initial consultation) and pre-operative length (day of surgery); (ii) the extent of surgical 'ease' when using the dilators to dilate the corpus cavernosa intraoperatively; and, (iii) frequency of using cavernotome during the surgery.

MATERIAL AND METHODS

Ethics and patients

This study received ethical approval from the Research Ethics Committee (Protocol number 14347/14) and received financial support from Hamad Medical Corporation, Doha, Qatar. Hence, we obtained the required ethical permits but had not pre-registered the trial. Fifty-one male patients with severe ED seeking PP insertion (September 2014–September 2015) were prospectively enrolled in this randomized controlled study.

The study's inclusion criteria comprised patients who would be able to use VED daily and be able to manipulate their VED with the use of both hands. The exclusion criteria included patients who had any hematologic disease/s (e.g. sickle cell disease), who have significant penile curvature and plaques (e.g. Peyronie's disease), who were using anticoagulant agents for any reason, patients who could not understand how to use VED, and those who either could not afford or refused to use VED. We also collected data about any comorbidities that the patients had, for example, diabetes mellitus, cardiovascular disease, hypertension, and any renal or hepatic dysfunctions.

Participants were randomized to VED use pre-operatively (Group A), or control group (Group B) which entailed no pre-operative intervention (non-VED). Patients were allocated into Group A or Group B using a computer-generated randomization list.

Because of the paucity of published data, there were no estimates with regard to the primary outcome to guide the sample size estimation for the current study. Therefore, we were unable to undertake a formal sample size calculation. We recruited 51 participants requiring PP insertion to partake in the randomization process, namely 25 patients with VED intervention (Group A) and 26 patients in non-VED group (Group B). Each patient agreed and signed a written informed consent to participate in

the study after being informed about of the study aims, objectives, and methods. Patients were also informed that they could withdraw from the study at any time they wished to do so. Data protection and confidentiality were observed at all times, with only the research team having access to the data, and computers used for the analysis were password protected.

Procedures and evaluation

A trained patient educator provided an educational session to each patient (10–15 min) about the proper use of the VED as per the product instructions and accompanying pictures. All patients used the automatic version of VED that has a power button and a release valve. Patients were also asked to trim the pubic hair in order to make the VED seal as airtight as possible. During the educational session, patients were asked to create an erection, but without using the constriction band to sustain the erection. VED is placed over the penis and then a vacuum is applied to promote an increase in penile blood flow because of negative pressure. Patients were trained to push the VED power button for 5 sec and wait 5–10 sec to allow the blood to flow into the penis. The device pumped until penile tingling and/or firmness occurs. The penis is then left in the cylinder for 10–15 min and then removed. If the erection failed during the sessions, patients restarted the process. No constriction band was applied. Patient compliance was self-reported (use of VED daily for 10 min) and recorded at the time of their surgery.

At baseline (initial consultation) and directly pre-operatively, flaccid stretched penile length (SPL) was measured dorsally with a rigid ruler by pressing down on the pre-pubic fat pad from the pubis to the penile corona. Patients in both groups underwent this SPL evaluation at their initial consultation (baseline) and immediately pre-operatively, using the same two anatomical points. In order to reduce inter-observer bias, one trained patient educator undertook all the SPL measurements; and the results were recorded without knowledge of the baseline measurements for each patient (i.e. blinding of assessor).

Post-operatively, the surgeon undertaking the PP implantation provided a report on the difficulty of the surgical procedure. The surgeon was also blinded to the patient status (i.e. Group A or Group B), and was asked whether there was any difficulty associated with the corporal dilatation, where corporal dilatation was categorically recorded as either 'smooth,' or 'difficult.' If a cavernotome was necessary for dilatation, it was considered difficult. In addition, we observed the presence or absence of intraoperative complications.

Statistical analysis

SPSS statistical program was employed for the analysis, with significance level set at $p < 0.05$. Categorical and continuous values were expressed as frequency (percentage) and mean \pm standard deviation (SD), respectively. Descriptive statistics were used to summarize the demographic and clinical characteristics of the sample. Pearson's or Spearman correlation assessed the associations between two quantitative variables. Quantitative variable means between the two independent groups (Group A and Group B) were analyzed using *t*-test.

RESULTS

Of the 51 patients, two had semi-rigid Genesis (11 mm in diameter) (Coloplast, Minneapolis, MN, USA), eight received

3-piece Titan (16–18 cm in length) (Coloplast), three had 2-piece Ambicor (12.5 mm in diameter; 14, 16, 18 cm in length) (American Medical Systems, Minnetonka, MN, USA), and 38 received CX700 (15, 18 cm in length) (American Medical Systems) PP. Average cylinders' length implanted in Group A and Group B was 22.0 cm and 20.5 cm, respectively. We did not use any narrow-based and small diameter PP (e.g. LGX700 of AMS or narrow-based product of Coloplast companies). All Group A patients completed the VED protocol and used the device for at least one but up to 2 months, with an average daily use of 10–15 min.

Baseline patient characteristics and demographics were mostly similar in both groups (Table 1). There were no differences across both groups in terms of general demographic and lifestyle variables (age, smoking habits) and the extent of ED, as well as in high blood pressure.

For the biochemical parameters, Group B had slightly more but nevertheless significant hematocrit level and luteinizing hormone; but we observed no differences between the groups in terms of the associated comorbidities (cardiovascular disease, hypertension, diabetes mellitus).

Regarding the outcomes: (i) Group A exhibited significantly better outcomes and we did not encounter any difficulties in Group A in terms of relatively smoother corporal dilations (their

corpora only needed to be dilated to 10 French, tissues were more compliant and PP could be inserted with minimal dilation), and also less ($n = 0$) cavernotome usage during surgery (as reported by the surgeons); and (ii) for each group individually, when we compared SPL-1 with SPL-2, we observed a statistically significant increase in penile length for Group A (an average of 0.80 ± 0.38 cm) but not for Group B.

DISCUSSION

Common causes of ED include diabetes mellitus, atherosclerotic disease, and radical lower abdominal surgeries (Mulhall *et al.*, 2003). VED is a second line of ED treatment and is easy to undertake, widely available, with few contraindications and requires no testing or investigations prior to use (Yuan *et al.*, 2010; Brison *et al.*, 2013). Additionally, VED plays a key role in the maintenance of length and girth, return to sexual activity, and recovery of erectile function following radical prostatectomy (Kohler *et al.*, 2007). An additional key point in VED use is that its pre-op use actively involves patients in their own care. Hence, such involvement of patients is considered an 'investment' of interest in an aspiration for a longer penile length. Most 'disappointed' or 'angry' patients after PP are those who had unrealistic expectations or poor counseling in terms of the final penile length; pre-op VED use actively renders patients aware of such concerns and hence contributes to mitigate such anxieties.

This novel study examined the effect of daily VED use for at least 1 month prior to PP surgery on important outcomes: (i) measured SPL (objective); (ii) intraoperative surgeon's ease of implant (subjective); and, (iii) frequency of using cavernotome during the surgery. Our results indicated that patients who used the VED for 10–15 min daily (Group A) gained approximately 0.8 cm SPL. In addition, it was clinically demonstrated that pre-operative use of the VED resulted in enhanced (relatively smoother) corpora cavernosal dilatation, and also less ($n = 0$) cavernotome usage during surgery.

In terms of penile length, our VED patients (Group A, 10–15 min use daily) gained approximately 0.8 cm SPL. This finding is in agreement with others, where in order to enhance the penile length and augment its blood flow, authors have supported VED use for 10 min several times per day, without the use of a ring (Pahlajani *et al.*, 2012). Indeed, reports showed that VED use was associated with preservation of penile length (Sellers *et al.*, 2009; Moskovic *et al.*, 2011; Pahlajani *et al.*, 2012). For instance, in penile rehabilitation post-prostatectomy treatment, 28 men randomized to either early daily VED use for 10 min/day starting at 1 month post-operatively for 5 months or on-demand VED use, showed after 6 months that penile length was maintained with the daily VED use (Kohler *et al.*, 2007). Likewise, VED use in men who underwent PP implantation for ED showed improved length and girth, and the concomitant use of VED and PP may be indicated in men with PP who are dissatisfied with size or rigidity (Soderdahl *et al.*, 1997). In addition, there was a 20% longer revision PP length and 4.4 cm increase in erect penile length following VED application twice daily for 10 min/session for 1 year, despite having the PP implantation 6 years earlier (Moskovic *et al.*, 2011). Recently, pre-operative VED use allowed for maximal cylinder size insertion providing patients with longer penile length, and therefore improved patient satisfaction (Sellers *et al.*, 2013). Hence, in support of our finding of pre-operative VED use associated with SPL gain of ~0.8 cm,

Table 1 Patients' demographic characteristics and measurements at baseline and at operation

Variable	Group A (VED; $n = 25$)	Group B (Non-VED; $n = 26$)	p
General			
Age (\pm SD)	56.12 \pm 10.59	54.19 \pm 12.35	0.311
Smoking n (%)	10 (40)	8 (30.2)	0.496
High blood pressure n (%)	13 (52)	13 (50)	0.886
Erectile dysfunction (years, M \pm SD)	4.28 \pm 2.54	3.846 \pm 2.60	0.882
Penile length (objective measurement)			
SPL-1 (initial baseline)	10.71 \pm 1.28	10.87 \pm 1.26	0.661
SPL-2 (day of surgery)	11.50 \pm 1.33	11.06 \pm 1.34	0.244
	$p = 0.020^a$	$p = 0.104^a$	
Biochemical			
HbA1c (%) \pm SD)	8.54 \pm 1.96	8.26 \pm 2.04	0.247
Hematocrit (M \pm SD)	41.68 \pm 4.32	44.88 \pm 4.87	0.005
Luteinizing Hormone (M \pm SD)	4.32 \pm 0.56	5 \pm 1.07	0.036
Comorbidities			
Cardiovascular disease n (%)	4 (16)	7 (26.9)	0.074
Hypertension n (%)	13 (52)	13 (50)	0.930
Diabetes mellitus n (%)	19 (76)	17 (65.4)	0.437
Outcomes			
Smooth corporal dilations n (%)	25 (100)	18 (69.2)	0.014
Cavernotome usage n (%)	0 (0)	4 (15.4)	0.001
Complications (intraoperative)	0 (0)	0 (0)	—

^aDifference of SPL in each individual Group (initial baseline vs. at day of surgery); VED: vacuum erection device; SPL-1: stretched penile length at baseline (initial consultation); SPL-2: stretched penile length at day of surgery (i.e. 1 month later).

these studies showed that there is a trend toward pre-operative interventions to maximize efficacy of PP implantation.

As for the ease of the intraoperative corporal dilatation, our Group A patients had relatively smoother corporal dilations, with zero cavernotome usage during surgery. Such findings are important, as in fibrotic corpora, perforation during dilatation of corpora cavernosa is particularly risky. A number of ways can overcome and manage this, for example, the dilator is introduced through the corpus by pushing it in an outward direction in order to avoid cross-over perforation; or in cases of fibrotic corpora, special dilators (Rossello dilators or Otis urethrotome) may be useful to create an appropriate space (Bettocchi *et al.*, 2008), but such strategies cannot completely eradicate the complication. During PP implantation, after exposing the corpora cavernosa and performing the corporotomy, the first step is dilating the corpora cavernosa cavities to the maximum using dilators of various sizes. Our surgeons' assessments confirmed that these steps were facilitated by pre-operative VED use.

Despite its practical application and implications for future use, this study has limitations and hence generalizations should exercise caution. A larger sample size (than the current 51 patients) would have been beneficial in providing more precise estimates for our comparisons. Our data are preliminary (3–6 months follow-up), and we do not currently have longer term outcomes/complications of PP implantation after VED use yet. We did not measure patient's perception of penile length post-operatively and did not assess patient and partner satisfaction. The ease of surgery as described by the implanting surgeon is a subjective account, and objective measures, for example, assessment of intraoperative factors (surgical time and bleeding risks) would have been beneficial in more accurately evaluating the difficulty of the procedure. Nevertheless, such subjective assessment remains valid as the surgeons were blinded to the cases, and hence, their calibration of the ease of the procedure remains impartial. Future studies should address these points.

CONCLUSION

When pre-operative VED is used, SPL could increase by a mean of 0.80 ± 0.38 cm. In addition, the surgeon is provided with better opportunity to restore longer penile length that replicates an appearance more consistent with the patient's natural erection. Ease of corporal dilation allows for an appropriate size cylinder to be inserted, and thus helps to maximize patient satisfaction post-operatively. There were no negative intraoperative complications associated with the use of pre-operative VED, and therefore, if patients have access to it, VEDs can safely be recommended. Future studies among larger samples will help assess the long-term outcomes and outline the role of VED as a valuable intervention prior to PP implantation.

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DISCLOSURES

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTIONS

O.C., A.A.A. and R.T. did the conception and study design; O.C. was the principal investigator and researcher; R.T. and J.C. conducted the data analysis and interpretation; O.C. and W.E.A. drafted the manuscript; all authors edited and revised the manuscript, and approved the final version of the manuscript.

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