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Original Article

Effect of Modified Vacuum in Patients with Peyronie's Disease and Erectile Dysfunction

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HIGHLIGHTS

- Peyronie's Disease (PD) is a connective tissue disorder involving the growth of fibrous plaques in the soft tissue of the penis.
- The average age of onset of PD in white men is about 53 years.
- There are several surgical techniques for PD including excision of plaque, incisions, graft, plication of the penis, and penile prosthesis.

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ABSTRACT

Introduction
Peyronie's disease (PD) is a penile disease that is characterized by penile pain, curvature, shortening, and plaque in the penis which usually ends up in erectile dysfunction (ED). This study is to assess the efficacy of modified vacuum therapy in patients with PD and ED. The basic principle of the study is similar to modeling performed during penile implant surgery.

Methods
This study is performed on 43 Patients who is practiced with three different vacuum cylinders 30 minutes, 3 times a day for 3 months. First, the second and third month with the smallest, the medium, and the biggest cylinder were used respectively. Parameters recorded before the beginning of the study at the end of each month. Assessment includes number and size of the plaque, angle of penile curvature (by erection induced with vacuum constriction device (VCD)), pain during erection, the status of morning erection, quality of an erection, and various previous treatments. There was a clinically and statistically significant improvement in the angle of curvature, size, and numbers of plaque.

Results
A total of 43 patients with a mean age of 56.3 years (40-74) years participated in the study. There was a significant reduction in plaque size and curvature. The mean of plaque size and curvature was 1.39cm and 31.28 degrees respectively at the presentation which was reduced to 0.64 (0-3) cm and 11.6 degrees respectively at the end of the study. At the end of study 30 (69.7%) patients were satisfied with the outcome and wanted no further treatment. There was no major side effect observed in patients using the device.

Conclusions
We recommend the use of a modified vacuum device with a mentioned method for PD and ED with curvature less than 45 degrees and plaque size less than 2cm. It is safe to use in all stages of the disease and can help patients to attain erection with VCD.

Keywords: Peyronie's Disease; Penile Curvature; Penile Plaque; Erectile Dysfunction; Vacuum Pump Therapy

Introduction

Peyronie's Disease (PD) is a connective tissue disorder involving the growth of fibrous plaques in the soft tissue of the penis. The symptom of PD includes pain, shortening, penile curvature, and a variable degree of erectile dysfunction. The cause is unknown, although abnormal wound healing due to minor sexual trauma will develop fibrotic tissue replacement at traumatized sites which could be due to underlying genetic predisposition (1,2). Fibrotic tissue will gradually tighten the penis even stony hard due to calcification. Due to low flow blood circulation in the tissues of the penis which will decrease the ability to transfer fibroblasts so fibrotic tissue reuptake of plaque will be deranged and the plaque will remain

there (3).

The incidence of symptomatic disease is estimated to be about 5%. The average age of onset of PD in white men is about 53 (range 19-83) years. The prevalence of symptomatic PD is estimated at about 0.4% to 9% (4,5). Incident of PD associated with ED is estimated to be around 70% (6).

PD treatment includes both non-surgical and surgical treatments. Surgical treatment is indicated in stabilized Peyronie (more than 12 month) in whom the patients despite having a good erection are unable to make intercourse due to deformity. Nonsurgical treatment such as oral treatment, intralesional injection, topical treatment, vacuum pumping. Conservative treatment is considered inpatient whom we are aiming to reduce curvature, pain, and penile shortening in the patient (5). There are several surgical techniques for PD including excision of plaque, incisions, graft, plication of the penis, and penile prosthesis, none of which is considered as gold standard treatment. The use of a vacuum device will increase blood circulation to genital and stretched fibrotic. The use of vacuum pumping will mechanically stretch the tunica and provide lengthening at the contracted site as well. The concept of moulding technique which had been used in penile surgery to reduce the curvature after insertion of the penile prosthesis for PD could be helpful in the management of PD by trying to mechanically straighten the penis with the use of VCD (7). A similar study has been also implicated by Raheem et al as conservative management in PD (8).

Methods

A total of 60 patients was enrolled in the study with PD who were suffering from ED as well. The mean age was 56.3 years, range 40-74. Exclusion criteria were potency, absence of penile curvature, previous penile surgery, and physical/mental inability to use the device.

After taking a history, physical examination, and diagnosis of the PD and ED by a urologist a form was given to all patients to announce their agreement to participate in the project. All study procedures were approved by the Shahed Medical University ethics committee. All patients were trained to obtain sufficient awareness about all the procedure before entering the study and signed the ethical form. Then patient questionnaire to the notice of the subjects (number and size of the plaque, angle of penile curvature, pain during erection, status of morning erection, quality of an erection, and various previous treatments) were filled by the project manager. Patients were given a flexible penis to show approximate penis curvature and VCD was used to assess the curvature by inducing erection and maintaining it by placing a constrictive ring at the penis base. Finally, the exact amount of the angle achieved using Goniometer. Patients were advised to use a modified vacuum device. All patients were trained by the project manager for proper use of the device. The device includes 3 cylinders (figure 1). All patients were adviced to use the device by the putting penis into the cylinder and vacuum pumping it until full erection was achieved and maintaining it for half an hour three times a day without the constrictive ring to stretch and expand the penis. Patients were advised to use the small, medium, and large cylinder in the first, second, and third months respectively. All patients were recommended not to increase vacuum pressure if they feel pain but try to achieved and maintained a full painless erection for half an hour. Patients were advised to complete a daily diary to monitor their pump use and assess their compliance. All patients were revisited at the end of each month and treatment progress was recorded. During 3 months period, the patients used a vacuum device (Hamrah VCD, Hamrah medico-engg group, Tehran, Iran). The study was approved by the local ethics committee.

Regarding the status of erection, the physician was asking about the status of morning erection from the patients. Whether it is horizontal, above, or below (when the patient is in a standing position). Then more precise questioning was done according to patient response to seeing that if it is above horizontal, is it fully rigid or just above horizontal and if it is below horizontal, or it is totally flaccid or had a mild erection as it is shown in Table 1. The type of study was case series.

All data were analyzed with the software of SPSS 20 and calculated with the adjustment of frequency distribution tables and descriptive statistics criteria and variables of research have described then with the usage of analytical statistics, paired T-test, VAS score examination assumed examination analyzed and we reach the goals. The test was conducted with a confidence interval of 95%. We used the following formula to determine the sample

Figure 1. The Hamrah vacuum device

Table 1. change in plaque size – curvature before and after treatment

	Before using vacuum	After using vacuum
Plaque size mm (SD)(min/max)	1.39(1.03) (0-3)	0.64(0.94) (0-3) (p<0.001)
Mean curvature (SD) (min/max)	31.28(15.4) (10-80)	11.6(17.7) (10-80) (p<0.001)
The mean reduction of curvature <45 (SD)(min/max)	27.6 (10.38) (10/45)	5.9 (4.98) (0/20)(p<0.001)
The mean reduction of curvature >46 (SD)(min/max)	66.25 (13.7) (46/80)	62.50(15/00) (50/80)

size:

$$n = \frac{\left(Z\,1-\frac{\alpha}{2}+Z\,1-\beta\right)^2(\delta 1^2+\delta 2^2)}{(\mu 1-\mu 2)^2}$$

Results

In this study 60 patients entered of whom 17 patients went out of the study due to the following reasons, failure to complete at least 90% of the exercise session (10 patients), discomfort and pain during pumping (5 patients) and dislike the method (2 patients). A total of 43 patients completed the study the mean age of patients was 56.3 years (40-74 years).

Regarding previous treatment 15 patients had received no treatment before the use of vacuum, 28 patients treated with vitamin E, verapamil and 1 patient give the history of shock wave therapy.

The mean (range) of plaque size was 1.39(0-3)cm at presentation. The mean (range) of curvature was 31.28 (10-80) degrees. Of 43 patients who completed the study mean (range) reduction in plaque size and curvature were 0.64 (0-3) cm and 11.6 (10-80) degree respectively which of significant value (p-value<0.001). The improvement in plaque size was having close relation with the size of plaque at presentation and had a better outcome in patients having lower numbers of plaque (Table 2) and plaque smaller than 2cm (Table 3). The change in plaque size and penile curvature was not significantly associated with patients' age.

The change in curvature was having a direct relation with its severity at presentation and demonstrate significant (p-value<0.001) improvement in patients with curvature less than 45 degrees.

Before the start of therapy 7 patients (16.3%) had pain. And 36 patients (83.7 %) of them had no pain. All patients had no pain at the end of the study.

There is a significant improvement in morning erection following the use of a vacuum device on 95 percent Confidence interval (p-value<0.001) in patients who have a horizontal erection in the morning. At the end of the study eight patients were able to do intercourse with 5 alpha-reductase inhibitors, 30 patients were using VCD for intercourse and 5 patients despitehaving full rigid erection with VCD were unable to have successful intercourse duo to severe penile curvature.

At the end of the study period, 30(69.7%) patients were satisfied with the outcome and wanted no further treatment, 10(23.2%) patients continue to practice with VCD in the hope to get more improvement in the long term, two (4.6%) stopped further treatment and one (2.6%) patient went under surgery for correction of curvature followed by using VCD to induce and maintain an erection. All patients experience vacuum pumping acceptable and without any major complications. Three patients experience minor bruising and ecchymosed which was improved by two weeks rest.

Discussions

Several controversial treatments have been introduced in PD with no confirmed therapeutic effect in clinical trials (9,11) .

In this study, we evaluate the effect of modifying vacuum devices to mechanically straightening the penis and decrease plaque size. Patients with PD and ED are a candidate for penile prosthesis and surgery is considered as the last remaining option to restore sexual function. Surgery is considered as the only treatment of choice for these patients (12). It may be considers as over treatment

Table 2. Plaque number before and after using a vacuum

Number of plaques	Absolute frequency Before using vacuum	Absolute frequency after using vacuum
0	2 (4.7%)	20 (46.5%)
1	30 (69.8%)	19 (44.2%)
2	5 (11.6%)	4 (9.3 %)
3	4 (9.3%)	0 (0%)
4	2 (4.7 %)	0 (0%)

Table 3. Plaque size classification based on recovery

Plaque size	Relative frequency (number of plaque)	Condition after treatment
0-2 cm	47	Completely cure
2-3 cm	39	Less than 2 cm
3cm <	14	No difference

Table 4. morning erection before and after using a vacuum

	Absolute frequency Before using vacuum	Absolute frequency after using vacuum
Loose (complete flaccid)	9 (20.9%)	2 (4.7%)
Sub horizontal	25 (58.1%)	8 (18.6%)
Horizontal	9 (20.9%)	22 (51.2%)(P<0.001)
Above the horizontal	0 (0%)	11 (25.6%)
Full rigid	0 (0%)	0 (0%)

while nonsurgical option is unlikely to be effective once the disease stabilizes. Moreover most of our patients had obtained no therapeutic effect from their previous medical treatments. Based on our experience we have been using vacuum pumping for the last 17 years for the treatment of patients with PD and ED. The same study was done by Levin et al which he used a penile extender device for the treatment of PD with promising results (13).

These studies help givehope to patients whom are worried about the future of their disease which would be observed in half of the patients (13).

The vacuum device is easy to be used and it can help patients to get involved directly in their treatment program which may affect a satisfactory rate to increase improvement as they avoid surgery. It seems that regular vacuum pumping would mechanically straight the penis and its fibrotic band causing remodeling of fibrous plaque leading to the straightening of the penis (14). Vacuum pumping with usual vacuum device which has a routine size cylinder will cause negative pressure on all penis surface and will expand penis in all directions which is not appropriate for straightening penile curvature. However, it does to reduce the curvature and size of plaque by its generalized effect. We try to act more precisely by using different size cylinders. Mentioning pressure formula (the molecule in area unit), we used the small cylinder which by vacuum pumping will pull penis forward from its distal end (glans) and will striate the penis (it will not have the side expansion), it not only implementing traction force on fibrotic bands but also increase the blood circulation as well (15).

By gradually increasing cylinder size, in addition to the striating the penis, it becomes expanded as well. At the end of the practice by using a constrictive ring at the base of the penis patient could benefit from its effect on his erectile dysfunction as well.

We did not observe any particular predictor for successful outcomes, so all patients can try vacuum device pumping for treatment of their peyronies disease even if they are waiting for surgery. Patients with plaque smaller than 2 cm and penile curvature of less than 45 degrees had a higher success rate than patients with larger a plaque and a higher degree of curvature. Raheem et al did also observed better respond in patients with soft plaque (8). We did not perform ultrasonography but it is possible that patients with calcified plaque would have less likely to respond to this type of therapy or may need a longer duration of practice. Most of the patients with penile curvature more than 45 degrees decided to continue practicing with the device in the hope to get improvement in longer-term.

Erectile function and the quality of nocturnal penile tumescence did improve in our patients as well. Raheem et al did not observe any significant sexual improvement (8).In our study 69.7% (30) patients were satisfied with the outcome and wanted no further treatment, patients were able to have a good erection with VCD sufficient for intercourse by using a constrictive ring at the base of the penis (15).

If deformity was not a major obstacle for vaginal penetration. The pain was observed in 7(16.3%) patients at the start of the study. And 36 (83.7 %) patients had no pain. All patients had no pain at the end of the study so we did not have any significant comment on this issue because it is the natural course of the PD. Raheem et al also report spontaneous pain resolution in all their patients which Is not related to the therapy (8).

This is the first study to describe the use of a modified vacuum device in PD and ED. Studies with more modifications, more patients, and longer duration if practicing with VCD need to have a better impression on its effects in PD.

Conclusions

Treatment of patients who present with peyronies disease and erectile dysfunction with vacuum pumping is safe and effective.This method not only enables the patient to have an erection by using a ring at the base of the penis to maintain an erection, it also improves the patient's sexual ability significant reduction in plaque numbers, plaque size, and curvature of the penis. The patient is directly involved in treatment (request for surgery decrease). Some predictors of successful outcome including presenting curvature below 45 degrees and presenting plaque size below 2cm.

Authors' contributions

All authors had an equal contribution.

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Conflict of interest
Fereydon Khayyamfar owns the patent on the VCD described in this report. He has received financial supports as a member of the Hamrah medico-engg group (manufacturer and seller of studied VCD). The other authors declare no potential conflict of interest.

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Ethical statement
Not applicable.

Data availability
Data will be provided by the corresponding author on request.

Abbreviations
ED Erectile dysfunction
PD Peyronie's disease
VCD Vacuum constriction device

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