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ORIGINAL ARTICLE

Erectile Dysfunction

Low-intensity extracorporeal shock wave therapy for Peyronie's disease: a single-center experience

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The aim of this article is to assess the outcomes of a low-intensity extracorporeal shock wave therapy (LiESWT) protocol for the treatment of Peyronie's disease (PD). Patients treated for PD were prospectively recorded, and data were retrospectively reviewed. Age, characteristics of fibrous plaques, concomitant treatments, International Index of Erectile Function (IIEF-5), Lue score, and pain score on Likert scale were collected. Patients in acute phase of PD and an angulation of <40° were included. The protocol consisted of 6 weekly sessions of 4000 pulses each, applied from different directions, with a maximal power of 20 W and 8 Hz frequency. We included 39 patients (median age: 56.8 years, interquartile range [IQR]: 35.8–62.2 years). The median number of sessions received per patient was 7.2. After treatment, the median Lue score decreased from 6.8 initially to 3.3 ($P = 0.003$), the median Likert pain score dropped from 1.8 to 0.7 ($P = 0.004$), the median plaque size was reduced from 2 cm to 1.2 cm ($P = 0.08$), and the median penile curvature diminished from 31° to 17° ($P = 0.07$). On univariate and multivariate analysis, the only predictors of success were younger age (odds ratio [OR] = 0.95, $P = 0.03$ and OR = 0.91, $P = 0.04$, respectively) and concomitant use of phosphodiesterase-5 inhibitors (PDE5i; OR = 0.92, $P = 0.02$ and OR = 0.93, $P = 0.01$, respectively). LiESWT had a favorable impact on Lue score and notably penile pain, curvature, plaque size, and erectile function in patients treated for PD during the early inflammatory phase, with no side effects. Younger age and concomitant use of PDE5i were the only success predictors.

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Keywords: erectile dysfunction; extracorporeal shock wave therapy; Peyronie's disease; piezoelectric waves

INTRODUCTION

Peyronie's disease (PD) is characterized by an initial acute painful inflammatory phase followed by a chronic stage where the plaque stabilizes. In one report, a spontaneous improvement was observed in 12% of patients, stabilization in 67%, and worsening of symptoms in 21%.[1,2] Patients usually seek medical care for pain during erection or penile deformity. The prevalence rates are unclear and vary between 0.39% and 22.5%.[3] PD can occur at any age, but most commonly, patients are in their fifth decade of life.[2]

Surgical treatment is reserved for selected cases of disabling disease, due to the perioperative risks and potential disadvantages of this procedure, including penile shortening, changes in penile sensation, and *de novo* erectile dysfunction.[1,2] Most patients prefer an initial trial of noninvasive treatment.[3,4] Oral and topical medications, traction and vacuum devices, extracorporeal shock wave therapy (ESWT), electromotive drugs, radiation therapy, and intralesional injections have been used with variable results.[3]

ESWT is a minimally invasive approach that has gained popularity due to its regenerative potential on several organs.[4,5] Mechanical stimulation of cells by the waves induces a cavitation effect with the generation of nitric oxide and vascular endothelial growth factor with subsequent neovascularization.[6,7] ESWT has shown promising results in penile rehabilitation after radical prostatectomy and vasculogenic erectile dysfunction and converted phosphodiesterase-5 inhibitor (PDE5i) nonresponders to responders. ESWT also had a neuroprotective effect and led to functional recovery in animal models.[8] However, conflicting results have been obtained after its use in the treatment of PD.[9,10] Previous studies have described variable improvement in pain, erectile function, and quality of life, whereas others have failed to show any benefit of ESWT.[2]

Our purpose was to assess the outcomes of low-intensity extracorporeal shock wave therapy (LiESWT) in the treatment of PD.

PATIENTS AND METHODS

Study design

Data were collected prospectively for all PD patients treated by LiESWT between January 2016 and January 2018 at APHP - Sorbonne University, Pitié Salpêtrière, Academic Urology Unit in Paris, France. After we obtained the institutional review board approval (No. 11052017), data analysis was performed retrospectively. The following data were recorded: age; disease duration; previous treatments; location, nature, number, and size of fibrous plaques; angulation; erectile dysfunction; and pain. Erectile dysfunction was evaluated using the simplified International Index of Erectile Function (IIEF-5), as shown in **Table 1**.[11] A Lue score was assigned to each patient before starting LiESWT. This score assesses PD severity on a scale of 0 to 15, based

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Table 1: Simplified International Index of Erectile Function scale[11]

Point	*How do you rate your confidence that you could get and keep an erection?*	*When you had erections with sexual stimulation, how often were your erections hard enough for penetration?*	*During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?*	*During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?*	*When you attempted sexual intercourse, how often was it satisfactory for you?*
1	Very low	Almost never/never	Almost never/never	Extremely difficult	Almost never/never
2	Low	A few times (much less than half the time)	A few times (much less than half the time)	Very difficult	A few times (much less than half the time)
3	Moderate	Sometimes (about half the time)	Sometimes (about half the time)	Difficult	Sometimes (about half the time)
4	High	Most times (much more than half the time)	Most times (much more than half the time)	Slightly difficult	Most times (much more than half the time)
5	Very high	Almost always/always	Almost always/always	Not difficult	Almost always/always

on plaque size, degree of penile curvature, and pain (**Table 2**).[12] The same physician assessed the deformity by angle determination of the erect penis taken after extracavernous vasoactive injection at the first consultation, and the assessment of the evolution was also done after administration of the same vasoactive substance. A goniometer was used before and after the treatment for the most accurate tracking of changes. Photographs of the erect penis were also taken before and at the end of the treatment. Plaque size was measured using ultrasound. The plaque was marked with a pen before every session and at the end of treatment. Pain intensity was evaluated on a 6-point Likert scale (**Table 3**), ranging from 0 (no pain) to 5 (excruciating pain).[13]

All patients in the acute phase had symptom onset <18 months before treatment. They were sexually active with penile pain, or a recent change in curvature and a palpable plaque. Patients with chronic PD and with a penile curvature of >40° were excluded. The characteristics of the patients are summarized in **Table 2**.

Treatment protocol

Written informed consent was obtained from the patients before the initiation of the new treatment protocol. This LiESWT treatment protocol was approved by the Research Ethics Committee of the French National Association of Urology in Paris, France. Eligible patients received six weekly sessions, of 8.3 min duration each, without anesthesia, in an outpatient setting. Some patients received follow-up sessions once a month. Patients were placed in dorsal lithotomy. The penis was stretched, and a commercial gel (LithoClear®, Next Medical Products Company, NJ, Chicago, USA) was applied to the genital area to ensure good shock wave transmission. The impulses were directed onto the penile shaft and crura bilaterally. In every session, patients received a total of 4000 shocks. Waves were delivered with an incremental level of energy from 0.064 mJ mm^{-2} to 0.160 mJ mm^{-2} and a frequency of 480 pulses per min (ppm; 8 Hz). The full treatment consisted of a minimum of 24 000 impulses over 6 weeks. Further sessions were added at the physician's discretion, and upon some patients' insisting request, these patients were satisfied from the evolution and wanted to expand their treatment duration seeking more improvement. Patients were monitored for local pain, hematoma, neurapraxia, and other adverse events.

Device characteristics

The Wolf Piezowave 2 (ELvation Medical, Kieselbronn, Germany) device was used.[14] This device, like some other devices, can offer full organ coverage in a shorter time interval and treatment parameters that are superior to other devices. The device uses piezoelectric elements for shock wave generation and linear double-layer technology for shock wave application to the target area. In linear shock wave therapy, the treatment area is 46 mm long and 4 mm wide, with a penetration depth of 5–20 mm. Shocks were delivered at a maximum rate of 480 ppm (8 Hz).

Table 2: Lue score[12]

Point	*Pain*	*Deformity (°)*	*Plaque size (cm)*
0	Absent	0	0
1	Slight during coitus	15	1
2	Slight during erection	30	2
3	Moderate	45	3
4	Severe	60	4
5	Constant - even in flaccid penis	>70	5

Table 3: Present pain intensity based on 6-point Likert scale[13]

Point	*Description*
0	No pain
1	Mild
2	Discomforting
3	Distressing
4	Horrible
5	Excruciating

Follow-up

Treatment was stopped after six sessions. Four weeks after the last session, we have assessed penile pain, deformity, and plaque size. Each patient was assigned a new Lue score and IIEF-5 score. The primary end point was the change in Lue score. Secondary end points were the change in erectile dysfunction (assessed by the IIEF-5) and side effects.

Statistical analyses

Continuous variables were described as medians and interquartile ranges (IQR: Q1–Q3) and nominal variables as numbers and percentages. Comparisons between groups were performed using the Chi-square test or Fisher's exact test for discrete variables and Mann–Whitney U test for continuous variables. Univariate and multivariate logistic regression analyses were performed to evaluate predictive factors of success.

Statistical analyses were performed using JMP, version 10.0 (SAS Institute Inc., Cary, NC, USA). All tests were two sided, with $P < 0.05$ considered statistically significant.

RESULTS

Study population

A total of 39 men were included (median age: 56.8 years, IQR: 35.8–62.2 years). Two-thirds of patients (64.1%) were taking PDE5i for more than one year before and during LiESWT treatment;

of these patients, twelve (30.8%) were taking tadalafil. All patients underwent at least six LiESWT sessions. The maximum number of sessions for a single patient was 18, but the median number of sessions per patient was 7.2. The median follow-up was 18 months. The median number of plaques per patient was 1.6 (IQR: 1.2–2.2), and the median plaque size was 20 (IQR: 14.9–23.2) mm. Plaques were nodular in 19 (48.7%) patients and calcified in 17 (43.6%) patients. Three patients (7.7%) had both plaque types. The major plaque was dorsal in 23 (59.0%) patients, ventral in four (10.3%), and lateral in 12 (30.8%). Mean pretreatment angulation was 31° (IQR: 19.9°–36.3°). The characteristics of the study population are summarized in **Table 4**.

Outcomes

Median Lue score decreased from 6.8 to 3.3 after treatment ($P = 0.003$). Median pain on the Likert scale decreased from 1.8 to 0.7 after LiESWT ($P = 0.004$). Thirty-two patients had pain reduction of at least 0.5 points on the Likert scale. Mean plaque size decreased from 2 cm to 1.2 cm ($P = 0.08$) and median penile curvature decreased from 31° to 17° after treatment ($P = 0.07$). No complications were observed. After completion of six sessions, total recovery was observed in nine (23.1%) patients. Erectile dysfunction improved in 17 (43.6%) patients, with an increase in IIEF-5 score from 14 to 21. Seven (17.9%) patients had a complete failure of LiESWT. These patients were switched to other alternative therapies. The outcomes are summarized in **Table 5**.

Table 4: Demographic and clinical characteristics of the study population

Characteristic	*Total population (n=39)*
Age (year), median (IQR)	56.8 (35.8–62.2)
Previous medical history, *n* (%)	
Diabetes	4 (10.3)
Hypertension	2 (5.1)
Coronary artery disease	1 (2.6)
Cerebrovascular disease	1 (2.6)
Number of plaques/patient, median (IQR)	1.6 (1.2–2.2)
Plaque size (mm), median (IQR)	20 (14.9–23.2)
Type of plaque, *n* (%)	
Nodular	19 (48.7)
Calcified	17 (43.6)
Mixed	3 (7.7)
Location of major plaque, *n* (%)	
Dorsal	23 (59.0)
Ventral	4 (10.3)
Lateral	12 (30.8)
Angulation (°), median (IQR)	31 (19.9–36.3)
Possible penetration, *n* (%)	27 (69.2)
Pain (Likert scale), *n* (%)	
0	9 (23.1)
1	21 (53.8)
2	6 (15.4)
3	3 (7.7)
Previous treatments, *n* (%)	
Monotherapy	7 (17.9)
Multiple therapies	32 (82.1)
Vitamin E	24 (61.5)
Herbal supplements	17 (43.6)
Tadalafil 5 mg daily	6 (15.4)
Tadalafil 20 mg daily	6 (15.4)
Sildenafil 100 mg daily	18 (46.2)
Vardenafil 10 mg daily	8 (20.5)
Avanafil 100 mg daily	1 (2.5)
Verapamil	10 (25.6)
Alprostadil	3 (7.7)
CCH	10 (25.6)
Vacuum	2 (5.1)
Median number of sessions per patient	7.2

CCH: collagenase clostridium histolyticum; IQR: interquartile range, Q1–Q3

Predictors of success

Patient age of less than 40 years was found to be a predictor of success in univariate (odds ratio [OR] = 0.95, $P = 0.03$) and multivariate (OR = 0.91, $P = 0.04$) analysis. Concomitant use of PDE5i was also a predictor of success in univariate (OR = 0.92, $P = 0.02$) and multivariate (OR = 0.93, $P = 0.01$) analysis. Disease duration, plaque size, penile curvature, and pain before treatment were not predictive of LiESWT success (**Table 6**).

DISCUSSION

The effectiveness of LiESWT in the treatment of PD is unclear.[15–20] The therapeutic effect of shock wave therapy on bony and connective tissues was first reported in 1988.[21] The first application of shock wave therapy in patients with PD was described 7 years later.[22] In their study, 11 over 12 patients re-experienced painless erections, and 6 over 12 patients had complete plaque disappearance after shock wave treatment. The therapeutic mechanisms of LiESWT on PD are poorly understood. Shock waves are thought to cause direct plaque damage by acoustic cavitation. The reflection of shock waves at interfaces of different acoustic impedance generates bubbles that collapse after their expansion due to surrounding pressure. When the bubbles collapse, large forces are generated causing direct plaque damage. This phenomenon is called cavitation.[23] An inflammatory reaction causes plaque lysis, resorption of calcifications, and their removal by macrophages. Heat-induced increased vascularity and decreased packing and clumping of collagen fibers within the plaques have been observed after ESWT. Subjectively, patients often perceive the plaque as being smoother or softened after ESWT.[24] Evidence of the efficacy of LiESWT for the treatment of PD is growing. However, it is still not recommended in European, Canadian, or American guidelines.[3] We used the 6-point Likert scale to standardize pain measurement among our patients. Median pain score decreased significantly from 1.8 to 0.7 after LiESWT ($P = 0.004$). Pain data from controlled and noncontrolled trials are variable.[18] Previous controlled studies showed that shock waves, alone,[17] or in combination with PDE5i,[16] significantly improved pain and erectile function. Previous studies have reported an improvement in penile pain in up to 84% of patients without using a standardized method of pain measurement.[22,25,26] Others reported similar results using a visual analog scale (VAS).[18] The Likert score seems to have greater acceptability and is easier to interpret than the VAS.[27,28] Conversely, Chitale *et al*.[15] failed to show any significant improvement in pain after shock wave therapy. However, their patients were in the chronic phase and had stable disease for >6 months, in contrast to our patients who were in the acute phase of the disease. Early treatment in the initial inflammatory phase has been suggested to bring greater therapeutic benefits. The mechanisms of pain relief of shock waves are related to inhibition of peripheral nerves (by the release of kinins that block transmission to sensory nerve endings), overstimulation of pain receptors (and subsequent blockade of nerve impulses), and reduction of pain receptors.[18] It should be noted, however, that during the natural history of PD, most patients experience spontaneous improvement

Table 5: Mean outcomes after low-intensity extracorporeal shock wave therapy for Peyronie's disease

	Pain-Likert scale (0–5)	*Penile curvature*	*Median plaque size (cm)*	*Lue score (0–15)*	*IIEF-5 score (1–25)*
Before LiESWT	1.8	31°	2	6.8	14
After LiESWT	0.7	17°	1.2	3.3	21
P	0.004	0.07	0.08	0.003	0.12

LiESWT: low-intensity extracorporeal shock wave therapy; IIEF-5: international index of erectile function

Table 6: Predictive factors for low-intensity extracorporeal shock wave therapy success in univariate and multivariate analyses

Variable	*Univariate analysis*			*Multivariate analysis*		
	OR	*95% CI*	*P*	*OR*	*95% CI*	*P*
Age <40 years	0.95	0.86–1.10	0.03	0.91	0.81–0.99	0.04
Pain (Likert Scale)	1.41	0.79–3.01	0.12	1.3	0.98–2.46	0.6
Penile curvature	0.95	0.89–1.30	0.11	1.1	0.93–1.41	0.97
Plaque size	0.97	0.91–1.18	0.59	0.97	0.93–1.33	0.91
Duration of disease	0.96	0.86–1.10	0.6	1.08	0.87–1.21	0.8
Concomitant PDE5i	0.92	0.89–1.10	0.02	0.93	0.79–0.97	0.01

OR: odds ratio; CI: confidence interval; PDE5i: phosphodiesterase-5 inhibitors

in pain.[1] Therefore, it is difficult to distinguish between the effect of ESWT on pain relief and self-resolution that typically presents during the disease process. However, the reduction in pain observed in our study occurred 4 weeks after the completion of treatment, which is short term compared to the long natural history of the disease, which might take ≥6 months to stabilize.[3] We demonstrated an improvement in penile curvature from 31° to 17°, in contrast to previous studies.[15–17,20] Palmieri *et al.*[16,17] used a total of 8000 shock waves (2000 per session for 4 weeks) in patients in the acute phase of PD. Hatzichristodoulou *et al.*[20] applied a total of 12 000 shock waves (2000 per session for 6 weeks) in patients in the chronic phase of PD. Chitale *et al.*[15] applied a total of 18 000 shock waves (3000 per session for 6 weeks) to patients also in the chronic stable phase of PD. In our study, we applied 1000 pulses every session to both sides of the shaft and crura (a total of 4000 shock waves per session for six sessions). Overall, each patient received at least 24 000 shock waves. The multidirectional approach to plaques during the acute inflammatory phase of the disease, combined with the high number of shock waves delivered (per session and in total), seems to be beneficial.

Despite the improvement in sexual function, evaluated with the IIEF-5, the results were not statistically significant in our study. Our findings are similar to those reported by Chitale *et al.*[15] and the meta-analysis of Gao *et al.*[19] and could be explained by the fact that erectile dysfunction in PD is multifactorial (psychological, conjugal, somatic, and vascular) and that shock waves cannot treat all of these related causes.[18] In our study, median plaque size decreased after LiESWT from 2 cm to 1.2 cm, although not statistically significant. Other controlled trials[15–17,20] and most uncontrolled studies reported in the meta-analysis of Krieger *et al.*[18] did not show any significant changes in plaque size after shock waves treatment. Our result is consistent with the findings of Shimpi and Jain.[29] In their study, shock waves were delivered separately to different parts of the plaque (300 to the proximal end, 900 to the middle part, and 300 to the distal end) with a total of 1500 per session over nine sessions (total 13 500 shock waves).[29] This multidirectional application of shock waves was common between the latter study and ours and different from all other studies that applied shock waves from a single direction only. Patient age and concomitant use of PDE5i were predictors of LiESWT success in our study. PDE5i limits collagen synthesis and differentiation of myofibroblasts, improving penis angulation and plaque size.[3] The efficacy of PDE5i + LiESWT in the treatment of PD was investigated previously[16] and could potentially become standard for plaque size reduction after further comparative randomized studies.

We also used the Lue score to measure the therapeutic effect of LiESWT.[12] LiESWT decreased the median Lue score significantly from 6.8 to 3.3. To our knowledge, this study is the first to report the outcomes of LiESWT on PD using a standardized score. This is important as it enables a systematic, objective, and reproducible comparison of studies that report outcomes of different treatment options.[1] Our study supports the safety of LiESWT, at least in the short term. No complication was reported during the 4-week study follow-up. Our results suggest that the multidirectional application of shock waves to the plaques might be necessary for plaque fragmentation and shortening. At the end of treatment, the delivery of at least 24 000 shock waves led to a considerable reduction in angulation that was not observed in previous controlled studies (administering a maximum of 18 000 shock waves).

Despite notable strength, including the assessment of PD symptoms using a standardized tool and the beneficial effects of our intervention on plaque size and angulation, our study has several limitations. Our sample size was limited to 39 patients, and there was no control group. Further studies are therefore needed to confirm our findings from a more robust point of view statistically. Not every penile angulation is associated with penetration difficulties. Thus, improvement in angulation does not necessarily mean higher intercourse satisfaction. The IIEF-5 score that we used has also some known limitations: it focuses only on current sexual functioning and provides a superficial assessment of domains of sexual functioning other than erection; also, it does not differentiate between different forms of vasculogenic impotence that can be identified by penile Doppler blood flow studies. This study suggests the lack of efficacy of ESWT on erectile function. However, this result may be influenced by the abovementioned defects related to the IIEF-5 questionnaire and taking into account of plasma testosterone levels that we did not measure in our patients undergoing LiESWT as proposed in the latest reports.[30] Finally, our study did not assess the impact of LiESWT on quality of life or sexual satisfaction. Patients were followed over a short period, and outcomes were measured 4 weeks after therapy completion. Thus, the long-term side effects of LiESWT were not determined.

CONCLUSIONS

LiESWT had a favorable impact on Lue score, penile pain, curvature, and plaque size in patients treated during the acute phase of PD. Younger age and concomitant use of PDE5i were predictors of success.

AUTHOR CONTRIBUTIONS

MA, AK, and MR participated in the project development, data collection, and manuscript writing. WA, AK, JP, MA, and MR did

the literature search and managed the data. TS, ECK, and MA edited the manuscript and analyzed the data. SJD and MR supervised the project and did the final revision. All authors read and approved the final manuscript.

COMPETING INTERESTS

All authors declare no competing interests.

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