IS THERE A PLACE FOR THE EXTERNAL VACUUM DEVICE (VED) IN THE TREATMENT OF POST-RADICAL PROSTATECTOMY (RRP) PATIENTS WHO FAIL PDE5 INHIBITORS?

Juza Chen • Gal Keren-Paz • Alexander Greenstein • Yuval Bar-Yosef • Nicola J Mabjeesh • Haim Matzkin

Department of Urology, Tel Aviv Sourasky Medical Center, Sackler Faculty of Medicine, Tel-Aviv University, Tel Aviv, Israel.

OBJECTIVE

To evaluate efficacy of VED in the treatment of post-RRP patients who fail oral PDE5 inhibitors.

INTRODUCTION

Prostate cancer is the leading cancer diagnosis in men and the third most common cause of cancer-related death in men worldwide. The lifetime risk of developing prostate cancer is 19% in the United States. Risk factors include older age, family history, race and ethnicity, and possibly dietary fat, but the etiology of this cancer remains unknown. With the widespread use of prostate-specific antigen testing and digital rectal examination as screening tools, the incidence of prostate cancer has increased.

Although several effective nonsurgical treatments developed during last 10-15 years, radical retropubic prostatectomy (RRP) still remains one of the principal treatment option for the localized prostate cancer.

Erectile dysfunction is one of the major concerns of patients undergoing treatment for prostate cancer. There are several recognized factors that determine the postoperative incidence of erectile difficulties, including patient age, degree of cavernosal nerve sparing during surgery, cancer stage, and associated vascular comorbidities. Post prostatectomy erectile dysfunction (ED) remains a serious quality-of-life issue. Recent advances in the understanding of the mechanism of post prostatectomy ED have stimulated great attention toward penile rehabilitation. Data generated from a number of clinical investigations document that pharmacologic rehabilitation programs provide a higher rate of recovery of erectile function following radical prostatectomy. Various neuroprotective and neurotrophic approaches are thought to provide integral roles for the maintenance of sexual function in men undergoing prostate cancer therapy.

Type 5 phosphodiesterase inhibitors (PDE5i), intracavernosal injection, intraurethral application of vasoactive agents, and vacuum erection devices have all been reported to speed the recovery period for return of erectile function in recent studies. PDE-5i are the first line of therapy in the management of erectile dysfunction in men who have undergone nerve-sparing radical prostatectomy. Improvements in frequency of penetration, the ability to maintain an erection, and both patient and spousal satisfaction are seen in up to 70% of cases. However, there is some variability in success rates with PDE-5i, which depend on patient age, dosage, and the extent of damage to the cavernous nerves. A recent study implicates the quantity of time following surgery as an additional variable in determining the success of the PDE5i following radical prostatectomy. In several studies has shown that PDE5i was ineffective when taken within the first 9 months following bilateral nerve-sparing radical prostatectomy.

Recent work has confirmed that patient satisfaction with PDE5i is a time dependent process, implying that there is a postoperative period of neurapraxia in which erectile dysfunction refractory to PDE5i. Finally, there are some patients who cannot tolerate PDE5i because of adverse effects or specific contraindications. The result is that some men do not use PDE5i following radical prostatectomy because of lack of either efficacy or tolerability.

With the introduction of sildenafil as the first effective oral treatment of erectile dysfunction, it was inevitable that patients would become interested in exploring the benefits of this new modality. Although sildenafil is currently the most widely used approach and has an excellent overall success rate (60% to 85%), a substantial portion of patients continue to have an inadequate response. Men not entirely satisfied with erectile function following the use of PDE5i and not yet interested in invasive therapy are offered the option of a VED before being switched to the more invasive alternatives.

Similar to other treatment options, VEDs have a reported success rate of 65% to 90% but, like oral medication, a significant number of patients have an inadequate response to VEDs as well. In previous study we evaluated the preference of patients with erectile dysfunction already being effectively treated with sildenafil that were then treated with a vacuum erection device and achieved the comparable level of efficacy. In another study we demonstrated the beneficial effect of the combined use of a VED and intracavernous injections of the vasoactive drugs.

In this study we evaluate efficacy of VED in the treatment of post-RRP patients who fail oral PDE5i.

MATERIAL & METHODS

After approval of the study protocol by the local Helsinki declaration committee on human rights (IRB) we evaluated medical files of 32 patients aged 63 years (range 49-75 years) who suffered from erectile dysfunction 3-6 months following RRP and did not respond to all three available oral PDE5 inhibitors and/or intracavernosal injection (ICI). All patients completed the IIEF and GaQ questionnaire before and after being treated with VED. Satisfaction rates of treated patients' sexual partners were also assessed. Data on preoperative sexual performance status, stage of disease, concomitant disease and pre and post treatment PSA levels and sexual partners satisfaction rate were recorded. Performance status after VED treatment was also evaluated. Characteristics of the study group are presented in table 1.

Table 1: Patients characteristics

No. of Pts	*32*
Age (yr)	
Mean (range)	*63 (49-75)*
Martial status	
Married	*25*
Single	*0*
Divorced	*5*
Widower	*2*
Diagnosis	
CaP	*29*
Radical Cystectomy (CaP on final histology)	*3*
Pre surgery potency (overall function stated by the patient)	
Yes	*27*
No	*5 (with PDE5I)*

Gleason grade	*Number of patients*
5	*3*
6	*19*
7	*6*
8	*2*
9	*2*

Pathological stage	*No. of Patients*
pT2	*27*
pT3	*5*
Sexual desire	
Yes	*31*
No	*1*
	Mean+SD (range)
Testosterone (ng/ml)	***10±4.6 (3-16.9)***
Bioavailable testosterone (ng/ml)	***1.2±0.5 (0.5-1.8)***
Bioavailable testosterone (%)	***25.2±7.4 (13.5-45.7)***
Pretreatment PSA (ng/ml)	***6.5±0.75 (2-15.6)***

RESULTS

Of 32 evaluated patients, 26 (81%) were successfully treated with VED and 6 (19%) failed VED. Sixteen (50%) patients were successfully treated with VED only and 10 (31%) ended up with a combination treatment: 5/10 using VED+ICI and 4/10 using VED+PDE5i and one patient using both (VED+ICI and/or VED+PDE5i). Most patients (25/32) (78%) and 15/23 (65%) of the partners were satisfied with the treatment (Pearson CC = 0.06 between couples satisfactions). There was significant improvement in Erectile function, ($p<0.001$); Intercourse satisfaction ($p<0.001$) and Overall satisfaction ($p<0.001$) domains of the IIEF score (table 2). Treatment outcome correlated with the preoperative sexual status. There was no correlation between the patients' age, stage of disease, PSA. Results of uni and multi variant analysis's of factors that effected treatment outcome is presented in table 3. No significant complications were reported following VED treatment.

Table 2:

IIEF before and after treatment			
	Before	***After***	***P value***
EF	*14±2.5*	*25±4*	*< 0.001*
IS	*6.2±1.5*	*11±3.1*	*< 0.001*
OF	*5.4±0.6*	*5.6±0.6*	*0.13*
SD	*6.5±0*	*7.6±1*	*< 0.001*
OS	*3.9±0.6*	*8±2.6*	*< 0.001*

Table 3: Uni and multi variate analysis

Factors effecting treatment outcome		
Factors	***P value***	
	Uni	***Multi***
Age	*0.77*	
Marital status	*0.3*	
Diagnosis	*0.35*	
Treatment	*0.35*	
Concomitant diseases	*0.4*	
Pre-surgery potency status	*0.9*	
Stage (pT2 vs pT3)	*0.2*	
Gleason score	*0.5*	
Sexual Desire	*0.6*	
Testosterone	*0.9*	
Bioavailabile testosterone	*0.8*	
Bioavailabile testosterone %	*0.9*	
Pre surgery PSA	*0.7*	
Pre treatment EF	***0.0001***	***0.002***
Pre IS	*0.031*	*0.117*
Pre OF	*0.116*	
Pre SD	*0.7*	
Pre OS	*0.002*	*0.605*
Post surgery PSA	*0.306*	
Initial treatment	*0.258*	
Use of VED	***< 0.001***	***< 0.001***
Partner's satisfaction	*0.569*	

CONCLUSIONS

VED as a single or combined treatment seems to have a significant beneficial effect, yielding high satisfaction rates from patients and their sexual partners. This treatment should be offered to post-RRP patients who failed medical treatment before referral for ICI or insertion of a penile prosthesis, during the rehabilitation period and as single or part of combination therapy.