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Original Article

The Impact of Vacuum Constrictive Device on the Treatment of Erectile Dysfunction in Spinal Cord Injured Patients

Feraidoon Khayyamfar[1], Seyed Kazem Foroutan[1], Ehsan Farhadi[2], Amir Ghasemlouei[*3]

[1]*Department of Urology, Shahed University of Medical Sciences, Tehran, Iran*

[2]*Department of Medicine, Shahed University of Medical Sciences, Tehran, Iran*

[3]*Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran*

HIGHLIGHTS

- VCD for ED in spinal cord injured patients can be effective.
- The patiemts whose spouses are virgin can apply this device following some preliminary (vaginal dilatation) treatments.

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***Corresponding Author**:
Amir Ghasemlouei
Email: ghasemloeeamir@yahoo.com
Address: Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran.

ABSTRACT

Introduction
Erectile dysfunction (ED) is a common problematic disease in spinal cord injured patients. The effect of this disease on the life quality in patients has been well stated. Therefore, this study examined the impact of the vacuum constrictive device (VCD).

Methods
The total number of sixty patients with spinal cord injury (SCI) were recruited at different levels of the spinal column, complaining of ED, who had not shown a positive response to sildenafil. Based on the international index of erectile function (IIEF) and single questioning patient's partner regarding the man's ability to perform vaginal penetration (APVP), the diagnosis of ED and treatment efficacy were evaluated.

Results
The mean age was 29.2±5.31 years old. It significantly improved the IIEF score between two target groups of pre-treatments (7.86±1.38) and post-treatment (24.41±4.70). IIEF scores of patients with APVP positive were signed ($p<0.001$) improved between pre-treatment (7.95±1.38) and post-treatment (26.35±2.26). Final 48 had successful sexual intercourse, and 12 patients needed accessory treatments due to spouse virginity.

Conclusions
The use of newly shaped and sized vacuum pumping and the massagor is an effective A vacuum constrictive device could be suggested as a suitable second-line of ED due to spinal cord injury. The VCD is effective in many spinal cords injured patients with erectile dysfunction. The devices were not accepted by any patients but significantly affected sexual function and sexual satisfaction. Vacuum constrictive is a choice of treatment in SCI men, along with other options for treatment of erectile dysfunction.

Keywords: Erectile Dysfunction; Spinal Cord Injury; Vacuum Constrictive Device; Virginity

Introduction

Erectile dysfunction (ED) is the persistent inability to reach or keep an erection satisfactory for sexual performance (1). ED is a common consequence of SCI. The prevalence of ED in patients with spinal cord injury (SCI) would be around 54% to 95% (2). The effect of this disorder on the quality of life and ensuing disorders in affected patients has been well explained, including depression, anxiety, loss of self-confidence, and family problems (3). The leading cause of ED in individuals with spinal cord lesions

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is the complete or incomplete disruption of the nervous tract between male genital organs and the brain, which is virtually an autonomic dysfunction (4). In general, in patients with incomplete spinal cord lesions, erection is more preserved (5). Erections achieved by external stimuli are regular, whereas psychogenic erections only occur in minority patients (6). Whichever type of erection is seen, the short time and unpredictability of erections in SCI patient satisfaction from sexual intercourse are unlikely (7). Many SCI men were young at their injuries and needed immediate treatment (8).

The ED treatment contains four steps. Step 1 includes decreasing smoking, weight loss, and increasing physical activity. Step 2 is a phosphodiesterase type 5 inhibitor (PDE5I) such as Sildenafil (Viagra), intracavernous injections of Papaverine or prostaglandins, and vacuum constriction devices. Step 3 is a penile prosthesis, and Step 4 is sacral neuromodulation (SNM) (9). As a non-invasive, effective, and safe, the VCD was known by the urological community and used as an accepted method for ED treatment by the American Urological Association in 1996 (10). Patients who fail oral drug therapy, who have a contraindication to specific oral drugs, or who experienced adverse effects from oral drugs might be a candidate for intracavernosal injection (ICI) Therapy or using VCD before proceeding to more invasive alternative therapies. Men, who are not satisfied with erectile function following the use of sildenafil or the administration of vasoactive drugs, are advised to use VCD before proceeding to more invasive alternatives (11).

VCD can be used to treat ED with indeed etiology (12). VCD increases the blood flow and its entrance into the corpora cavernous by implementing negative pressure within a cylinder placed on the penis, leading to erection eventually, by the placement of a ring at the base of the penis, the blood would be trapped and not evacuated, maintaining an erection (13). Contraindications of VCD include a gravitate for spontaneous priapism, or intermittent prolonged erections, and those with severe penile anomalies (either Congenital or acquired) (13). Relative contraindications include cultural taboo, cervical or high thoracic spinal cord injuries, neurological disease, or degenerative joint diseases with poor manual skill (14). Patients with coagulopathy or anticoagulation therapy are considered at high risk of developing petechiae, ecchymosis, or hematoma (13). However, it was shown that the risk did not exceed that of the general population (15). The purpose of this study was to evaluate the effect of VCD on Patients to assess the efficacy, orgasmic function, sexual desire, and overall satisfaction in spinal cord injured patients using VCD for treatment of their ED.

Methods

This research was done at the family health research center. We confirmed The diagnosis of ED, according to the National Institute of Health statement of ED (16). VCD was introduced to treat these patients; all patients were married, and couples voluntarily agreed to participate in this research, and the study was approved by Shahed University of Medical Sciences Ethical Committee (IR.SHAHED.REC.1393.83). This study was performed on 60 patients with spinal cord injury at different levels of the spinal column, complaining of ED from May 2018 until August 2020. Patients were selected on consecutive bases that were referred for treatment to the ED clinic of the family health center. Patients who were not expecting full co-operation to complete the study were excluded. Phosphodiesterase type-5 inhibitors were not effective in all of the patients. More than 35 patients used ICI (Intracavernosal injection), which was no more effective. Before using a vacuum device, the patients would be examined meticulously. In case of any wound or skin inflammation of the penis, initial treatment to cure local problem would be started by removing condom sheath catheter and fixation of a Foley catheter or clean intermittent catheterization (CIC)followed by administration of topical ointments till the condition of penile skin improved. It notes worthy that application of VCD concurrently with skin ulceration or inflammation could aggravate skin lesion and inflammation. At the first visit, each patient answered a questionnaire regarding past medical history, sexual activity before and after the SCI, and prior treatments for ED. According to the history and physical examination, there were no contraindications for using a VCD. Couples adequately used the VCD in the clinic prior to home use. The treatment efficacy was evaluated by the International Index of Erectile Function (IIEF) questionnaire based on the score for five separate response domains. These five domains contain an erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. (17) The questionnaire was interpreted in the Persian language. The final score for each domain was computed as the sum of the scores assumed to the individual queries in each domain. All patients were revisited the clinic at the end of the sixth month for re-evaluation.

Treatment

All Patients were trained by an expert urologist regarding VCD and watched an instructional video of locally manufactured VCD (HAMRAH medical group. Tehran. IRAN). The manufacturer provides VCDs to patients at a 50 percent discount, and they also prepare different size vacuum device cylinders that could be adapted to the patient's penis. Additionally, if the patient and the physician did not consider induced Erection with VCD to be satisfactory for penetration at the first visit, the patient was advised to practice with VCD for one week by putting a penis inside VCD cylinder, inducing negative vacuum pressure till he gets full erection and maintaining it for 20 minutes 3 times a day. Technical advice was

Table 1. Display the IIEF score before and after VCD therapy for all patients

Stage of Treatment	Erectile Function	Intercourse Satisfaction	Orgasmic Function	Sexual Desire	Overall Satisfaction
Pretreatment	7.86±1.38	4.15±1.80	3.16±1.06	3.90±1.11	2.68±0.85
Post-treatment	24.41±4.70	12.16±3.45	8.15±2.33	7.35±1.81	7.00±1.71

(P-value < 0.001, considered statically significant in all domains)

Table 2. IIEF scores of patients, according to APVP

Response to APVP	Number of Patients	Stage of Treatment	Erectile Function	Intercourse Satisfaction	Orgasmic Function	Sexual Desire	Overall Satisfaction
APVP Positive	48	Pre-treatment	7.95±1.38	4.22±1.87	3.25±1.04	4.06±1.06	2.75±0.86
		Post- treatment	26.35±2.26	13.66±1.32	9.12±1.14	8.08±0.82	7.62±0.98
APVP Negative	12	Pre-treatment	7.50±1.38	3.83±1.52	2.83±1.11	3.25±1.13	2.41±0.79
		Post-treatment	16.66±3.84	6.16±2.72	4.25±1.71	4.41±1.72	4.5±1.78

(P-value < 0.001, considered statically significant in all domains)

made available by revisit or phone call from the patient on a daily demand basis.

Mandatory educations about vacuum device application and its likely side- effects that might develop relevantly would be explained to all patients. The IIEF questioner was administrated before treatment and again after 6months using this method. Patients were asked if they experienced any bruising, injury, or skin Changes sufficient to decrease or stop the use of the device. If there was a failure, the patient was advised to revisit the clinic with his partner for re-evaluation; regarding quadriplegics or patients lacking required physical strength and capability, necessary educations have been taught to their partners for participation.

Results

Ninety-four men with ED due to SCI participated in this study. Out of 94 men, 60 completed the study. Twenty-four patients did not meet the study, four patients refused the therapy due to discomfort, and six were not satisfied with the use of the VCD. 50 (83.3%) patients attained complete erection during a first training session. Full erections obtain in other ten patients after two weeks of practicing with the device. Eight patients had cervical spinal cord lesions, 37 patients had spinal lesions at the Thoracic level, and 15 patients were affected by a lumbar spine injury.

At the end of the sixth month, following use of VCD is regarding APVP, 48 of 60 Patients (80%) were able to have successful sexual intercourse with the help of VCD, but 12 patients (20%), despite having good erection with VCD, still unable to have sexual intercourse at the end of the sixth month. These patients were advised to attend the clinic accordingly to solve their problems. These patients had a virgin wife and were unable to maintain an erection during intercourse due to narrow, tighter vaginal orifice and lumen despite having an excellent initial erection. These patients lost their erection due to the escape of blood from the penis with the true constrictive ring while pressing the penis into the tight vaginal canal during intercourse. 59 out of 60 patients (98.3%) were satisfied with VCD and used the device at six months follow up; among these 59 patients, only one patient's wife was not satisfied, and they have agreed to have implantation of a penile prosthesis. Interestingly, they were becoming more disappointed because penis size was smaller than when they were using VCD, so he is also using VCD for sexual intercourse. There were no differences in the outcome of VCD efficacy relating to the level of SCI.

Five patients (8.3%) had difficulty with the operational manner of the device for inducing an erection, which after giving them the necessary training, they were able to use the device easily.

No significant complications were seen. It may result from good training in the use of the device, in line with the manufacturer's recommendations.

In our study, the cornerstone of criteria for success was considered APVP (Table 1). Table 2 demonstrated the result IIEF scores, analysis in all patients regarding APVP before and after treatment. The result of table-3 showed that 48 patients (80%) were able to have vaginal penetration with a mean ED score of 26.35±2.26 and 12 patients (20%) were unable to have vaginal penetration with mean ED 16.66 ± 3.84.

Table 3 shows response to 6 items (Erectile function) IIEF questioner in a patient with APVP negative and positive comparing pre-treatment and post-treatment at six months follow up. It shows that VCD can induce a full erection in all patients. IIEF Q1 and IIEF Q2 have similar domains score in men with a virgin wife and men whose wife was not a virgin. However, regarding IIEF Q3, Q4, Q5, Q15, patients who were not having a virgin wife had improved IIEF domains compared to pre-treatment.

Table 3. Respond to abridged six items (erectile function). A version of IIEF questioners in patients responded negative APVP pre and post-treatment at the end of the 6th month at the start of treatment.

IIEF–questionnaire	Pretreatment for all patients	Post- treatment for all patients	APVP Positive Pretreatment	APVP Negative Pretreatment	APVP Positive Post- treatment	APVP Negative Post- treatment
IIEFQ1	1.21±0.41	4.3±0.64	1.22±0.42	1.16±0.38	4.29±0.68	4.33±0.49
IIEFQ2	1.35±0.48	4.48±0.67	1.35±0.48	1.33±0.49	4.41±0.70	4.75±0.45
IIEFQ3	1.38±0.49	3.88±1.19	1.41±0.49	1.25±0.45	4.35±0.60	2.00±1.12
IIEFQ4	1.23±0.42	3.85±1.25	1.25±0.43	1.16±0.38	4.35±0.63	1.83±1.11
IIEFQ5	1.31±0.46	4.00±1.22	1.33±0.47	1.25±0.45	4.50±0.68	2.00±0.73
IIEFQ15	1.36±0.48	3.90±1.27	1.37±0.48	1.33±0.49	4.43±0.50	1.75±1.13

Discussion

The results showed that VCD induces an appropriate erection in all patients with spinal cord injury. Those who had a lack of erection for a long time will have disuse atrophy and need practice for a week till the improving effect of the device is well revealed. Spouses of all the patients who had previous sexual experience expressed their satisfaction from this manner of treatment. The most common complaint was the loss of erection during sexual activity, which leads to dissatisfaction. It seems that one of the significant reasons for VCD failure is narrowing of the vaginal lumen, which could be due to virginity, or vaginal atrophy, which, if managed accordingly, could increase the success rate of VCD therapy.

In Sekin study (18), four patients discontinued treatment because of serious complications (ecchymosis, petechiae, and lack of motivation), and six patients refused treatment due to negative cultural perception. However, in our clinic, we explained the importance of sexual intercourse to couples and its impact on the interpersonal relationship and the couple's understanding. Most of our patients agreed to treat and improve their sexual relationships. Moreover, all patients were explained about different treatment modalities; it is advantages and disadvantages. Finally, most of the patients adopted VCD for treatment, but none of the patients discontinued treatment because of side effects in our study.

The manufacturer was responsible for our research's guaranty and warranty, and transportation. So we did not have any patients abounded the device because of a malfunction.

In addition, proper training was the main reason for the high success rate in our study, while in the Earle CM study (19), 81% of the patients abounded the device because it was not working.

Comparing our study with Denil's study (2), we did not have high dissatisfaction (67%). We think that the main reason for accepting the VCD was mainly explaining the advantages and disadvantages of the various treatment modalities. Also, ICI was not effective in most of our patients.

In virgin women, due to vaginal tightness, more resistance would be exerted on their partner's erected genital organ, which causes extrusion of blood through the pressure ring out of the penis leading to detumescence. After dilatating the vaginal canal and the feasibility of sexual intercourse with VCD, these women were also satisfied with this treatment. So, it is recommended that individuals whose wives are virgins be advised stepwise vaginal dilatation until reaching the size of their partner's penis at the entire erection state and then try sexual intercourse. With the use of VCD, slight side effects such as penile inflammation or subcutaneous ecchymosis may be developed in beginners, which by repeated practice and education, these complications would be avoided (20). Training of the device application is a significant matter; the most common cause of revisiting in the clinic was their need for instruction and education regarding solving relevant problems.

Comparing IIEF Erectile function issue among APVP negative patients between pre-treatment and post-treatment regarding various domains, we found that it was significantly improved regarding Q1 and Q2. However, there was no significant difference at Q3, Q4, Q5, and Q15, which showed loss of erection despite having good tumescence before intercourse. We attempt to offer our patients non-invasive therapy. These patients usually have a UTI, so advising VCD is more appropriate for treating ED patients. Penile prostheses may have an increased risk of infection (21).

We believe specific training would decrease the side effect and increase the effectiveness of VCD. Handling problems regarding its failure can prevent the need for alternative, more invasive therapy.

Conclusions

Application of the VCD for the treatment of ED in spinal cord injured patients that do not respond to Phosphodiesterase type-5 inhibitors or ICI is effective. Furthermore, patients whose spouses are virgins can apply this device following some preliminary (vaginal dilatation) treatments to make VCD feasible.

Authors' contributions
All authors contributed equally.

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Conflict of interest
The other authors declare no potential conflict of interest.

Funding
There was no founding.

Ethics statement
The ethics committee of Shahed Medical University approved the study procedures (IR.SHAHED.REC.1393.83).

Data availability
Data will be provided on request.

Abbreviations

CIC	Clean intermittent catheterization
ED	Erectile dysfunction
ICI	Intracavernosal injection
IIEF	International index of erectile function
PDE5I	Phosphodiesterase type 5 inhibitor
SCI	Spinal cord injury
SNM	Sacral neuromodulation
VCD	Vacuum constriction device

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Author (s) biosketches

Khayyamfar F, Associate Professor**,** Department of Urology, Shahed University of Medical Sciences, Tehran, Iran.
Email: khayyamfar@yahoo.com

Foroutan SK, Associate Professor, Department of Urology, Shahed University of Medical Sciences, Tehran, Iran.
Email: foroutan@yahoo.com

Farhadi E, MD**,** Department of Medicine, Shahed University of Medical Sciences, Tehran, Iran.
Email: farhadi.ehsan@yahoo.com

Ghasemlouei A, MD, Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran.
Email: ghasemloeeamir@yahoo.com

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