

MEN'S SEXUAL HEALTH

Low-Intensity Extracorporeal Shockwave Therapy in Sexual Medicine: A Questionnaire-Based Assessment of Knowledge, Clinical Practice Patterns, and Attitudes in Sexual Medicine Practitioners



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ABSTRACT

Introduction: Low-intensity extracorporeal shockwave therapy (LI-ESWT) has emerged as a treatment option for male sexual dysfunction. However, results have been contradictory.

Aim: To investigate the knowledge, practice patterns, and attitudes regarding LI-ESWT among experts in sexual medicine.

Methods: A study-specific questionnaire was handed out at the 18th Congress for the European Society for Sexual Medicine. Participants were queried on their knowledge about LI-ESWT and about their use of the equipment.

Main Outcome Measures: Descriptive data on the knowledge of LI-ESWT and perception of treatment effects.

Results: One hundred ninety-two questionnaires were available for analysis. Most respondents were physicians (79.7%) and most of these specialized in urology (58.9%). Overall, 144 of 192 (75%) reported that they were familiar with LI-ESWT in sexual medicine. Twenty-seven (14.1%) had performed the treatment. Of the 117 non-users who were familiar with LI-ESWT, 37 sometimes referred patients for the treatment. Nevertheless, 103 of 144 (71.5%) stated that they considered LI-ESWT an effective treatment for erectile dysfunction (ED) and 10 of 144 (6.9%) considered it an effective treatment for Peyronie disease. Of participants who regarded LI-ESWT an effective ED treatment, 91.2% would consider the treatment specifically for vasculogenic ED and 81.6% would combine it with phosphodiesterase type 5 inhibitors. Most participants (83.7%) regarded LI-ESWT as safe. A urology background (odds ratio = 2.4; 95% CI = 1.3–4.8; $P = .0093$) and working in a private setting (odds ratio = 2.8; 95% CI = 1.5–5.3; $P = .0084$) were significant predictors of familiarity with LI-ESWT in sexual medicine and of being an LI-ESWT user. Likewise, urologists were significantly more likely than non-urologists to consider the treatment effective (odds ratio = 2.8; 95% CI = 1.1–7.1; $P = .033$).

Conclusion: LI-ESWT is well known among experts in sexual medicine and the treatment is perceived as safe and effective against vasculogenic ED when combined with phosphodiesterase type 5 inhibitors. The treatment is mainly offered by urologists. **Fode M, Lowenstein L, Reisman Y. Low-Intensity Extracorporeal Shockwave Therapy in Sexual Medicine: A Questionnaire-Based Assessment of Knowledge, Clinical Practice Patterns, and Attitudes in Sexual Medicine Practitioners. Sex Med 2017;5:e94–e98.**

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Key Words: Erectile Dysfunction; Low-Intensity Extracorporeal Shockwave Therapy; Peyronie Disease; Sexual Medicine; Surveys and Questionnaires

INTRODUCTION

In recent years, low-intensity extracorporeal shockwave therapy (LI-ESWT) has emerged as a treatment option in male sexual dysfunction. The treatment has been proposed for Peyronie

disease (PD) and erectile dysfunction (ED). Although results have generally been disappointing for PD, there is currently hope that the method might provide a cure for ED, thus rendering it superior to the common symptomatic treatments.^{1–3} Although

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the molecular and cellular mechanisms of the effect of LI-EST are unknown, different machines have been tested in randomized trials. However, results have been contradictory, with some studies implying a potential benefit and others showing inconclusive or even discouraging results.^{4–6} Moreover, the optimal treatment regimen regarding energy densities and timing and number of treatment sessions is unknown. Nevertheless, it is clear that LI-ESWT has already been adapted into clinical practice.

AIMS

The purpose of this study was to investigate the knowledge, practice patterns, and attitudes regarding LI-ESWT among experts in sexual medicine.

METHODS

A specific questionnaire was developed by the study group. This was handed out to delegates at the 18th Congress for the European Society for Sexual Medicine (ESSM) in Madrid from February 4–6, 2016 at a booth with information on the ESSM. The conference overall had 1,117 registered participants. The questionnaire captured demographic data, professional background, and experience with sexual medicine. Participants were queried on their knowledge about LI-ESWT and about the use of the equipment in their own practice. The general questions centered on attitude toward the treatment, possible indications, perception of benefits and risks, clinical evaluation of effects, and scientific evidence. Delegates who used LI-ESWT in their own practices were asked about treatment regimens and side effects to the treatment.

Descriptive statistics were performed and multivariate logistic regression analyses were used to identify independent predictors for familiarity with LI-ESWT, use of treatment, perception of effectiveness, and attitude toward scientific evidence on the treatment. Age, professional background, workplace (academic, private, or public settings), years in practice, and percentage of time spent dealing with sexual medicine were evaluated for each of these outcomes. All statistical analyses were conducted using SAS 9.4 for Windows (SAS Institute, Cary, NC, USA). Two-sided *P* values less than .05 were considered statistically significant.

MAIN OUTCOME MEASURES

The primary outcome was to provide descriptive data on the knowledge of LI-ESWT and perception of treatment effects among sexual medicine practitioners. Secondary outcome measurements included assessments of concrete treatment patterns and attitudes toward clinical and scientific evaluations of LI-ESWT in sexual medicine.

RESULTS

One hundred ninety-two questionnaires were available for analysis. The responders consisted of 77% men and 23% women

from 33 different countries, which corresponded well to that of the overall congress participants. The median age was 46 years (range = 23–71). One hundred fifty-three of 192 (79.7%) were physicians and 113 (58.9%) of these specialized in urology. Sixteen of 192 (8.3%) were psychologists and 14 of 192 (7.3%) identified themselves as sexual therapists. Most participants had practiced for at least 10 years and almost everyone devoted at least one fourth of their time to sexual medicine. Further demographics are listed in [Table 1](#).

Overall, 144 of 192 (75%) reported that they were familiar with the use of LI-ESWT in sexual medicine. Twenty-seven (14.1%) had performed the treatment themselves and/or had participated in studies, 30 (15.6%) recommended it to their patients, and 87 (45.3%) knew it only from the literature. The 27 LI-ESWT users had performed a median of 50 treatments (range = 3–1,000). Of the 117 participants who were familiar with LI-ESWT but did not offer it themselves, 73 never referred their patients to the treatment, 27 did so less than once per

Table 1. Demographics of study participants

Demographics	All participants (N = 192)
Responders' age (y), median (range)	46 (23–71)
Sex, n (%)	
Men	138 (71.9)
Women	42 (21.9)
Undisclosed	12 (6.3)
Occupation, n (%)	
Physician (urologist)	113 (58.9)
Physician (other)	40 (20.8)
Psychologist	16 (8.3)
Sexual therapist	14 (7.3)
Physical therapist	1 (0.5)
Nurse	1 (0.5)
Preclinical researcher	5 (2.6)
Undisclosed	2 (1.0)
Setting of practice, n (%)	
Academic hospital	71 (37.0)
Private clinic or private practice	44 (22.9)
Public health care system	29 (15.1)
Private and public	45 (23.4)
Undisclosed	3 (1.6)
Years in sexual medicine practice, n (%)	
<5	41 (14.6)
5–10	45 (23.4)
>10	105 (54.7)
Undisclosed	1 (0.5)
Percentage of practice in sexual medicine, n (%)	
100	28 (14.6)
75	42 (21.9)
50	74 (38.5)
25	35 (18.2)
<25	12 (6.8)

month, and 10 did so at least a few times per month. Nevertheless, 103 of 144 (71.5%) stated that they considered LI-ESWT an effective ED treatment, 10 of 144 (6.9%) considered it an effective PD treatment, and 2 of 144 (1.4%) considered it effective for “other indications” specified as chronic prostatitis and chronic pelvic pain. Of LI-ESWT users, 21 of 27 considered it effective for ED and 2 of 27 considered it effective for pelvic pain. One user did not consider LI-ESWT effective in sexual medicine and 3 of 27 were unsure of its effects. The main results are presented in [Table 2](#).

Of participants who regarded LI-ESWT an effective ED treatment, the vast majority (91.2%) would consider the treatment specifically for vasculogenic ED, whereas 6.5% would consider it for neurogenic or post-prostatectomy ED. In addition, 81.6% would combine LI-ESWT with phosphodiesterase type 5 (PDE5) inhibitors, whereas 17.3% considered it the sole treatment. Most participants (83.7%) regarded LI-ESWT as safe, although the use of anticoagulants and local skin disease were quoted as possible contraindications.

LI-ESWT users used six different machines. None of the delegates provided comprehensive data on their treatment regimens and two specifically stated that it was private. Six of the

27 users reported side effects in their patients in the form of small hematomas and pain. No serious adverse effects were reported.

Of the entire cohort of participants 30.3% stated that randomized trials were needed to provide evidence for the use of LI-ESWT in sexual medicine, whereas 29.7% stated that they would follow guideline recommendations. Moreover, 31% were willing to accept expert opinion and 10.3% believed that it would be reasonable to directly translate basic science evidence to clinical practice. For the use of LI-ESWT in clinical practice, most participants believed that the use of objective measurements or validated questionnaires was best suited to evaluate treatment effects for ED (91.4%) and PD (88.4%).

On multivariate analyses, a urology background (odds ratio [OR] = 2.4; 95% CI = 1.3–4.8; $P = .0093$) and working in a private setting (OR = 2.8; 95% CI = 1.5–5.3; $P = .0084$) were significant predictors of familiarity with LI-ESWT in sexual medicine. Of the 144 delegates who were familiar with LI-ESWT, a urology background (OR = 4.1; 95% CI = 1.2–14.2; $P = .027$) and working in a private setting (OR = 4.7; 95% CI = 1.5–14.3; $P = .0063$) also were significant predictors of being an LI-ESWT user. Thus, 21 of 27 LI-ESWT users were urologists and 20 of 27 worked in private practice. Likewise, urologists were significantly more likely than non-urologists to consider the treatment effective for ED or PD (OR = 2.8; 95% CI = 1.1–7.1; $P = .033$). After further evaluation of LI-ESWT, delegates who worked in an academic hospital were more likely to require randomized trials as evidence of LI-ESWT efficacy (OR = 9.0; 95% CI = 3.5–23.3; $P < .0001$). In addition, those who had practiced sexual medicine for more than 10 years were more likely to require randomized trials compared with those who had practiced for less than 5 years (OR = 6.9; 95% CI = 1.03–46.4; $P = .027$).

Table 2. Summary of results

Knowledge of LI-ESWT	All participants (N = 192)
Extent of familiarity, n (%)	
Not familiar	48 (25.0)
Know from literature	87 (45.3)
Recommend to patients	30 (15.6)
User	14 (7.3)
Participate in basic or clinical studies	13 (6.8)
	Familiar with LI-ESWT (n = 144)
Perception of effect, n (%)	
Effective in ED	103 (71.5)
Effective in PD	10 (6.9)
Effective for other indications	2 (1.4)
Not effective	6 (4.2)
Undisclosed	23 (16.0)
	Non-users familiar with LI-ESWT (n = 117)
Frequency of referral, n (%)	
Never	73 (62.4)
<1 per month	27 (23.1)
1–4 per month	7 (6.0)
>1 per week	3 (2.6)
Daily	0 (0.0)
Undisclosed	7 (6.0)

ED = erectile dysfunction; LI-ESWT = low-intensity extracorporeal shock-wave therapy; PD = Peyronie disease.

DISCUSSION

Our survey is the first of its kind on the use of LI-ESWT in sexual medicine. The data suggest that most sexual medicine practitioners are familiar with LI-ESWT. This finding was expected because the treatment modality has received much attention in recent years. Likewise, it is logical that urologists were most likely to be familiar with or use LI-ESWT. Thus, organic male sexual dysfunction is most commonly treated by urologists. However, the overwhelmingly positive attitude toward LI-ESWT in sexual medicine is somewhat surprising considering the limitations in the available literature. Delegates in general and users in particular were especially positive regarding LI-ESWT as a treatment for vasculogenic ED, although only a minority seemed to regard it as a curative treatment. Thus, more than 80% would combine it with PDE5 inhibitors. This seems somewhat contradictory and could imply some skepticism toward LI-ESWT after all.

The proposed mechanism of action for LI-ESWT in ED is that it improves endothelial function and triggers angiogenesis

through induction of local growth factors and endothelial nitric oxide synthase.^{7,8} The literature generally confirms that LI-ESWT is safe and cohort studies investigating the clinical effects have generally been encouraging.^{2,3,9–11} In contrast, randomized trials have been less convincing. Thus, a randomized trial of 67 PDE5 inhibitor responders showed statistically greater improvements in the erectile function domain of the International Index of Erectile Function (IIEF) with active LI-ESWT treatment compared with sham treatment ($P = .032$). However, the difference in mean scores was only 3.7 points (6.7 vs 3.0), which is below the minimal clinically important difference for most ED categories.¹² Another randomized study by Olsen et al⁶ ($N = 58$) failed to show a significant benefit of LI-ESWT in vasculogenic ED altogether, whereas a third randomized study ($N = 105$) found that LI-ESWT improved the Erection Hardness Score but not the IIEF-5 score compared with sham treatment. Despite these drawbacks and discrepancies among trials, a meta-analysis published after our questionnaire study concluded that LI-ESWT might significantly improve erectile function for at least 3 months.¹³ However, the validity of this meta-analysis has been called into question owing to drawbacks of the original studies and problems in the statistical analyses.¹⁴ In addition, the mean difference compared with sham treatment was only two points on the IIEF scale, which is—again—below the minimal clinically important difference. Therefore, results from the meta-analysis should be interpreted with caution and higher-quality randomized trials are still awaited.

Only a small number of delegates considered LI-ESWT effective for neurogenic or post-prostatectomy ED. Considering the proposed mechanism of action and the limited data on these ED categories, this was expected.¹⁵ Similarly, very few delegates believed that LI-ESWT is effective against PD and none of the users applied the treatment in this context. This is in line with the literature and it is especially encouraging because a recent randomized trial showed that LI-ESWT is not only ineffective against PD but that it can worsen the condition.¹⁶ Because pelvic pain is generally not considered a sexual medicine issue and was not given as a predefined option on the questionnaire, the findings regarding this issue should be interpreted carefully.

The finding that only a minority had clinical experience with LI-ESWT could be due to the relatively high price of the machines and the lack of a universally accepted treatment protocol. This also might explain why delegates in private practice were more likely to have experience with the treatment. Unfortunately, the answers regarding LI-ESWT treatment regimens were generally unclear and no conclusions can be drawn on the topic. However, our results do imply the lack of consensus on the issue, especially because as many as six different LI-ESWT machines were used.

The vast majority of participants agreed that vigorous evaluation of LI-ESWT effects is needed in the clinic. However, less than one third of the delegates stated that randomized trials are needed to evaluate the use of LI-ESWT in sexual medicine and

many were willing to accept expert opinion or even findings from basic science studies. The tendency was especially pronounced in delegates working outside academic institutions and in less experienced practitioners. The finding is surprising and it is a cause for concern because treatments might be able to enter sexual medicine practice without the proper scientific documentation. It must be emphasized that there might be an ethical issue with charging payment for a treatment that can still be considered experimental because of inconsistencies of treatment protocols and discrepancies of the published data on efficacy. The issue warrants further investigation in studies designed specifically for this purpose. The main limitation of our study is the selection of participants and the relatively limited number of respondents because the questionnaire was handed out at a conference for sexual medicine. Thus, the results cannot be generalized beyond sexual medicine experts. Moreover, the questionnaire was handed out at the ESSM booth and the purpose of assessing LI-ESWT was not advertised. Therefore, we likely captured a representative sample of the conference delegates. The sample size corresponds to that of previous similar studies.¹⁷ Further limitations include the small absolute number of LI-ESWT users and the fact that most have their practice in a private setting. In this regard, we lack data on LI-ESWT regimens.

CONCLUSIONS

LI-ESWT is well known among experts in sexual medicine and the treatment is perceived as safe and effective against vasculogenic ED when combined with PDE5 inhibitors. The treatment is mainly offered by urologists. Participants had high demands when evaluating LI-ESWT in clinical practice but only approximately one in three stated that randomized trials were necessary before implementing LI-ESWT in clinical practice.

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REFERENCES

- Hatzimouratidis K, Eardley I, Giuliano F, et al. EAU guidelines on penile curvature. *Eur Urol* 2012;62:543-552.
- Gruenwald I, Appel B, Vardi Y. Low-intensity extracorporeal shock wave therapy—a novel effective treatment for erectile dysfunction in severe ED patients who respond poorly to PDE5 inhibitor therapy. *J Sex Med* 2012;9:259-264.
- Vardi Y, Appel B, Jacob G, et al. Can low-intensity extracorporeal shockwave therapy improve erectile function? A 6-month follow-up pilot study in patients with organic erectile dysfunction. *Eur Urol* 2010;58:243-248.
- Vardi Y, Appel B, Kilchevsky A, et al. Does low intensity extracorporeal shock wave therapy have a physiological effect on erectile function? Short-term results of a randomized, double-blind, sham controlled study. *J Urol* 2012;187:1769-1775.
- Yee CH, Chan ES, Hou SS, et al. Extracorporeal shockwave therapy in the treatment of erectile dysfunction: a prospective, randomized, double-blinded, placebo controlled study. *Int J Urol* 2014;21:1041-1045.
- Olsen AB, Persiani M, Boie S, et al. Can low-intensity extracorporeal shockwave therapy improve erectile dysfunction? A prospective, randomized, double-blind, placebo-controlled study. *Scand J Urol* 2015;49:329-333.
- Qiu X, Lin G, Xin Z, et al. Effects of low-energy shockwave therapy on the erectile function and tissue of a diabetic rat model. *J Sex Med* 2013;10:738-746.
- Liu J, Zhou F, Li GY, et al. Evaluation of the effect of different doses of low energy shock wave therapy on the erectile function of streptozotocin (STZ)-induced diabetic rats. *Int J Mol Sci* 2013;14:10661-10673.
- Bechara A, Casabe A, De BW, et al. Effectiveness of low-intensity extracorporeal shock wave therapy on patients with erectile dysfunction (ED) who have failed to respond to PDE5i therapy. A pilot study. *Arch Esp Urol* 2015;68:152-160.
- Chung E, Cartmill R. Evaluation of clinical efficacy, safety and patient satisfaction rate after low-intensity extracorporeal shockwave therapy for the treatment of male erectile dysfunction: an Australian first open-label single-arm prospective clinical trial. *BJU Int* 2015;115(Suppl 5):46-49.
- Pelayo-Nieto M, Linden-Castro E, Alias-Melgar A, et al. Linear shock wave therapy in the treatment of erectile dysfunction. *Actas Urol Esp* 2015;39:456-459.
- Rosen RC, Allen KR, Ni X, et al. Minimal clinically important differences in the erectile function domain of the International Index of Erectile Function scale. *Eur Urol* 2011;60:1010-1016.
- Lu Z, Lin G, Reed-Maldonado A, et al. Low-intensity extracorporeal shock wave treatment improves erectile function: a systematic review and meta-analysis. *Eur Urol* 2017;71:223-233.
- Fode M, Albersen M. Re: Zhihua Lu, Guiting Lin, Amanda Reed-Maldonado, Chunxi Wang, Yung-Chin Lee, Tom F. Lue. Low-intensity extracorporeal shock wave treatment improves erectile function: a systematic review and meta-analysis. *Eur Urol* 2017;71:e76-e77.
- Frey A, Sonksen J, Fode M. Low-intensity extracorporeal shockwave therapy in the treatment of postprostatectomy erectile dysfunction: a pilot study. *Scand J Urol* 2016;50:123-127.
- Hatzichristodoulou G, Meisner C, Gschwend JE, et al. Extracorporeal shock wave therapy in Peyronie's disease: results of a placebo-controlled, prospective, randomized, single-blind study. *J Sex Med* 2013;10:2815-2821.
- Shechter A, Lowenstein L, Serefoglu EC, et al. Attitudes of sexual medicine specialists toward premature ejaculation diagnosis and therapy. *Sex Med* 2016;4:e209-e216.