

Shock Wave Therapy for Erectile Dysfunction: Patterns of Care and Efficacy

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The nonsurgical options for the management of erectile dysfunction (ED) have remained largely unchanged since the U.S. Food and Drug Administration (FDA) approval of phosphodiesterase type 5 inhibitors (PDE5i) in 1998 and the 2005 AUA panel update incorporating PDE5i as first-line therapy for ED patients.¹ The 2018 guidelines reflect the importance of shared decision making rather than step-wise progression of interventions, and notably highlight that low-intensity extracorporeal shock wave therapy (LiSWT) should be considered investigational.²

Despite this, clinical practice has seen continued growth of LiSWT to treat men suffering from ED. One driving factor has been its rapid incorporation by direct-to-consumer (DTC) men's health clinics. A recent evaluation of the DTC use of shock wave therapy across the 8 most populous cities in the United States identified 152 clinics offering shock wave therapy for the treatment of ED. In these clinics, the majority (75%) of providers were not urologists and 15% were not physicians.³ The average price charged per treatment course was more than \$3,300 (Table 1), and importantly, clinics did not specify the type of treatment offered, whether LiSWT or radial shock wave technology.

Table 1. Average Cost of Shock Wave Therapy per Session and per Treatment Course Across Metropolitan Areas

City, State	Average \$ price of SWT per session	Average \$ price of SWT per treatment course	Range of \$ prices for SWT treatment course
Atlanta, Georgia	372.5	2,625.00	600.00-4,500.00
Boston, Massachusetts	502.55	2,912.50	1,800.00-4,200.00
Dallas, Texas	489.00	3,292.31	1,800.00-6,900.00
Los Angeles, California	612.18	3,930.56	2,100.00-7,000.00
New York, New York	522.00	3,330.00	1,800.00-16,200.00
Philadelphia, Pennsylvania	458.25	3,623.75	3,000.00-4,500.00
Washington, D.C.	497.92	3,292.31	1,500.00-5,000.00
Houston, Texas	475.36	3,157.14	2,500.00-5,000.00
Overall average	491.22	3,338.28	600.00-16,200.00

Abbreviation: SWT, shock wave therapy.
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“A recent evaluation of the DTC use of shock wave therapy across the 8 most populous cities in the United States identified 152 clinics offering shock wave therapy for the treatment of ED. In these clinics, the majority (75%) of providers were not urologists and 15% were not physicians.³ The average price charged per treatment course was more than \$3,300 (Table 1), and importantly, clinics did not specify the type of treatment offered, whether LiSWT or radial shock wave technology.”

LiSWT is similar to extracorporeal shock wave therapy used in other medical applications where acoustic waves are generated and transferred to target tissues where they cause mechanical stress. Compared to extracorporeal shock wave therapy for nephrolithiasis treatment, LiSWT shock waves utilize lower energy levels but are spread over a larger focal volume. LiSWT devices are classified as FDA class II and require medical supervision to operate. Early studies have shown promise of LiSWT to treat mild to moderate vasculogenic ED via regenerative mechanisms including neo-angiogenesis, stem cell stimulation, and corporal remodeling.⁴

In contrast, radial shock wave technology utilizes dispersive pressure waves with significantly lower energy and lower tissue penetrance compared to LiSWT.⁵ Due to the lower energy, radial shock wave technology is FDA class I and does not require medical supervision to operate. Although frequently advertised as ED treatment by DTC men’s clinics, radial shock wave therapy has significantly fewer supporting data than LiSWT and should not be grouped together with LiSWT when critically assessing the therapeutic benefit of shock wave therapy in treatment of ED.

Although early pre-clinical studies have shown mechanistic promise in LiSWT treatment for ED, high-quality clinical data have been difficult to attain with only a handful of prior RCTs to date. Against this backdrop, Kalyvianakis et al recently published the results of their double-blind, randomized controlled trial (RCT) comparing LiSWT and sham treatments for moderate ED.⁶ The authors identified 70 adult men with moderate ED, identified by International Index of Erectile Function scores of 11-16 when not using PDE5i, and were randomized to 12, twice-weekly sessions for a total of six weeks. During the study period, participants agreed to suspend other ED treatments. The LiSWT device used in the study was the ARIES 2 with Smart Focus probe. During each session patients received 5,000 impulses along the penis at an energy flux density of 0.096 mJ/mm² and frequency of 5 Hz. At 3 months, 79% (27) patients undergoing LiSWT achieved minimal clinically important difference defined as at least a 5-point improvement in International Index of Erectile Function score, compared to 0 patients undergoing sham treatment (Table 2). As expected for LiSWT, there were no adverse events. Taken together, this study represents another RCT showing benefit of LiSWT to patients with ED, and the authors highlight their study is the first to do so with a carefully defined, homogeneous population with moderate ED. The authors concede the results are limited by the single-institution nature of the investigation and lack of long-term follow-up. It is important to note that the ARIES 2 is not available in the United States and the UroGold 100 has similar energy settings and has been evaluated for this indication.⁷

Table 2. Absolute Between-group Difference Across all Time Points of Low-intensity Extracorporeal Shock Wave Therapy vs Sham Therapy in the International Index of Erectile Function and Sexual Encounter Profiles Question 3: “Did Your Erection Last Long Enough for You to Have Sexual Intercourse?”

Parameter	Baseline	1 Mo	3 Mo
IIEF-EF, mean (SD)			
LiSWT	14 (1.7)	19 (3.3)	20 (2.4)
Sham therapy	14 (1.6)	15 (2)	16 (2.2)
P value for between groups		<0.001	<0.001
SEP question 3 (% yes), mean (SD)			
LiSWT	20 (16)	41 (18)	48 (22)
Sham therapy	25 (12)	23 (14)	26 (16)
P value for between groups		<0.001	<0.001

Abbreviations: IIEF-EF, International Index of Erectile Function–Erectile Function; LiSWT, low-intensity extracorporeal shock wave therapy; SEP, Sexual Encounter Profile.
The 2-sample t test was performed for between-group comparisons. Bold type indicates statistically significant P values. Adapted with permission from J Urol. 2022;208(2):388-395.6

With this most recent study, there are now 14 clinical trials of LiSWT demonstrating benefit in patients without severe ED; 6 are randomized trials including sham group comparison and 3 of these are double-blind, randomized trials comparing therapy to sham/placebo.^{6,8} With this growing body of evidence supporting LiSWT as a safe, viable option for patients with ED, it begs the question, should the AUA and other national guidelines adopt LiSWT as a treatment option for appropriate patients? Some may reasonably advocate first for higher-powered, multi-institutional studies with longer follow-up. On the other hand, the logistical considerations involved in establishing and completing a well-powered trial assessing long-term efficacy of LiSWT with sham/placebo randomization will be challenging. For instance, the European Association of Urology guidelines recommend the use of LiSWT in patients with

mild vasculogenic ED or as an alternative first-line therapy for patients who do not wish to have or are not suitable for oral vasoactive therapy.⁹

Given that LiSWT is a non-invasive treatment option and there is evidence of patients turning to therapies with no or limited evidence, it is important to continue critically evaluating shockwave therapy to understand the following:

1. Do different shock wave machines or protocols yield better outcomes?
2. Do the effects of LiSWT last? Is maintenance therapy required?
3. Can early LiSWT use result in regeneration of tissue potential, reducing rates of progression to severe ED?
4. Beyond guidelines and position statements, how can urologists and specialty associations highlight differences between radial shock waves and LiSWT?

Conflicts of Interest

The Authors have no conflicts of interest to disclose.

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