

# Role of extracorporeal shock wave therapy in management of Peyronie's disease: A preliminary report

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## Abstract

**Introduction:** Peyronie's Disease (PD) is a disease causing psycho social trauma to the patient. Multiple treatment options are available with variable results. Extra Corporeal Shock Wave Therapy (ESWT) is a new insight into the non invasive modality of management. It focuses on the mechanism of inducing angiogenesis in the penile cavernous tissue.

**Materials and Methods:** The aim of the study is to determine the role of ESWT in the management of PD. The objectives include demonstrating the improvement in mean International Index of Erectile Function Score (IIEFS), improvement in pain score by Visual Analogue Scale (VAS), change in cavernosal artery flow on colour penile Doppler, reduction in plaque size, and improvement in penile curvature degree after the therapy. 30 patients, between 25-65 years, who were non responders to conservative line of management, were treated with ESWT. The results were evaluated at baseline and 18-24 weeks after the therapy.

**Results:** ESWT significantly improves the cavernosal artery velocity, thereby supporting the theory of angiogenesis. ESWT improves all the domains of IIEF including Erectile Function, Sexual Desire, Sexual Satisfaction, Orgasm and Overall Satisfaction. There is a significant improvement in the pain and penile curvature, and reduction in the plaque size. No adverse effects have been recorded.

**Conclusion:** ESWT offers a safe, minimally invasive, OPD based option to the management of the patients of PD in the stable phase of the disease. Patients who do not respond to the conservative line of management can be really benefited by ESWT.

**Key Words:** Cavernosal artery velocity, extracorporeal shock wave therapy, International Index of Erectile Function Score, Peyronie's disease, plaque, visual analogue score

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## INTRODUCTION

Peyronie's Disease (PD) (also known as "induratio penis plastica"), is a connective tissue disorder involving the growth of fibrous plaques in the soft tissue of the penis.<sup>[1]</sup> Specifically, scar tissue

forms in the tunica albuginea causing pain, abnormal curvature, and erectile dysfunction (ED). PD is a psychologically and physically devastating disorder. Especially patients refrain from early presentation due to the social restraints, embarrassment,

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and lack of awareness. As the definitive pathophysiology of PD has not been completely elucidated, further basic research is required to make progress in the understanding of this enigmatic condition. Similarly, research on effective therapies is limited. As scientific breakthroughs in the understanding of the mechanisms of this disease process evolve, novel treatments for the many men suffering with PD are anticipated multiple treatment options are available ranging from medical,<sup>[2-4]</sup> intralesional therapies<sup>[5-7]</sup> to surgical plication and grafting techniques.<sup>[8-11]</sup> All the treatment options have variable results. Extracorporeal shock wave therapy (ESWT) is a new insight into the noninvasive modality of management. In this report, the use of ESWT has been evaluated as one of the modalities of treating PD. Being a noninvasive and safe modality, it offers a good treatment option to the patient. The role of ESWT and the results obtained with it in our study have been elicited.

## MATERIALS AND METHODS

### Aim

To determine the role of ESWT (Extra Corporeal Shockwave Therapy) in the management of Peyronie's Disease.

### Objectives

- To determine the improvement in mean IIEFS (International Index of Erectile Function Score) after the therapy
- To determine the change in cavernosal artery flow on colour penile Doppler after the therapy
- To study the role of ESWT for the painful erections and erectile dysfunction caused by Peyronie's Disease
- To determine the reduction in plaque size after the therapy.
- To correlate the improvement of mean VAS (Visual Analogue Scale) and pain relief after the therapy
- To determine the improvement in penile curvature degree after the therapy.

### Ethics

The study protocol was reviewed and approved by the scientific committee and ethics committee of our hospital. Each participant was given detailed information about the nature of the disease and the ESWT treatment and written informed consent was taken.

### Study design

The population selected for the research includes 30 men in the age group of 25-65 years, who presented on OPD basis with Peyronie's Disease from Feb 2013 to Feb 2015. These men were non responders to conservative line of management. The conservative measures included oral Potassium Amino Benzoate (POTABA), Tamoxifen, Colchicine, Vitamin E, local verapamil ointment and intra lesional verapamil and steroids. These patients had single or multiple plaques, demonstrated clinically and on penile Doppler. No patient had co morbidities

such as Diabetes Mellitus; Peripheral Vascular Disease or history of fracture penis, penile trauma or surgery. Sample size was selected according to the statistical formula considering the reported incidence of 1%.<sup>[12]</sup>

Data [Table 1] was collected on the basis of an interview in the form of history [Table 1a], IIEFS<sup>[13]</sup> and VAS<sup>[14]</sup> pre and post therapy [Table 1b]. Clinical examination, subjective assessment of the plaque [Table 2] and penile curvature [Table 3] was done. IIEFS and VAS were calculated at baseline and 24 weeks post therapy [Table 1b]. The therapy was instituted as an outdoor patient basis, and The patients were followed up at 24 weeks post therapy. Color Doppler of the penis was done pre- and post-therapy [Table 1a and b]:

- The presence of plaque: Pre- and post-therapy
- Character of plaque (calcified or fibrous)
- Site of plaque (dorsum, ventral, lateral)
- Size of the plaque (length and breadth of the plaque): Pre- and post-therapy
- Right and left cavernosal artery velocity distal to the plaque: Pre- and post-therapy.

With informed consent, the therapy was commenced on OPD basis as the predetermined schedule. The patients came for the further sessions as per the prescribed schedule. There were no dropouts, and the patients came for regular sessions and follow-up. No other therapy for PD or ED was continued during this period. Phosphodiesterase 5 inhibitors were discontinued about 3 weeks before the ESWT. The patients continued to have their regular lifestyle, sexual status, and other routine medications.

Shockwaves are delivered by a special probe that is attached to a compact electro-hydraulic unit with a focused shockwave source (Omnispec ED1000, Medispec Ltd., Germantown, MD, USA) [Figure 1].<sup>[15-17]</sup> We apply a standard commercial gel normally



**Figure 1:** Extracorporeal shock wave therapy machine

**Table 1: Clinical and doppler characteristics of the patients**

	Pre (n=30)		Post (n=30)		Wilcoxon Z value	P
	Mean	SD	Mean	SD		
Pre- and post-therapy IIEF score						
Total IIEF score	33.37	5.436	43.1	6.9996	4.71	<0.0001
Domain wise improvement in IIEFS posttherapy						
Erectile function	15.73	1.982	19.8	2.398	4.39	<0.0001
Sexual satisfaction	5.5	1.925	7.17	2.036	3.64	<0.0001
Orgasmic function	4.23	1.569	5.17	1.262	2.79	<0.005
Sexual desire	3.87	1.332	5.3	1.418	3.94	<0.0001
Overall satisfaction	4.03	1.474	5.67	1.539	4.34	<0.0001
Improvement in cavernosal artery velocity on colour penile doppler posttherapy						
Right	7.59	2.608	9.4	4.979	2.62	<0.05
Left	7.79	2.631	9.64	4.015	4.21	<0.0001
Comparison of pre- and post-therapy VAS score in study group						
VAS score	3.03	0.669	2.77	0.626	2.53	<0.05
Change in the plaque size (cm) posttherapy on Doppler						
Length	1.05	0.589	0.76	0.619	5.38	<0.0001
Breadth	0.86	0.536	0.58	0.471	7.01	<0.0001
Pretherapy versus posttherapy subjective assessment of plaque						
Plaque score	1.17	1.053	0.67	0.711	3.42	<0.001
Pre- and post-therapy subjective assessment of curvature						
Curvature score	0.5	0.682	0.3	0.535	2.45	<0.05

**Table 1a: Pre therapy**

Age	Painful erection	Curvature during erection	Duration of symptoms (months)	Doppler character of plaque	Site of plaque
32	1	1	12	Fibrous	Dorsum
52	1	1	14	Calcified	Dorsum
50	1	0	18	Calcified	Lateral
43	1	0	18	Calcified	Ventrum
46	1	1	16	Calcified	Dorsum
50	1	1	16	Calcified	Lateral
45	1	0	14	Calcified	Lateral
32	1	1	16	Calcified	Dorsum
65	1	0	36	Fibrous	Lateral
50	1	0	18	Fibrous	Dorsum
52	1	1	28	Calcified	Dorsum
43	0	0	26	Calcified	Ventrum
44	0	0	28	Fibrous	Dorsum
46	1	0	38	Calcified	Dorsum
34	1	0	30	Calcified	Ventrum
45	1	1	14	Calcified	Dorsum
56	1	1	36	Calcified	Lateral
36	1	0	26	Fibrous	Lateral
35	1	0	16	Fibrous	Dorsum
44	1	0	24	Calcified	Lateral
53	1	1	12	Calcified	Dorsum
52	1	0	16	Calcified	Lateral
50	1	0	15	Calcified	Ventrum
30	1	0	28	Fibrous	Dorsum
54	1	0	30	Calcified	Dorsum
51	1	1	15	Fibrous	Lateral
52	1	1	30	Calcified	Dorsum
52	1	0	28	Calcified	Dorsum
55	1	1	15	Fibrous	Lateral
50	1	0	16	Calcified	Ventrum

used for sonography without any local anesthetic effect on the penis. The penis is manually stretched; the shockwaves are delivered to the plaque, proximal to the plaque, and distal to the plaque.

The session comprises of 3 sets of 300 shock waves to the plaque (900 total), 300 shock waves each proximal and distal to the plaque. Hence, the total shock waves delivered are 1500 per session. The duration of each low-intensity ESWT (LI-ESWT) session is about 20 min. The shock waves are delivered at an energy density of 0.09 mJ/mm<sup>2</sup> and a frequency of 120/min. The volume of penile tissue that is exposed to shock waves at each site was cylindrical (diameter: 18 mm; height: 100 mm). ESWT consists of 9 weekly treatment of 20 min duration at the intensity of I. The results were evaluated at baseline and 18–24 weeks after the therapy [Figure 2].<sup>[15-17]</sup>

### Statistics

Data Analysis was done under the guidance of our statistics expert, using SPSS version 17 (Statistical Package for Social Science. SPSS Inc. Released 2008. SPSS Statistics for Windows, Version 17.0. (SPSS Inc., Chicago, IL). Available from <http://www-01.ibm.com/support/docview.wss?uid=swg21476197>. Z-test, unpaired t-test, Man–Whitney and Wilcoxon Z-tests were used for the analysis. Q-Q plot is used to evaluate the normality of distribution. Values on total IIEFS, sexual satisfaction (SS), orgasmic function, sexual desire, and overall satisfaction (OD) are shown as mean and standard deviations (SDs) due to normal distribution; the rest of the values are median and inter-quartile range due to nonnormal distribution. P values by Wilcoxon's signed rank test. P < 0.05 is considered to be statistically significant [Tables 4 and 5].

### RESULTS

The most common age group of presentation of PD is males above 50 years of age. 16 out of 30 patients were more than

**Table 1b: Post therapy**

Total IIEFS pre	Total IIEFS post	Change in right cavernosal artery velocity	Change in left cavernosal artery velocity	Change in visual analogue score	Change in length pre-post	Change in breadth pre- post	Change in curvature
29	43	3.3	0.6	1	0.4	0.4	0
27	33	2.2	0.2	0	0.5	0.4	1
30	44	3.5	0.5	0	0.5	0.5	0
30	48	0.6	2.9	0	0.5	0.5	0
31	44	2.5	1.4	1	0.5	0.4	0
41	43	3	2.7	0	0.2	0.2	0
37	50	0.7	1.2	0	0.3	0.4	0
41	52	1.2	2	0	0.3	0.4	0
39	45	0.8	1.7	0	0.5	0.4	0
40	47	1.2	2.9	0	0.2	0.2	0
32	47	17	13	1	0.3	0.3	1
38	54	0	0.3	0	0.4	0.5	0
39	49	4.3	2.6	0	0.5	0.5	0
41	54	2.1	2	0	0	0	0
29	37	2.6	3.1	0	0	0	0
30	44	2.5	1.6	1	0.3	0.3	1
27	36	2.5	2.7	0	0.3	0.3	1
27	36	3	3.2	1	0.6	0	0
28	42	2.5	3	1	0	0	0
28	44	1	1.2	1	0.8	0.8	0
27	33	1.5	1.6	0	0.1	0.2	1
33	40	-0.3	-0.6	-1	0	0	0
34	37	0.2	0.3	0	0.4	0.2	0
29	30	0.4	-0.2	0	0	0	0
29	31	0.4	0.6	0	0	0	0
30	45	-0.8	-0.6	1	0.5	0.5	0
34	36	1	1	0	0.4	0.4	0
40	52	3.6	1.4	1	0.5	0.5	0
41	54	3.7	3	0	0.6	0.2	0
43	43	0	0.2	0	0	0	0

IIEFS: International Index of Erectile Function Score

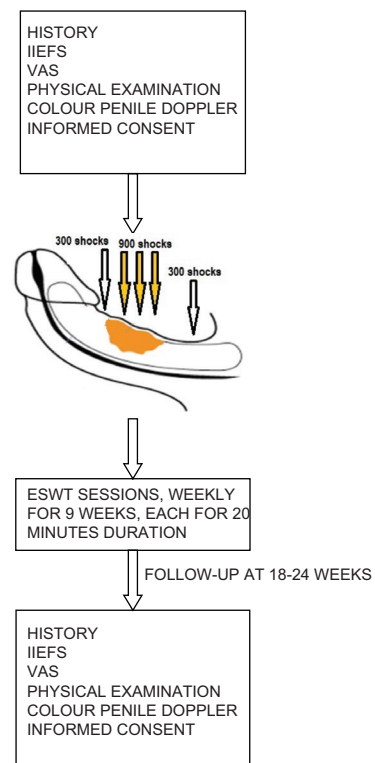
**Table 2: Grading for the subjective assessment of the plaque on clinical examination, pre- and post-therapy**

Score	Subjective assessment of plaque
0	Not palpable
1	Palpable, soft in consistency
2	Palpable, moderately hard consistency
3	Palpable, hard in consistency

**Table 3: Grading for the subjective assessment of the penile curvature during erection pre- and post-therapy**

Score	Subjective assessment of penile curvature during erection
0	No curvature
1	Mild curvature
2	Significant curvature

50 years of age (53%) while males between 40 and 50 years are the 2<sup>nd</sup> most common (27%). 28 patients (93%) presented with pain during erection (93%), while penile curvature is found in 12 patients (40%). Penile plaque is found in all the patients. Dorsal plaques are present in 15 patients (50%), being the most common site followed by lateral (33%) and ventral plaques (17%). Calcified plaques are present in 21 patients (70%), thus being more common than fibrous plaques (30%) on color Doppler. Seventeen patients (57%) presented at around 12 months to 23 months, followed by 10 patients between 24 and 36 months (33%). This correlates with the phase of stabilization of the disease.



**Figure 2: Management protocol for the extracorporeal shock wave therapy for Peyronie's disease patients**

**Table 4: The comparison of pre- and post-operative scores of various parameters studied**

	Preoperative (n=30)		Postoperative (n=30)		Wilcoxon's Z	P
	Mean/median	SD/IQR	Mean/median	SD/IQR		
Pre- and post-therapy IIEF score						
Total IIEF score	33.37	5.44	43.1	6.99	4.71	<0.001
Domain wise improvement in IIEFS posttherapy						
Erectile function	16.00	14.75-17.25	20.00	18.00-21.25	4.39	<0.001
Sexual satisfaction	5.5	1.93	7.17	2.04	3.64	<0.001
Orgasmic function	4.23	1.57	5.17	1.26	2.79	<0.01
Sexual desire	3.87	1.33	5.3	1.42	3.94	<0.001
Overall satisfaction	4.03	1.47	5.67	1.54	4.34	<0.001
Improvement in cavernosal artery velocity on colour penile Doppler posttherapy						
Right	7.25	5.93-9.10	9.10	7.00-10.33	3.79	<0.001
Left	7.60	6.23-9.05	9.10	7.53-10.85	4.39	<0.001
Comparison of pre- and post-therapy VAS score in study group						
VAS score	3.00	3.00-3.25	3.00	2.00-3.00	2.53	<0.05
Change in the plaque size (cm) posttherapy on doppler						
Length	0.95	0.50-1.40	0.65	0.30-1.23	3.55	<0.001
Breadth	0.65	0.50-1.20	0.55	0.18-0.83	4.14	<0.001
Pretherapy versus posttherapy subjective assessment of plaque						
Plaque score	1.00	0.00-2.00	1.00	0.00-1.00	3.42	<0.001
Pre- and post-therapy subjective assessment of curvature						
Curvature score	0.00	0.00-1.00	0.00	0.00-1.00	2.45	<0.05

Values on total IIEF score, sexual satisfaction, orgasmic function, sexual desire and overall Satisfaction are shown as mean  $\pm$  SDs due to normal distribution; the rest of the values are median and IQR due to nonnormal distribution. *P* values by Wilcoxon's signed rank test. *P* < 0.05 is considered to be statistically significant. VAS: Visual analogue score, IIEFS: International Index of Erectile Function Score, IQR: Interquartile range, SD: Standard deviation

**Table 5: The distribution of assessment of normality of pre- and post-operative difference of various parameters studied**

	Shapiro Wilk's value	P	Normality
Pre- and post- therapy IIEF score			
Total IIEF score	0.933	0.059	Accepted
Domain wise improvement in IIEFS posttherapy			
Erectile function	0.912	0.016	Rejected
Sexual satisfaction	0.956	0.245	Accepted
Orgasmic function	0.945	0.127	Accepted
Sexual desire	0.935	0.067	Accepted
Overall satisfaction	0.939	0.085	Accepted
Improvement in cavernosal artery velocity on colour penile Doppler posttherapy			
Right	0.689	0.001	Rejected
Left	0.640	0.001	Rejected
Comparison of pre- and post-therapy VAS score in study group			
VAS score	0.687	0.001	Rejected
Change in the plaque size (cm) posttherapy on Doppler			
Length	0.879	0.003	Rejected
Breadth	0.894	0.006	Rejected
Pretherapy versus posttherapy subjective assessment of plaque			
Plaque score	0.718	0.001	Rejected
Pre- and post-therapy subjective assessment of curvature			
Curvature score	0.492	0.001	Rejected

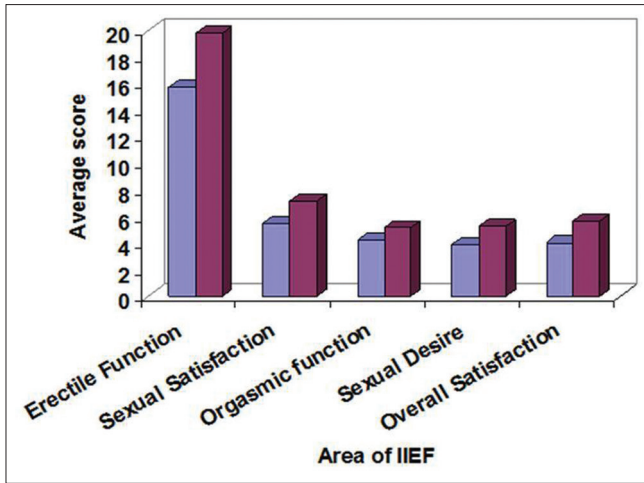
IIEFS: International Index of Erectile Function Score, VAS: Visual analogue score

ESWT has been utilized as a treatment modality in the patients who have previously not responded to the conservative line of management. It is particularly used during the

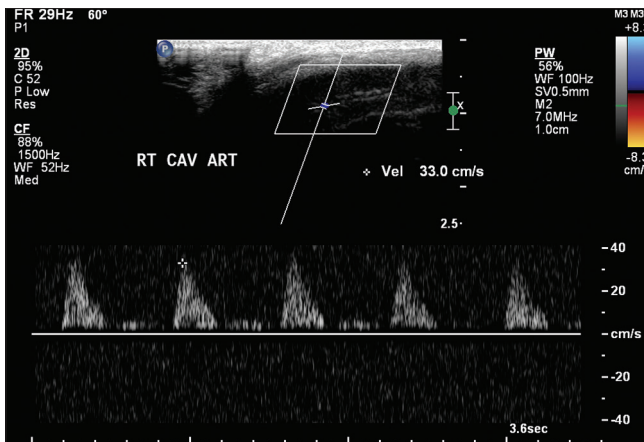
stable phase of the disease. ESWT improves the erectile function (EF) [Table 4] and improves all the domains of IIEF: EF, sexual desire, SS, orgasm, and OD (*P* < 0.0001) [Figure 3]. The use of LI-ESWT significantly improves the postplaque cavernosal artery velocity (*P* < 0.05) [Figures 4-7]. The improvement in IIEF correlates with the improvement in the cavernosal artery supporting the mechanism of ESWT promoting angiogenesis [Table 4]. The improvement in IIEFS correlates with the improvement in VAS supporting the overall symptomatic improvement (*P* < 0.01). ESWT improves the pain in these patients (*P* < 0.05) [Table 4]. ESWT reduces the plaque size, demonstrable clinically and by penile Doppler (*P* < 0.0001) [Table 4, Figures 8 and 9]. There is a significant reduction in the curvature of penis during erection posttherapy (*P* < 0.05) [Table 4]. None of the patients have reported any adverse effects following ESWT. None of the patients in our study reported any allergic reaction to the gel used for ESWT. No complications have been recorded in our study as well as the studies available in the literature.<sup>[15-17]</sup>

## DISCUSSION

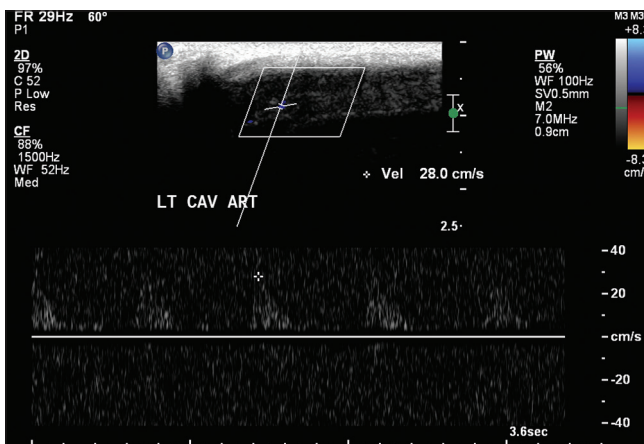
PD is a disease affecting the adult-aged men. It is a psychosocial disease as it affects the sexual life of the patient. The symptomatic incidence is 1%; the prevalence is 3.2–8.9%.<sup>[1]</sup> However, the true prevalence of PD may be even higher on account of patient embarrassment and lack of awareness about the disease among the medical fraternity. Similarly, less research has been done in the understanding of the disease,



**Figure 3:** Domain wise comparison of International Index of Erectile Function Score pre- and post-extracorporeal shock wave therapy

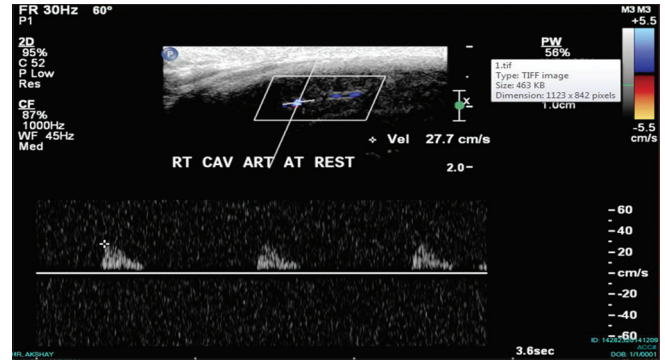


**Figure 5:** Right cavernosal artery velocity postextracorporeal shock wave therapy

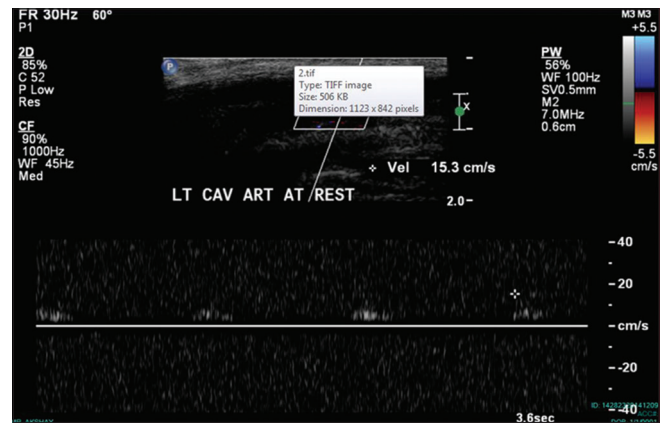


**Figure 7:** Left cavernosal artery velocity postextracorporeal shock wave therapy

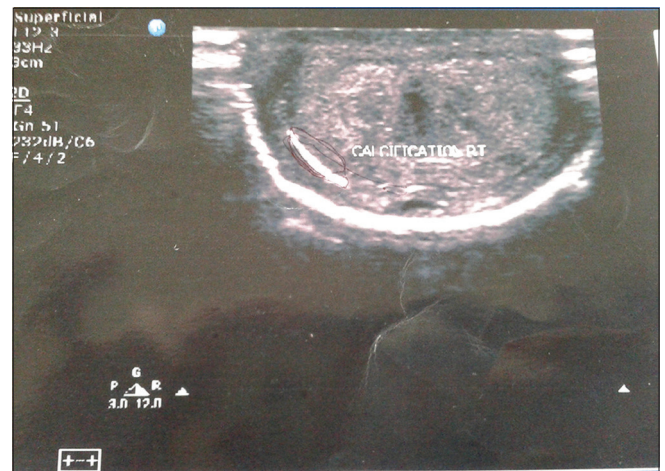
the pathophysiology of the disease and the various modalities to diagnose it.



**Figure 4:** Right cavernosal artery velocity preextracorporeal shock wave therapy

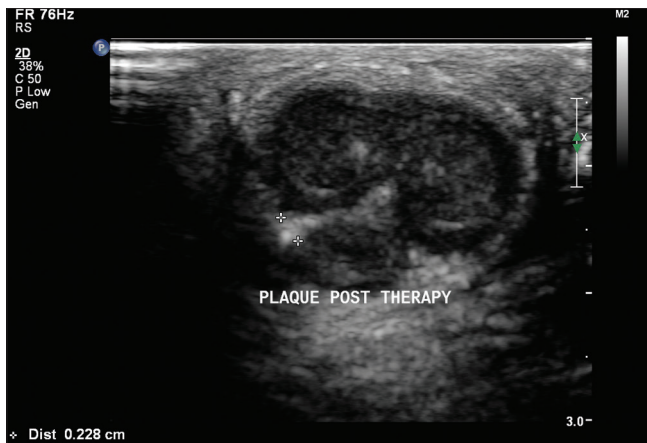


**Figure 6:** Left cavernosal artery velocity preextracorporeal shock wave therapy



**Figure 8:** Plaque size preextracorporeal shock wave therapy

A myriad of treatment options is available ranging from noninvasive medical therapies,<sup>[2-4]</sup> intralésional therapies<sup>[5-7]</sup> to surgery.<sup>[8-11]</sup> All the therapies have shown inconsistent results in various studies with respect to improvement in many parameters. Being a sexual disorder, the patients tend to be inclined to selecting noninvasive therapies. Therefore, the research pertaining to this subject is dominated by the quest



**Figure 9:** Plaque size postextracorporeal shock wave therapy

for searching new and better noninvasive therapies which could provide long-lasting, consistent, and better results with minimal adverse effects.

ESWT has been in vogue since many years in the field of urology, mainly for the treatment of renal stones. Continued research into this modality has led researchers to use it in the field of cardiology, musculoskeletal disorders and diabetic foot ulcers.<sup>[18-24]</sup> The basic mechanism purported for the use of ESWT is its potential to increase angiogenesis. At low energy density ( $0.03 \text{ mJ/mm}^2$ ), ESW, originally developed for clinical lithotripsy, have successfully been used for the anti-inflammatory treatment of soft tissues. Since nitric oxide (NO) plays a critical role in inflammation, it was hypothesized for ESW to increase NO production in cells.<sup>[25,26]</sup>

The most commonly affected are the adult males with an age of more than 50 years followed by patients aged 41–49 years. Mulhall *et al.* reported in the literature review of more than 1500 patients with PD, the mean reported age at disease presentation was 53.5 years. Thus, it seems that PD is a disease of middle-aged men.<sup>[27]</sup>

The most common symptom is pain during erection. Curvature of the penis during erection has been reported in few patients.<sup>[28]</sup> These are the results similar to the studies done by Williams.<sup>[28]</sup>

The most common duration of presentation is at around 12–23 months (56%) followed by 1–2 years (33%). This correlates with the time when the disease progresses from acute phase to stable phase. Development of plaques signifies the cessation of acute inflammatory stage of the disease. The ESWT has been instituted only in the chronic phase of the disease.<sup>[28]</sup>

On color penile Doppler, the most common character of plaques found was calcified as compared to the fibrous variety.

The most common site of the plaque was dorsum of the penis, followed by the lateral and ventral side of the penis. Byström<sup>[29]</sup> reported plaques are typically located on the dorsal or lateral aspect of the penis, causing an upward or lateral defection during erection. These results are similar to the various Doppler studies available in the literature.<sup>[30-33]</sup>

Pre-therapy, the mean IIEFS was 33.7 which improved to 43.10 posttherapy, calculated at 24 weeks. This was a statistically significant improvement in the IIEFS ( $P < 0.0001$ ) [Table 4]. Vardi *et al.*<sup>[15]</sup> reported in his study significant increases in IIEF-ED domain scores at 1 month follow-up. Palmieri *et al.*<sup>[17]</sup> also reported that at follow-up, mean VAS score, mean IIEF-5 score ameliorated significantly in patients receiving ESWT.

The improvement in IIEFS was marked by an overall improvement in all the domains of IIEF: The mean EF score, the mean SS score, the mean OR score, the mean SD score and the mean OS score. Improvement in all the domains was statistically significant [Table 4]. This also correlated with the results in studies done by Vardi *et al.*,<sup>[15]</sup> Gruenwald *et al.*,<sup>[16]</sup> Palmieri *et al.*<sup>[17]</sup>

The mean right cavernosal artery velocity improved from 7.59 cm/s (pretherapy) to 9.4 cm/s (posttherapy). The mean left cavernosal artery velocity improved from 7.79 cm/s (pretherapy) to 9.64 cm/s (posttherapy). This is a statistically significant improvement in the right cavernosal artery velocity ( $P < 0.05$ ) and left cavernosal artery velocity ( $<0.0001$ ) on color Doppler posttherapy [Table 4]. Thus, our study on the use of LI-ESWT proves improved penile hemodynamics posttherapy. This correlates with the improvement in penile hemodynamics obtained in the studies by Vardi *et al.*<sup>[15]</sup> and Gruenwald *et al.*<sup>[16]</sup> Vardi concluded in his study that LI-ESWT improved penile hemodynamics and was positively correlated with improvements in IIEF EF. This supports the mechanism of ESWT promoting angiogenesis.

The mean VAS pretherapy was 3.03 which improved to 2.77 posttherapy. This shows statistically significant ( $P < 0.05$ ) improvement in the pain score of the patients posttherapy [Table 4]. Palmieri<sup>[17]</sup> and associates in their study evaluated pain during erection (VAS). At follow-up, mean VAS score and mean the quality of life (QoL) score ameliorated significantly in patients receiving ESWT. The authors concluded that ESWT represents a valuable therapy modality for PD patients, leads to pain resolution, Ameliorates erectile function, and QoL.<sup>[16]</sup> This also correlated with the results in studies done by Vardi *et al.*,<sup>[15]</sup> Gruenwald *et al.*,<sup>[16]</sup> Palmieri *et al.*<sup>[17]</sup> There is a statistically significant correlation between the improvement in VAS and improvement in IIEFS

posttherapy ( $P < 0.01$ ). This also correlated with the results in studies done by Vardi *et al.*<sup>[15]</sup> and Palmieri *et al.*<sup>[17]</sup>

Pretherapy, the mean plaque length was 1.05 cm and plaque breadth was 0.86 cm. This reduced to 0.76 cm in length and 0.58 cm in breadth on color penile Doppler done at 24 weeks posttherapy. The reduction in the size of the plaque (length and breadth post) therapy was statistically significant for both length and breadth ( $P < 0.0001$ ) [Table 4]. Palmieri *et al.*<sup>[17]</sup> and associates in their study evaluated that mean plaque size and mean curvature degree were significantly higher in the placebo group when compared with both baseline and ESWT values. These results may suggest that ESWT has a potential protective effect on disease progression. The authors concluded that ESWT represents a valuable therapy modality for PD patients, leads to pain resolution, ameliorates erectile function, and QoL. This also correlates with the reduction in plaque size in the studies done by Vardi *et al.*,<sup>[15]</sup> Gruenwald *et al.*,<sup>[16]</sup> Palmieri *et al.*<sup>[17]</sup>

Pretherapy, the mean subjective assessment of the plaque was 1.17 ranging from I (palpable, soft) to 2 (palpable, moderately hard). Posttherapy, at 24 weeks, the mean subjective assessment improved to 0.67, ranging between 0 (not palpable) and I (palpable, soft). Thus, the study shows significant improvement in the subjective assessment of the plaque posttherapy ( $P < 0.001$ ) [Table 4].

The study shows mean subjective assessment of the curvature of penis in the erect state, improving from 0.5 (pretherapy) to 0.3 (posttherapy). This is a significant improvement in the subjective assessment of the penile curvature pre- and post-therapy ( $P < 0.05$ ) [Table 4].

None of the patients have reported any adverse effects following ESWT. None of the patients in our study reported any allergic reaction to the gel used for ESWT. No complications have been recorded in our study as well as the studies available in the literature.

## CONCLUSION

ESWT is a new modality in the horizon of men's health and a new armamentarium for the andro-urologist. It focuses on the mechanism of inducing angiogenesis in the penile cavernous tissue. ESWT has been used successfully in the musculoskeletal, cardiac diseases, and diabetic foot ulcers. ESWT significantly improves penile hemodynamics in the patients of PD, thereby supporting the theory of angiogenesis. ESWT improves all the domains of IIEF including erectile function, sexual desire, SS, orgasm, and OD. The improvement in painful erections is significant, which is the most common complaint of these patients. There is a significant improvement in the curvature

as well. The reduction in the plaque size improved subjective assessment of the plaque and curvature all correlate with the improved sexual life of these patients. No adverse effects have been recorded in the study post-ESWT, thereby implying it to be a safe modality. Thus, ESWT offers a good option to the management of the patients of PD in the stable phase of the disease. Patients who do not respond to the conservative line of management can be really benefited by ESWT. Being a safe and OPD modality, it can be really an embarking option for the patients of PD before resorting to surgery.

## Limitations

This is a single institute nonrandomized clinical trial to evaluate the usefulness of ESWT in the management of PD. The availability of the LI-ESWT machine especially for the PD patients and the necessary expertise made the study feasible. However, more randomized controlled trials would be of worth before making ESWT a valuable recommendation. A larger sample size, multi-institutional case controlled double blind study and comparison with other noninvasive modalities of management would supplement the essential information. More research into the LI-ESWT machine, better shock delivery, and applicability for more cases of organic ED would be desirable. Cost effectiveness and wider availability like the ESWT machine for renal stones can be a blessing for the PD patients. A longer follow-up period would also serve to gain a better understanding of the potential limitations of the therapy. Thus, this study aims to be a small stepping stone toward research in the field of urology.

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## Conflicts of interest

There are no conflicts of interest.

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