

Original Article

Effect of Newly Designed Vacuum Cylinders Along with Mini Massagor on Peyronie Disease at Acute Phase

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HIGHLIGHTS

- Peyronie treatment in the acute phase by vacuum pumping with newly shaped vacuum cylinders and massagor can be safe and effective.
- Our data indicated a better erection, penile length, reduction in plaque numbers, plaque size, and curvature of the penis.
- In diabetic patients, our treatment strategy was less effective than the general population.

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ABSTRACT

Introduction

Peyronie's disease (PD) is penile and may present with penile pain curvature, shortening, and plaque in the penis and erectile dysfunction (ED) in some cases. This study assesses the efficacy of vacuum therapy and massagor in patients with PD at the acute phase. The basic principle of the study is similar to modeling performed during penile implant surgery.

Methods

This study was performed on 200 Patients with Peyronie's disease in the acute phase who were referred to the family health clinic of shahed university. Patients were trained to practice with three different sized and shaped vacuum cylinders in addition to mini vibrating massagor for 30 minutes, three times a day for three months. They used the smallest curve cylinder (being used in the opposite direction of penile curvature) in the first and the second, respectively, followed by using the most oversized cylinder and bending the penis toward the opposite direction. In contrast, placing a constrictive ring at the base of the penis in the third month and massagor is used intermittently. Parameters were recorded before the beginning of the study and at the end of each month. Assessment includes pain during erection, number and size of the plaque, curvature of penile, quality of an erection, and penile shortening.

Results

A total of 200 patients with a mean age of (17-70) years participated in the study. At the presentation, the mean of plaque size and curvature were 1.21 ± 1.21 cm and 51.62 degrees, respectively, which were reduced to 0.74 ± 1.01 cm. and 31.87 degrees. Respectively at the end of the study.

Conclusions

The use of newly shaped and sized vacuum pumping and the massagor is an effective method in treating Peyronie's disease in the acute phase and can significantly reduce pain, curvature, plaque size, and increase erectile function.

Keywords: Peyronie's Disease; Penile Curvature; Penile Plaque; Vacuum Therapy, Acute Phase, Conservative Therapy

Introduction

Peyronie's Disease (PD) is a healing process disorder involving the remaining fibrous plaques in the soft tissue

of the penis. Insufficient activation of fibrinolysis and fibroblast activation is the cause of the rapid growth of the plaque (1). Peyronie's disease usually has two phases:

The acute phase, in which the most common symptoms of this phase are painful erections and usually may lead to deviation of the penis. The acute phase may last for 5 to 7 months but can take even up to 18 months (2). In the chronic phase, the curvature of the penis may be the only symptom of this phase. The usual PD symptoms are pain, penile narrowing, curvature and shortening, and variable degrees of erectile dysfunction (3, 4). The cause is unknown, although minor sexual trauma and abnormal wound healing may lead to fibrotic tissue replacement at traumatized sites, which could have an underlying genetic predisposition (5-10). Fibrotic tissue may gradually get hard inside the corpus cavernosum or even stony hard due to calcification. Due to the low flow of blood circulation in the penis as an end-organ which will limit the ability of fibroblasts and decrease deranging fibrotic tissue reuptake of plaque in the penis and eventually will let the fibrotic tissue remain there (11). A vacuum constrictive device (VCD) is a non-invasive treatment of PD with a similar mechanism of action as penile traction therapy (PTT). Its primary mechanism of action is reordering disordered collagen in the inelastic scar through mechanotransduction by inducing active tissue remodeling in a rat model, Lin H et al., (11, 12).

Whether an animal model presents the human condition is not clear. Li J et al., showed that the VCD could decrease not only Peyronie's-like plaque size but also simultaneously improve erectile function (13). The incidence of symptomatic disease is about 5%. The average age of onset of PD is about 53 (range 19-83) years in white men. The prevalence of symptomatic PD is at about 0.4% to 9% (1-4). PD treatment includes non-surgical and surgical treatments. Surgical treatments are not indicated in patients with acute phases. Conservative treatment should also be considered, especially in patients who have contraindications for surgical treatment, such as severe concomitant somatic diseases (5). The therapy with vacuum devices may represent a viable therapeutic option for treating PD, so Penile traction by vacuum therapy may improve penile curvature (6). Conservative treatments aim to reduce curvature, pain, and penile shortening in the patient (2). The use of a vacuum device will stretch the fibrotic tissue and increase blood circulation to the genital. The use of vacuum pumping will imply traction force on the tunica and provide lengthening at the contracted site (7). The use of VCD has a similar concept of moulding technique used in penile surgery to reduce the curvature following insertion of the penile prosthesis for PD and could be helpful in the treatment of PD by trying to straighten the penis with VCD (8). A similar study has also been implicated by Raheem et al., and us as conservative management in PD (7, 9). In another randomized, open-label study, Ralph et al., showed that VCD combined with collagenase *Clostridium histolyticum* treatment might improve the penile curvature (10). A locally applied

vibrating device was demonstrated to reduce pain (11, 12) and regenerate new vessels and lymphatics (13). Our study uses a mini vibrator massager to lysate the fibrotic tissue and decreases penile pain. The watchful waiting approach of the acute phase could be dangerous for the patients due to the possible worsening of the curvature and penile shortening (14).

VCD and Traction devices are non-invasive options under study and may be reversing pathological penile curvature and could halt disease progression (9). Applying Penile traction force by VCD or PTT in PD is hypothesized to work by the exact mechanism as is effective in the biologically similar Dupuytren's scar, where repeated traction lengthens the contracted fibrinous plaque by reorganization of the extracellular collagen matrix (4, 15). There is weak evidence for VED therapy in PD in acute phase (9, 16). VED may be an effective and non-invasive treatment option for PD in acute phase with the potential to save patients from more invasive treatments.

Methods

A total of 200 patients were enrolled in the study with PD in acute phase. The mean age was 50.6 years, range 37-70. Inclusion criteria were all patients complaining of penile pain or may have penile plaque and deformity (shortening or narrowing) that have passed less than six months from the beginning of the symptoms in which the disease is still in progress and not yet stabilized. Exclusion criteria were patients with PD for more than six months, patients not completing 90% of practicing therapy sessions, previous penile surgery, mental/physical inability to use the device, and if the patient elected to undergo other treatments or other treatments injectable management for PD.

After a urologist's history, physical examination, and diagnosis of the PD in acute phase, a form was given to all selected patients to agree to participate in this project. The ethics committee of Shahed Medical University approved the study procedures (Shahed.rec.1393.32).

All the patients were trained to learn about the procedures before entering the study and signed the ethical form. Then patient's questionnaire, the subject's size, the number of the plaque, and relative hardness (if it was felt to have calcification, were considered hard plaque, and if not, it was considered soft plaque). Pain during erection, the amount of penile shortening, angle and direction of penile curvature, quality of an erection using Shim questionnaire, and various previous treatments were filled by the project manager. Patients were given a flexible penis to show approximate penis curvature, and a vacuum device was used to evaluate the curvature by inducing erection and maintaining it by placing a constrictive ring at the penis base. The photos were taken from the right, left, and above view of the penis. The exact amount of the angle achieved using a Goniometer was recorded. Patients were advised to use a set of vacuum



Figure1. Peyronies kit



Figure2. Massagor

cylinders and a mini vibrator massagor for therapy. The project manager trained all patients for proper use of the device. The device includes three cylinders (Figure 1).

At the first visit, all patients were advised to use the smallest vacuum cylinder by putting the penis into the cylinder and vacuum pumping until full erection was achieved and maintaining it for 5 minutes, followed by massaging the penis with a mini vibrator massagor by moving massagor from the base (Figure 2). The sides and dorsal of the penis glans and move it back from the tip of the penis through the ventral surface of the penis till the perineum and repeat it again and again for five minutes (lubricant jelly was used for easy movement of massagor). The duration of massaging was five minutes, followed by pumping again and massaging again for two times more, till the whole duration of therapy reaches 30 minutes, three times a day, which means one and half hours a day. The vacuum device was used without the constrictive ring to stretch and expand the penis. At the second visit, Patients were advised to use the curve cylinder in the way that the curve of the cylinder stands in the opposite direction of patients' penile curvature for ten minutes, followed by massagor for 5 minutes and repeated until the entire therapy session reached half an hour, three times a day. All patients were recommended not to increase vacuum pressure if they feel pain but try to achieve and maintain a full painless erection for half an hour without getting penis rotated during vacuum pumping. At the third month, patients were advised to induce full erection with vacuum, and after applying the constrictive ring at the base of the penis, they should bend their penis by their hand very slowly and gently in the direction opposite the curvature of the penis until full detumescence achieved. This maneuver's duration took about ten minutes, and the patient should do it three times in each treatment session

and make 30 minutes in each practicing episode three times a day. Patients were advised to complete a daily diary to monitor their pump and massagor to assess their compliance. At the end of each month, Patients were revisited to assess the treatment progress. During three months, the patients used a vacuum device (Hamrah Peyronies Kit, Hamrah medico-engg group, Tehran, Iran) and mini face massagor. The local ethics committee approved the study.

All data were analyzed with the SPSS 20 and calculated with the adjustment of frequency distribution tables. Descriptive statistics criteria and research variables have been described using 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%.

Results

In this study, 279 patients entered of whom 79 patients were excluded from the study due to the following reasons, failure to complete at least 90% of the exercise session (47 patients), did not believe in the treatment (23 patients), and it did not attend the clinic for follow-up (9 patients). A total of 200 patients completed the study. The mean age of patients was 50.6 (17-70) years.

Regarding previous treatment, 103 patients had received no treatment before the use of vacuum, four patients treated with vitamin E alone, 56 patients received Para-aminobenzoic acid (PABA) alone, 67 patients PABA and Vit E, 43 intra-lesional verapamil injection, 40 colchicine alone, and ten patients give the history of shock wave therapy.

The first presenting symptoms were pain, plaque, and curvature observed in 57.5%, 5%, and 37.5%, respectively. Regarding direction of penile deviation were toward dorsal, ventral, right, left and no deviation in 25%, 27.5%,

Table 1. Effect of vacuum therapy on pain in patients with Peyronie disease in the acute phase

	Pain during therapy	Numbers of Patients	Percentage
Before using a vacuum device	Patients complaining of pain	145	72.5%
	Patients without pain	55	27.5%
After using a vacuum device	Patients complaining of pain	40	20%
	Patients without pain	160	80%

10%, 35% and 2.5%, respectively. Ninety-six patients (72.5%) had pain only at erection. The mean age of patients with pain was 48 ± 8 compared with those without pain was 55 ± 8 , and there was a significant difference in mean age between two groups (P -value <0.05).

Table 1 demonstrated the effectiveness of treatment with vacuum pumping, massagor, and its numbers and percentages of distributions in patients with PD in acute phase before and at the end of treatment.

Effect of vacuum therapy on numbers of plaque before and after vacuum treatment shows in Table 2. The mean range of plaque size was 1.21(0-3) cm at presentation. The mean range of curvature was 51.62 (10-80) degrees. Of 200 patients who completed the study, the mean range of reduction in plaque size and curvature were 0.74 (0-3) cm and 31.87 (10-70) degrees, respectively, which is of significant value (p -value <0.001). The improvement in plaque size was related to the hardness of plaque at presentation and had a better outcome in patients with softer plaque than patients with hard plaque. The mean reduction in size before and after treatment for the hard plaque was 2.2 cm and 1.7 cm, respectively. The mean reductions in the size of soft plaque before and after treatment were 1.22 cm and 0.4 cm, respectively. The finding was of significant value, but it was of a higher p -value in soft plaque (p -value <0.001) than patients with hard plaque (p -value <0.05).

The use of vacuum caused a significant reduction in the plaque length (p -value <0.001). At the beginning of the study, this reduction in size in patients with soft plaque was significantly more than those with hard plaque (p -value <0.05) (Table 3).

Regarding sexual function, Sexual Health Inventory for Men (SHIM) questionnaires was used for evaluation, and the mean score before and at the end of the study were 13.4 and 18.1, respectively, which represent a significant improvement from mild to moderate ED (12-16) before the start of the therapy to mild ED (17-21) at the end of the therapy. A significant erectile function improvement following a vacuum device and massagor on a 95 percent

Table 2. Effect of vacuum therapy on numbers of plaque before and after treatment

Plaque Number	Before vacuum therapy	After vacuum therapy
0	(35%)	85(42.5%)
1	70(37.5%)	90(45%)
2	(20%)	25(12.5%)
3	(5%)	0(0%)
4	(2.5%)	0(0%)

Confidence interval (p -value <0.001). At the end of the study, 126 patients were able to do sex by themselves. Forty-six patients could have intercourse with five alpha-reductase inhibitors, 22 patients with VCD, two patients underwent modified Nesbet surgery (one of the doses had sex with VCD and another with his spontaneous erection). Moreover, despite having a fully rigid erection with VCD, four patients could not have successful intercourse due to severe penile curvature (Table 4).

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 continued to practice with VCD and massagor 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 significant complications. Three patients experienced minor bruising and ecchymosed, which was improved by two weeks of rest.

On the analysis of patients with PD in acute phase who were having diabetic Mellitus (DM) as well, improvement in decreasing penile deviation was less than the general population, which was of significant value (p -value <0.05) but regarding reduction in plaque size (p -value=0.86) and improvement in erectile function (p -value=0.54), despite being less than the general population but they were not of significant value. The effect of treatment in diabetic and non-diabetic patients an independent t-test found that the average reduction of penile curvature after treatment in diabetic patients is significantly less than in non-diabetic patients. (p -value <0.05). However, concerning the size of the plaque and the amount of erection, this relationship is not significant (p -value=0.86, p -value=0.54) (Table 5).

Regarding side effects total of 10 patients experience (5%) pain, 10 patients (5%) blister, 16 patients (8%) Ecchymosis, 5 patients (2.5%) Skin rush, 1 patient (0.5%) shock Vasovagal. All of them were managed conservatively without the need to stop treatment for

Table 3. Effect of vacuum therapy on plaque size in patients with hard plaque and soft plaque

Type of plaque	Before vacuum therapy(cm)	After vacuum therapy(cm)	p-value
Hard plaque	2.2	1.7	<0.05
Soft plaque	1.22	0.4	<0.001

Table 4. Effect of vacuum therapy on plaque size, curvature, SHIM value and penile length

	Plaque size (cm)	Curvature	SHIM value	Decreased penile length (cm)
Before vacuum therapy	1.2	51.62	13.4	2.7
After vacuum therapy	0.74	31.33	18.1	1.37

Table 5. Effect of vacuum therapy in patients with and without diabetes mellitus

Type of the patients	Mean decrease in curvature	Mean decrease in plaque size (cm)	Improvement in erectile function (%)
Diabetic (55 patients)	14.45	0.33	19.9
Non diabetic (145 patients)	21.72	0.45	20.9

long.

Discussion

Several controversial treatments have been introduced in PD at acute phase with no confirmed therapeutic effect in clinical trials (17, 18). Most urologists do not choose VCD as the treatment modality when surveyed (19), due to the limited number of studies that have evaluated its effectiveness. This study evaluates the effect of a set of different shaped vacuum cylinders and massager on straightening the penis, plaque size, erectile function, and penile shortening effect of PD in acute phase. Patients with PD in acute phase are candidates for conservative and noninvasive treatment (20), and if their treatment is not successful, they may be considered the last option for surgery (20). Although in the study performed by Lin H, the PTT group had a more significant reduction in penile curvature, the VED group had more remarkable erectile function preservation, which they hypothesized due to decreases in TGF- β 1 and cell apoptosis (21). 22 (11%) of patients in this study used VCD for sexual intercourse, which is another advantage of using this kind of treatment for patients with Peyronies disease and ED (22). Surgery is considered the only treatment of choice for these patients (23).

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 23 years to treat patients with PD and ED (24). A similar study was done by Levin et al., in which he used a penile extender device for the treatment of PD with promising results. These studies may give hope to patients in the initial stage of the disease who are worried about the outcome of their disease, which would be observed in half of the patients (25).

The vacuum device and massager are easy to use, and they can help patients get involved directly in their treatment protocol which may affect a satisfactory rate to increase improvement and avoid other less invasive treatment and surgery. It seems that regular vacuum pumping would mechanically straighten the penis and its fibrotic band, the use of curve cylinder in the opposite direction causing remodeling of fibrous plaque leading to the straightening of the penis and bending of the penis after applying constrictive ring at the base of the penis will help the remodeling mechanism to be more effective (17). Vacuum pumping with a standard vacuum cylinder with standard size and shape will cause negative pressure on all penis surfaces and expand the penis in all directions, which is inappropriate for straightening penile curvature. However, it does reduce the curvature and size of plaque by its generalized effect. We try to act more precisely by using different sizes and shaped cylinders. Mentioning pressure formula (the molecule in area unit), we used

the small cylinder which by vacuum pumping will pull the penis forward from its distal end (glans) and will striate the penis (it will not have the side expansion) and eventually will have more penile lengthening effect to overcome the decreased in size by PD in acute phase. It not only increases the blood circulation but also implements traction force on fibrotic bands as well (26). The use of massager is to help fibrotic tissue absorption and help in improving PD in acute phase.

By gradually increasing cylinder size, in addition to striating the penis, it becomes expanded as well. At the end of the practice, using a constrictive ring at the base of the penis patient could benefit from its effect on his erectile dysfunction if indicated (27). We did not observe any particular predictor for successful outcomes, so all patients can try vacuum device pumping and massager to treat their Peyronies disease even at the acute phase. In the study performed in the out center, patients with plaque smaller than 3 cm and penile curvature less than 45 degrees had a higher success rate than patients with the more significant plaque and a higher degree of curvature (28). We did not have any comparative study based on size and angulation in this study, but our findings were similar to Raheem's regarding the hardness of plaque. Raheem et al., also observed better respond in patients having soft plaque (29). We did not use ultrasonography, but it seems patients with calcified plaque would have less likely to respond to this type of therapy in the short term or may need a longer duration of practice which was also observed in Raheem study (2) it, therefore, might be wise to assess all prospective patients with x-ray for more accurate evaluation. The erectile function did improve in our patients as well. Raheem et al., did not observe any significant sexual improvement (21). Most of the patients who did not improve in the study period decided to continue practicing with the device in the hope of improvement in the longer term. In our study, 69.7% (30) of patients were satisfied with the outcome and sought 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 (30).

The deformity was not a significant obstacle for vaginal penetration, and only two patients underwent surgery for their penile deformity. The pain was observed in 32 (16. %) patients at the start of the study. Moreover, 168 (84 %) patients had no pain. A decrease in the number of patients complaining of pain at the end of the study was also observed in other studies, 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, unrelated to the therapy (21). The mean age of patients with pain was 48 ± 8 compared with those without pain was 55 ± 8 , and this deference was of significant value (P -value <0.05). Pain on erection was a part of presenting symptom complex,

which was also mentioned in other studies. Patients in the younger age group have better erection than patients in the older age group, and it seems reasonable to have less pain as a presenting symptom in older patients due to the increased rate of ED with aging.

This study is the first to describe the use of a newly shaped and various size vacuum cylinder and massager in PD in acute phase. Studies with more modifications, more patients, and longer clinical trial practice duration will show its result more precisely. They were minor side effects, managed conservative, and were not of significant value.

In a comparative study performed by L P. MacDonald, no significant dereferences were observed in patients regarding VCD effects on patients with DM to non-DM patients. The effects of diabetes were taken into account to determine their effects on VED therapy efficacy. There was no significant difference between the two groups who had the same characteristics (31). However, in our study, DM patients responded lower than general population between groups with the characteristics mentioned above. On the analysis of patients with PD in acute phase who were having diabetic Mellitus (DM) as well, improvement in decreasing penile deviation was less than the general population, which was of significant value (p -value <0.05) but regarding reduction in plaque size (p -value=0.86) and improvement in erectile function (p -value=0.54), despite being less than the general population but they were not of significant value.

Due VEDs have been previously studied in combination with injections and surgery. Lue et al., instituted the use of a VED following the use of circular venous grafting. Three patients who used the VED had an increase in penile length of two inches, whereas the one patient who did not use the VED had a one-inch increase. Due to the low number of patients, it is difficult to draw any concrete conclusions other than that VEDs was well-tolerated (32).

In the LP.MacDonald studied 20 participants who received VED therapy observed a statistically significant improvement in curvature of $23 \pm 16^\circ$; all patients using VCD had a reduction in their penile curvature. The 33 untreated participants had a $3.6 \pm 12^\circ$ reduction in penile curvature. Only nine untreated participants had a reduction in penile curvature, 20 had no change, and four had increased penile curvature in their study (31). We came to the point that our patients continue to use the VED for more extended periods to gain more substantial improvement in a longer period of using this therapeutic method, as it was also observed in L P. MacDonald's study (31).

The evidence for PTT in the setting of PD shows comparable improvement in penile curvature to our results and others (33). IT seems VED may be a better option for

patients, as it is easier to use and more comfortable (34). it can help patients with PD and ED use the device for intercourse, although the VED price is more than a penile traction device (35).

Our curvature and narrowing data relied upon using a photograph taken at an office in four directions. (From write, left, above, and front while the patient is standing after inducing full rigid erection by VCD and applying constrictive ring at the base of the penis). This method is very accurate, as the three-dimensional curvature is projected on an actual image. We agree with Levine et al. that using a protractor could be a consistent and reliable technique (36). L P ManDanald A A.Raheem and our previous study reported results from only 53, 31 and 43 patients, respectively. Participants in these studies were selected if they opted not to pursue surgical management of PD, which may have biased our study and may include less severe cases of PD that were more amenable to conservative therapy. A randomized, single-blinded control trial would provide more reliable evidence for using VEDs in the setting of PD within or without acute phase. Data on the effectiveness of VED therapy for PD in acute phase is scarce in the literature (35, 36). More comprehensive studies are necessary to investigate further the variables involved in VED therapy, such as treatment course, duration treatment duration, the relation between duration of practice and severity of the curvature, and size and hardness of plaque and its modifications. It seems patients having DM should be studied in a more precise manner.

Conclusions

Treatment of patients with Peyronies disease in the acute phase by vacuum pumping with a newly shaped vacuum cylinder and massagor is safe and effective. The patients are directly getting involved in the treatments. This method enables the patient to have a better erection, recovers penile length, and significantly reduces plaque numbers, plaque size, and curvature of the penis. This study is the first one performed in Peyronies disease patients in the acute phase. For a diabetic patient, the effect of treatment is less than the general population. The pain was more in younger patients as a presenting symptom.

Authors' contributions

All authors contributed equally.

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Conflict of interest

The other authors declare no potential conflict of interest.

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Ethics statement

The ethics committee of Shahed Medical University approved the study procedures (Shahed.rec.1393.32).

Data availability

Data will be provided on request.

Abbreviations

DM	Diabetic mellitus
ED	Erectile dysfunction
PD	Peyronie's disease
PTT	Penile traction therapy
VCD	Vacuum constriction device

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