Evaluating the efficacy of vacuum constrictive device and causes of its failure in impotent patients

Feraidoon Khayyamfar,[1,2] Seyed Kazem Forootan,[1,2] Hassan Ghasemi,[3] Seyed Roohollah Miri,[4] Ehsan Farhadi[4]

[1] Family Sexual Health Clinic and Research Center, Shahed University, Tehran, Iran
[2] Department of Urology, Shahed University, Tehran, Iran
[3] Department of Ophthalmology, Shahed University, Tehran, Iran
[4] Medical student, School of Medicine, Shahed University, Tehran, Iran

Corresponding author:

Hassan Ghasemi, MD
Associate professor, Department of Ophthalmology, Medical School, Shahed University, Tehran, Iran.

Tel: +98 21 8896 3122
Fax: +98 21 889 63122

E-mail: ghasemi518@yahoo.com

Received May 2012
Accepted April 2013

Purpose: This study evaluates the efficacy of Vacuum constrictive device (VCD) and the reasons for its failure.

Materials and Methods: In this cross-sectional study, 1500 men with organic erectile dysfunction (ED) were enrolled from July 2003 to July 2010. The treatment efficacy was analyzed using International Index of Erectile Function (IIEF) and questioning patient's partner regarding the man's ability to perform vaginal penetration (APVP). The patient's spouses, who responded negatively to APVP, were evaluated by a midwife for virginity, vaginal atrophy and abstained sex.

Results: Totally 1310 (87.4%) patients attained full erection at first training session, remaining 188 (12.6%) were able to have full erection one week after practicing with VCD, 1419 (94.6%) were able to have successful intercourse and responded positively to APVP, 81 (5.4%) were unable to have intercourse as stated by their wife's (negative response to APVP) that in 43 (53%), 30 (37%), and 8 (9.8%) cases the causes of failures were their wife's virginity, sex abstinence, and senile vaginal atrophy, respectively. Regarding erectile issue of IIEF scores in patients responded positive to APVP there were significant improvement from the scores of 9.3 ± 3.0 to 27.5 ± 5.0 after treatment ($P < .05$).

Conclusion: With proper training and appropriate devices, VCD could induce sufficient erection in all patients. VCD in patients with virgin wife is ineffective, and female factors affect on success rate in VCD therapy.

Keywords: erectile dysfunction; therapy; treatment outcome; vacuum; penile erection.

INTRODUCTION

Currently, erectile dysfunctions (ED) are managed based on the couples interactions, in which the patient and his wife's satisfactions are the main factors for eventual therapeutic purposes.[1] American Urological Association has recommended to use VCD as a safe therapeutic tools for treatment of ED since 1996.[2] Introduced in 1998, sildenafil is already the first line therapy for most men with ED, delegating traditional VCD therapies and injectable agents to the second line of approaches.[3,4] Patients that failed to respond or develop side effects when receiving the first and second lines of treatment are candidate for surgical approaches.[4] Patients that are not suitable for oral medications due to ineffectiveness, development of side effect or having any contraindications may be considered for intracavernosal injection (ICI) of vasodilators or VCD.[5, 6] VCD can be used successfully in treatment of ED with any kinds of etiology.[7] The VCD mechanism is due to its ability in raising the arterial inflow by the vacuum effect. The venous outflow decrease from the penis by applying a constructive rubber band while the penis is erected. The purposes of this study were 1) to evaluate the efficacy of VCD in inducing erection and to find out the causes of its failure in impotent patients, and 2) the success rates of VCD in performing vaginal penetration.

MATERIALS AND METHODS

Patient selection

Totally 1530 men with ED due to an organic etiology for more than 3 months, who were referred for treatment to the ED clinic of the family health center Shahed University, participated in this cross-sectional study. The participants were informed of the purpose of study and gave their informed consent. The study protocol was based on the Declaration of Helsinki and approved by ethics committee of Shahed University. The diagnosis of ED was established according to the National Institute of Health statement of ED.[8] At first visit, all patients would provide their detailed medical and sexual histories, and would undergo specific physical examinations, also the level of free and total testosterones would be determined if patients lack secondary sex characters. Patients with low testosterone level were offered hormonal replacement and were excluded from the study. Patients with psychogenic impotence (i.e. normal non-sexual erection, performance anxiety, premature ejaculation), who were determined by history, if required further evaluation was done by testing nocturnal penile tumescence (NPT), and if this showed normal patterns of nocturnal erection, the patient were excluded from the study. Based on the patient's history and physical examination, an attempt was made to determine the etiology of impotence. Each participant had a steady co-operative female partner. Partner's were not evaluated medically before the initiation of the study but were given the opportunity and encouraged to attend, each appointment. During evaluation if patients' wife was suspicious of having any medical or psychological problem regarding sexual performance, couple were excluded from the study. Patients using medication that affect sexual performance where referred to the physician or psychiatrist for modification of treatment and advice of oral drugs for treatment of ED but if it was failed or modification of drugs were not possible the patient was advised to use VCD for treatment of ED.

Treatment evaluation

The clinical efficacy of the various treatments was evaluated using the International Index of Erectile Function (IIEF) questionnaire that is based on the scores for five separate response domains. These domains addressed as the issues of erectile function (EF) and also intercourse satisfaction (IS), orgasmic function (OF), sexual desire (SD) and finally overall satisfaction (OS). Because of the absence of a validated questionnaire for Iranian population, we translated the IIEF questionnaire[2] in to the Persian. The entire questionnaires were completed after full explanations to the patients by urologist. The ultimate score for each field was calculated as the summation of the scores attained for each individual question in that field or domain. In addition to the IIEF questionnaire, the men were asked about the state of their wife's virginity by answering yes or no; moreover all patients' partner were requested to respond either yes or no, regarding the men's ability to perform vaginal penetration (APVP).

Table 1. IIEF scores before and after the treatment with vacuum constrictive device.

OS (*P* value)	S Des (*P* value)	OF (*P* value)	IS (*P* value)	EF (*P* value)	Stage of treatment
3.9 ± 1.7	6.3 ± 1.9	5.6 ± 2.4	6.7 ± 2.4	9.3 ± 2.9	Pretreatment (SD)
8.6 ± 1.5 (*P* < .0001)	7.4 ± 3.1 (*P* < .0001)	11.1 ± 1.2 (*P* < .0001)	11.1 ± 1.2 (*P* < .0001)	26.6 ± 4.9 (*P* < .0001)	Post-treatment (SD)

Key: IIEF, international index of erectile function; EF, erectile function; IS, intercourse satisfaction; OF, orgasmic function; S Des, sexual desire; OS, overall satisfaction; SD, standard deviation.

Treatment method

All Patients were trained by an urologist who was expert in VCD as well as watching an instructional locally produced video for VCD (HAMRAH medical group, Tehran, IRAN). The manufacturer had provided vacuum device cylinders and constrictive rings of different sizes that could be adapted to the patient's penis sizes. Furthermore, if patient did not achieve full erection that was considered by the patient and the physician to be unsatisfactory for penetration at the first visit, he was advised to practice with VCD for one week by putting penis inside VCD cylinder, producing negative vacuum pressure until achieving full erection and maintaining it for 20 minutes three times a day without using single constrictive ring.[6,9,10,11,12] Technical advice was made available by revisiting the patients on a daily basis if demand.

Study protocol

The IIEF questionnaire was administrated before the treatment, and after 15 times using of this method during one year of follow up. Patients were asked for any bruising injury or skin changes sufficient to decrease the number of the times using the device, or stop using of the treatment altogether. If there was a failure the patient was advised to revisit in the clinic with his partner for re-valuation, all of the patients were examined by both an urologist and a midwife for the status of wife's virginity, and vaginal atrophy.

Statistical Analysis

The scores of IIEF in each domain compared with VCD before and after treatment. To determine the changes in response to VCD treatment we used Chi square and paired T test using the statistical package of social science (SPSS Inc, Chicago, Illinois, USA) version 16.

The *P* value less than .05 was considered statistically significant. The use of VCD for APVP was also assessed by asking the patients' spouses to respond either positive or negative. Using mean statistics values, these responses were compared before and after treatment with VCD regarding various response domains. The patients responses' were compared with each other in domains of EF, IS, OF, SD, and OS. The ultimate score for each domain was calculated as the summation of the scores attained for each individual query in that domain. The data were presented as means and percentage as summary statistics. Finally the positive and negative responses to APVP question were compared with each other in patients' with virgin wife regarding abridge six items of EF post treatment to assess the exact difference induced by VCD on the erectile function of these patients.

RESULTS

A total of 1530 referred patients with ED were enrolled in this study. Age range was between 22 to 85 years (mean ± SD, 48.2 ± 12.5). Thirty patients out of 1530 cases were excluded from the study. Of those, 15 patients reported that VCD was socially inconvenient. Thirteen cases discontinued their treatment because of psychological discomfort in performing sex and attempting sexual intercourse less than 15 times using their devices during one year of follow up and were excluded from the study and referred to psychologist. The two remainder patients were unable to get full erection in clinic due to the history of prolonged priapism and severe corporal fibrosis and therefore were excluded from the study. VCD was able to induce full erection in clinic during initial training and we didn't have any failure in inducing and maintaining erection in all patients. Because of attaining full erection in all patients, we didn't separate the patients to age subgroups. Sum of 1500 pa-

Table 2. IIEF scores of patients according to ability to perform vaginal penetration.

Response to APVP	Age, years	Treatment period	Patients (no.)	EF *P* value	IS *P* value	OF *P* value	S Des *P* value	OS *P* value
APVP Positive	23-88 (Mean = 49)	Pretreatment (SD)	1419	9.3 ± 3.0	6.7 ± 2.4	5.6 ± 2.1	1.8 ± 6.3	3.9 ± 1.8
		Post- treatment (SD)		27.3 ± 5.1 ($P < .0001$)	11.3 ± 1.2 ($P < .0001$)	6.3 ± 1.8 ($P < .0001$)	7.5 ± 3.2 ($P < .0001$)	8.9 ± 1.5 ($P < .0001$)
APVP Negative	22-55 (Mean = 34)	Pretreatment (SD)	81	9.2 ± 1.5	7.6 ± 2.7	5.3 ± 2.3	6.4 ± 3.3	4.4 ± 1.6
		Post-treatment (SD)		13.77 ± 3.03 ($P < .001$)	7.2 ± 2.7	5.2 ± 2.3	6.3 ± 2.1	4.1 ± 1.2

Key: IIEF, international index of erectile function; APVP, ability to perform vaginal penetration; EF, erectile function; IS, intercourse satisfaction; OF, orgasmic function; S Des, sexual desire; OS, overall satisfaction; SD, standard deviation.

tients were evaluated in this study. Those patients with penile bruising were advised to stop using VCD for 2 weeks. Full erection was achieved on the first training session in 1310 (87.4%) patients, but 188 (12.6%) of the patients were able to have full erection one week after practicing with VCD.

Of 1500 patients a total of 1419 (94.6%) were able to have successful intercourse and responded positively to APVP (Table 1). In different domains of EF, IS, OF, SD and OS scores, all patients with positive APVP had improvement compared with the pretreatment scores ($P < .05$). Eighty one patients (5.4%) were unable to have intercourse as stated by their wife, (responded negatively to APVP) in spite of having full erection on clinical trainings. Among these patients 43 (53%) were having virgin wife, 30 patients (37%) had histories of sexual abstinence (sex abstinence defined as couples whom had not having intercourse with full rigid penis for more than six months that had lead to vaginal lumen narrowing) and a number of 8 (9.8%) patients had senile vaginal atrophy. Regarding the technical problems, 78 patients needed retraining sessions. In addition, 50, 20, and 5 patients needed repeated 2, 3 and 4 training sessions by the urologist, respectively, of them, 3 patients needed their wives attendance and training due to their husband's illiteracy and physical inadequacy.

Table 1 demonstrated the IIEF score before and after VCD therapy in all of the patients. Table 2 summaries the IIEF scores of patients with APVP positive in which there were significant improvement between pretreatment and post treatment regarding various issues of erectile function ($P < .05$). IIEF scores of patients with APVP negative whom were not having significant improvement compared with pretreatment, except EF in which sum score of domain was improved from 9.2 ± 1.5 pretreatment to 13.77 ± 3.03 ($P < .05$). Table 3 shows that VCD can induce full erection in all patients. IIEF Q1 and IIEF Q2 have similar domains score in men with virgin wife and men whom their wife weren't virgin. But regarding IIEF Q3, Q4, Q5, and Q15 patients whom were not having virgin wife had improve IIEF domains as compared to pretreatment. Comparing IIEF scores erectile function issue among APVP negative and APVP positive after treatment that regards various domains, we find that it was similar at IIEF Q1 and Q2 ($P > .05$). In both group but there were significant differences at IIEF Q3, Q4, Q5 and Q15 ($P < .05$).

DISCUSSION

Previous studies on VCD had demonstrated variable success rates. Some studies have shown high success rates[4,6,7,10,13,14,16,17] but other studies have come up with lower success rates.[15,18,19,20,21] Some researchers have agreed those success rates are highly affected by the degree of the training.[6, 22] The reason for the wide range in success rates in different studies was applying of the different evaluation criteria. For example, in Moulmein's study[23] their criterion for success was the ability to attain erection.

Table 3. Response to the abridged six-item (erectile function) version of the IIEF questionnaire comparing the APVP positivity and APVP negativity in all patients, post-treatment among patient having virgin wife.

IIEF questionnaire	APVP Positive	APVP Negative	*P* value
IIEF Q1 (SD)	4.71 ± 0.86	4.60 ± 0.84	.255
IIEF Q2 (SD)	4.60 ± 0.96	4.75 ± 0.75	.088
IIEF Q3 (SD)	4.10 ± 0.86	1.02 ± 0.23	< .001
IIEF Q4 (SD)	4.61 ± 0.86	1.11 ± 0.35	< .001
IIEF Q5 (SD)	4.76 ± 0.74	0.86 ± 0.21	< .001
IIEF Q15 (SD)	4.52 ± 0.73	1.43 ± 0.65	< .001
Total (SD)	27.3 ± 5.01	13.77 ± 3.03	< .001

Key: IIEF, International index of erectile function; Q, Question; APVP, ability to perform vaginal penetration; SD, Standard deviation.

In Cookson and Nadig's study,[14] long-term use of VCD was taken as a criterion of success, and in Broderick and colleagues'[9] study patient satisfaction was considered for evaluation and success. In our study the criterion for success was patient's ability for vaginal penetration along with fully erected penis. Moreover our success rate were higher than the other studies, because of the using proper sizes of VCD cylinders or constrictive rings and proper training of the patients by an expert urologist that was also advised in other studies.[10,22]

Our research was a first study that noticed the importance of female factor in VCD failure. Denil and colleagues[24] also reported 93% of their patients obtained erection, but only 83% of them were having sufficient rigidity for vaginal penetration, and we think that it was not only quality of penis rigidity, but also the vaginal resistivity that was the main cause of failure for their patients whom were unable to have vaginal intercourse despite having erections. In Wada and colleagues' study25 they used locally manufactured VCDs and their ability to induce successful erection was hundred percent (in 20 patients) of their patients which is similar to finding in our study, having a same finding on a much larger scale. In Earle and colleagues study,[26] 81% of patients abandoned the VCD that is quite high, but in our clinic VCD was found acceptable by most of the patients who were advised; it might be due to the good explanation of different therapeutic methods, the proper training of the patients, solving side effects, explaining their advantages, disadvantages to the patients and their wife. Nadig and colleagues[7] mentioned that one of his patient's penile rigidity began to decrease five to ten minutes after the sexual activity, even though it would not change over a thirty-minute period that once originally tested in the laboratory. In Gilbert and Gingell's study although 38 patients were able to obtain an erection-like state using a vacuum constriction device, only 12 were able to enjoy satisfactory sexual intercourse.[18] In a retrospective study, Sidi and colleagues concluded that the pain, inconveniency, and early loss of rigidity were the most important causes for dissatisfactions.[12] Our findings indicate that vaginal resistance causes early loss of rigidity and failure to penile entrance during the intercourse. In this research, 43 patients had virgin wife that were not noticed in any of the studies, this may be due to the fact that our clinic has known as is a referral center, and virginity is culturally preserved in unmarried ladies in our country. As we attained hundred percent erections in our study so we believe the effect of VCD on quality of erection is not affected by the etiologies e.g. arteriogenic,[13] corporeal veno-occlusive dysfunction[21] and diabetic ED[27,28] which was mentioned in other studies as well.

Comparing IIEF Erectile function issue among APVP negative and APVP positive before and after the treatment that including various domains, we found that it was similar in IIEF Q1, Q2 in both groups but there was significant differences for IIEF Q3, 4, 5 that showed loose of erection despite having full tumescence before the intercourse which is believed to arise from severe vaginal resistance in patients with narrow vagina (virginity, abstinence sex, and vaginal atrophy) causing an escape of blood from the corpus cavernosa through the constrictive ring at the penis base. Moreover, patients whom wife responded negative to APVP had lower scale in IIEF Q15 too.

In this study we encountered with some limitations. The patients' spouses that had positive response to APVP were not advised to admit the clinic if they were having successful sexual intercourse. Because they have not examined by the midwife, we could not provide any comments regarding the significance of the vaginal atrophy or abstinence in VCD

failure. This issue could be of importance for future investigations. Also due to significance of the issue we suggest to validate a questionnaire for Iranian population.

Comparing the patients' partner for the virginity, none of the partners responding positive to APVP were virgin. On the other hand, all patients with virgin wife were unable to have sexual intercourse with their partner that means vaginal tightness could directly affect the success of the intercourse in patients using VCD. Therefore, we could consider the presence of virginity as one of the major factors in VCD failure. We tried to suggest non-invasive treatments to our patients and believe careful training decreases the side effects, and increase the effectiveness of VCD. Handling problems regarding its failure can prevent more invasive alternative therapy.

Patients with bleeding disorders or those on anticoagulation therapy are considered at high risk to develop petechiae, echymosis or hematoma.[6] In our study we had 53 patients whom were using anticoagulant therapy and we did not observed any major side effects to be developed in them, it was shown that the risk did not exceed that of the general population.

All patients whose wife accepted vaginal, dilatation could take advantage of VCD for the sexual intercourse. Mechanisms of erection induced by VCD are entrapment of blood in corporal sinusoids.[29] Most probably practicing with VCD in initial steps would be of great help on its effectiveness.[30]

CONCLUSION

The VCD device could induce sufficient effective erection in all patients provided that using proper training and appropriate vacuum cylinders size and constrictive rings. Moreover; using VCD in patients with virgin wife is ineffective, and female factors could affect the success rate in VCD therapy.

ACKNOWLEDGMENTS

Kind thanks to Shahed University due to logistical supports. Also we kindly appreciate Mrs. Khadijeh Mohammadi the midwife, for her help in patients' partner examination.

CONFLICT OF INTEREST

Dr. F Khayyamfar owns patent on the VCD described in this report. He has received financial supports as a member of HAMRAH medical group (manufacturer and seller of study VCD). The other authors declare no potential conflict of interest.

REFERENCES

1. Chen J, Sofer M, Kaver I, Matzkin H, Greenstein A. Concomitant uses of Sildenafil and a Vacuum Entrapment Device for the Treatment of Erectile Dysfunction. J Urol. 2004;171:292-95.
2. Montague DK, Barada JH, Belker AM, et al. Clinical guidelines panel on erectile dysfunction: summary report on the treatment of organic erectile dysfunction. The American Urological Association. J Urol. 1996;156:2007-11.
3. Montague DK, Jarow JP, Broderick GA, et al. Chapter 1: the management of erectile dysfunction: an AUA update. J Urol. 2005;174:230-39.
4. Canadian Urological Association Guidelines Committee. Erectile dysfunction practice guidelines. Can J Urol. 2002;9:1583-87.
5. Chen J, Godschalk MF, Katz PG, Mulligan T. Combining intracavernous injection and external vacuum as treatment for erectile dsfunction. J Urol. 1995;153:1476-77.
6. Lewis RW, Witherington R. External vacuum therapy for erectile dysfunction: use and results. World J Urol. 1997;15:78-82.
7. Nadig PW, Ware JC, Blumoff R. Noninvasive device to produce and maintain erection-like state. Urology. 1986;27:126-31.
8. NIH Consensus Conference. Impotence. NIH Consensus Development Panel on Impotence. JAMA. 1993;270:83-90.
9. Broderick GA, Allen G, McClure RD. Vacuum tumescence devices: the role of papaverine in the selection of patients. J Urol. 1991;145:284-86.
10. Witherington R. Vacuum constriction device for management of erectile dysfunction. J Urol. 1989;141:320-22.
11. User survey report 1995. Data on File. Osbon Medical Syatems: Augusta, GA, USA, 1995.
12. Sidi AA, Becher EF, Zhang G, Lewis JH. Patient acceptance of and satisfaction with an external negative pressure device for impotence. J Urol. 1990;144:1154-56.
13. Baltaci S, Aydos K, Kosar A, Anafarta K. Treating erectile dysfunction with vacuum tumescence device: a retrospective analysis of acceptance and satisfaction. Br J Urol. 1995;76:757-60.
14. Cookson MS, Nadig PW. Long-term results with vacuum constriction device. J Urol. 1993;149:290-94.
15. 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;54:891-3.

16. Bosshardt RJ, Farwerk R, Sikora R, Sohn M, Jakse G. Objective measurement of the effectiveness, therapeutic success and dynamic mechanisms of the vacuum device. Br J Urol. 1995;75:786-791.

17. Segenreich E, Shmuely J, Israilov S, Raz D, Servadio C. Treatment of erectile dysfunction with vacuum constriction device. Harafuah. 1993;124:326-28,.

18. Gilbert HW, Gingell JC. Vacuum constriction devices: second-line conservative treatment for impotence. Br J Urol. 1992;70:81-83.

19. Meinhardt W, Lycklama A, Nijeholt AA, Kropman RF, Zwartendijk J. The negative pressure devices for erectile disorders: When does it fail? J Urol. 1993;149:1285-87.

20. Vrijhof HJ, Delaere KP. Vacuum constriction devices in erectile dysfunction: acceptance and effectiveness in patients with impotence of organic or mixed etiology. Br J Urol. 1994;74:102-5.

21. Kolettis PN, Lakin MM, Montague DK, Ingleright BJ, Ausmundson S. Efficacy of vacuum constriction device in patients with corporeal venous occlusive dysfunction. Urology. 1995;46:856-58.

22. Tan HL. Economic cost of male erectile dysfunction using a decision analytic model: for a hypothetical managed-care plan of 100 000 members. Pharmacoeconomics. 2000;17:77-107.

23. Meuleman EJ. Experiences with a vacuum apparatus in the treatment of erection disorders. Ned Tijdschr Geneeskd 1993;137:412-16.

24. Denil J, Ohl DA, Smythe C. Vacuum erection device in spinal cord injured men: patient and partner satisfaction. Arch Phys Med Rehabil. 1996;77:750-53.

25. Wada H, Sato Y, Suzuki N, et al. A study on the erectile response with the vacuum constriction device compared with intracavernous injection of a vasoactive drug. Nippon Hinyokika Gakkai Zasshi. 1995;86:321-24.

26. Earle CM, Seah M, Coulden SE, Stuckey BG, Keogh EJ. The use of the vacuum erection device in the Management of erectile impotence, Int J Impot Res. 1996;8:237-40.

27. Arauz-Pacheco C, Basco M, Ramirez LC, Pita JM, Pruneda L, Raskin P. Treatment of diabetic impotence with a vacuum device: efficacy and effects on psychological status. Am J Med Sci. 1992;303:281-84 .

28. Bodansky HJ. Treatment of male erectile dysfunction using the active vacuum assist device. Diabet Med. 1994;11:410-12.

29. Yuan J, Hoang AN, Romero CA, Lin H, Dai Y, Wang R. Vacuum therapy in erectile dysfunction--science and clinical evidence. Int J Impot Res. 2010;22:211-9.

30. Engel JD. Effect on sexual function of a vacuum erection device post-prostatectomy. Can J Urol. 2011;18:5721-5.

EDITORIAL

This article is pretty interesting, but I would like to point out some matters, since I have been interested in this subject for many years. Of 1500 patients in the study 94.6% had had successful intercourse using vacuum constriction device (VCD). This rate of positive response to VCD is amazing. The initial overall response rate is approximately 80% to 90%. However, satisfaction with VCD treatment typically fades with time, as patients report dissatisfaction with how awkward or unnatural the devices are to use, hinging or buckling of the erection with thrusting, and dissatisfaction with the fact that the erection is false one (and therefore cold) which can be off-putting to the partner.

Patients who have diminished sensation in their penis, especially men with spinal cord injury, are at higher risk for trauma with repeated use of the constriction ring. It should be used with extreme caution in this group of patients and the band should be applied for only short periods of time. Unlike the manufacturer (HAMRAH Co.) which advertise the use of VCD for correction of penile curvature too, men with Peyronie's disease (PD) (acquired penile curvature) or congenital penile curvature, with significant degrees of curvature should be discouraged from using a VCD, as the even curved cylinder may exert significant stress on the bent penis resulting in trauma to the already curved shaft of the penis. I have visited many men with congenital penile curvature who developed sever and progressive PD, after using VCD with curved cylinder for treatment of ED. Other authors also reported development of PD with long term VCD use.[1]

I strongly disagree with recommendation of VCD in patients with ED and curvature correction. Also patients with hematologic types of veno-occlusive priapism (sickle cell disease, thalassemia, or leukemia) should not use a VCD at all. Moreover, for considerable number of patients the VCD is unacceptable. They believe this way due to two important factors, namely cosmetics and difficulty integrating intercourse with VCD into love-making. In the white men the entry of blood alongside with the application of a constriction ring renders the penis cool and results in a large amount of superficial vein swelling. These factors make the VCD induced erection a non-cosmetic one and the younger men and the impotent patient who is currently not in a stable long-term relationship often find this undesirable and unacceptable. In an average man using VCD will typically take 10-20 minutes to result in a significant penile rigidity sufficient for penetration. This time frame plus the unnatural erection, makes this treatment option cumbersome for most men and they may have great difficulty integrating it into sexual life. In additions, the VCD has own complications. Bruising, skin breakdown, and penile pain associated with the application of the constructive ring have already been known. The tightness of the band, most of the time result in failure to achieve an antegrade ejaculation and sexual satisfaction. One of the important drawback with the erection obtained with the VCD is that it may cause penile hinge at the point of ring application. As a result, the penis behind the constrictive band is soft and only that portion of the penile shaft that is past the ring has any degree of unnatural rigidity. Hence, the constrictive ring must be applied as far towards the base of the penis as possible.

Drop-out rates of up to 65% have been reported[2] and the most common reasons for drop-out include, penile pain, poor rigidity, failure to ejaculate, dissatisfaction with penile appearance

Mohammad Reza Safarinejad M.D

Clinical Center for Urological Disease Diagnosis and Private Clinic Specialized in Urological and Andrological Genetics, Tehran, Iran

E-mail: info@safarinejad.com

and temperature, bothersome, and embarrassment. Embarrassment is an important factor and affected mostly with cultural issue. As a result the rate of embarrassment varies in different community. In my opinion, the most important factor in our community for the reluctance to use the VCD is embarrassment. On the contrary with the results of present study, of patients who address themselves to me for treatment of impotence and are good candidate for using the VCD, less that 10% accept even to try the VCD.

The severity of erectile dysfunction (ED) is a significant factor in drop-out rates. Unfortunately, despite a large study sample size (n=1500), study subjects have not been categorized by severity of ED. The participants can be categorized into three subgroup according to IIEF erectile function domain score, namely patients with mild, moderate, and sever ED. In a study by Dutta and Francois's 129 patients with organic ED who were interested in the VCD received the device after thorough training.[(2)] Their attrition rate was 65% overall and was lowest among patients with moderate ED (55%). All patients with mild ED discontinued use, and 70% of patients with complete ED also discontinued use. Of the patients who discontinued, most stopped VCD use early (median 1 month, mean 4 months). The overall failure rate was 65%.

The authors of present study claim that success rates are highly influenced by the degree of training. In Dutta and colleagues' study the participants were highly motivated and best trained cohort of patients clinically possible. Before drawing final conclusion we should wait for further studies from the same region.

REFERENCES

1. Kim JH, Carson CC 3rd. Development of Peyronie's disease with the use of a vacuum constriction device. J Urol. 1993;149:1314-5.
2. 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;54:891-3.

REPLY BY AUTHORS

With respect, I would like to inform you that all patients participated in this study were either refused or had failure to respond to intracavernosal injection of vasodilator drugs. Meanwhile the patients and their spouses where explained about advantages and disadvantage of vacuum constrictive device (VCD) and penile prosthesis (e.g. cost, probability of infection and malfunction, smaller penis and invasiveness). The success rate of 94.4% is regarding ability to perform vaginal penetration and issues regarding success rate have been discussed in detail at the discussion of the article. Patient and their spouses where free to choose any treatment modality. Despite the disadvantages' of VCD most of them were happy using VCD for treatment of erectile dysfunction (ED) than going for prosthesis surgery or doing nothing.

We did not ordinarily include patients with Peyronie's disease (PD), congenital penile curvature, and hematologic types of veno-occlusive priapism in the study. Kim's finding on development of PD with long term use of VCD is just a case report and no other such report or study exists in the literature. Also we have a group of patients with spinal cord injury and ED under observation and the paper of the study will be released in near future.

I admire editor's opinion regarding reluctantly of using VCD in our community and his points of views but we know that personal points of view have its own level of value.

Amongst our patients only less than 2% discontinued and excluded from the study.

This is very different from the Duttas's study, which possibly may be due to easily available other effective modalities (penile prosthesis) in those countries.

The aim of our study was to evaluate the effect of VCD on erection and the cause of losing it during intercourse, and we have evaluated the issue in detail for the first time and no other study have mentioned importance of patients' spouses in men using VCD for treatment of their ED.

With respect to the editorial comments, that repeatedly has emphasized over the disadvantages of VCD, I would like to mention a point that considering all side effect and disadvantages, VCD is considered as the first line of therapy after phosphodiesterase type 5 inhibitors in guidelines published by EAU 2013.

At the end I believe it is better to be fair regarding various treatment modalities rather than writing only and only about VCD drawbacks.