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Effect of low-intensity extracorporeal shockwave therapy on nocturnal penile tumescence and rigidity and penile haemodynamics

Yan-Ping Huang | Wei Liu | Yi-Dong Liu | Ming Zhang | Shi-Ran Xu | Mu-Jun Lu

Department of Urology, Renji Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai Institute of Andrology, Shanghai, China

Correspondence
Mu-Jun Lu, Department of Urology, Renji Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai Institute of Andrology, No. 145, Shandong Rd. Shanghai 200001, China.
Email: lumujun@163.com

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Abstract

The study aims to evaluate the effect of low-intensity extracorporeal shockwave therapy (Li-ESWT) on nocturnal erection and penile haemodynamics. Patients with erectile dysfunction (ED) were enrolled from January 2018 to March 2019. Self-reported erectile symptoms, the International Index of Erectile Function-5 (IIEF-5) and Erection Hardness Scores (EHS), nocturnal penile tumescence and rigidity (NPTR) and cavernous duplex Doppler ultrasound (CDDU) were evaluated. NPTR and CDDU were evaluated by Rigiscan and vascular ultrasound system respectively. Comparisons of NPTR and CDDU parameters were performed before and after Li-ESWT (Renova, once a week, 4 weeks in total). A total of 35 cases (mean age 36.51 ± 11.47 years) were enrolled for analysis. The IIEF-5 (10.60 ± 5.99 vs. 15.13 ± 6.22, $p = .003$), EHS ($p = .016$) and self-reported erectile hardness ($p = .014$) were significantly improved after 1-month treatment. Nocturnal erection frequency ($p = .010$), duration of total erection ($p = .017$), duration of erectile rigidity ≥60% at penile tip and base ($p = .014$ and $p = .002$) and the best erectile rigidity at penile tip and base ($p = .012$ and $p = .005$) improved significantly after treatment. However, no CDDU parameters improved after Li-ESWT (all $p > .05$). Li-ESWT can effectively improve subjective erectile function and nocturnal erection in ED patients. Large sample and well-designed studies need to be developed for supporting the current findings.

KEYWORDS

erectile dysfunction, low-intensity extracorporeal shockwave therapy, nocturnal penile tumescence and rigidity, penile haemodynamics, therapeutic effect

1 | INTRODUCTION

Erectile dysfunction (ED) is one of the most common sexual disorders in men. It is estimated that one in every five men present erectile problems in the ageing male population (Wessells, Joyce, Wise, & Wilt, 2007), and it is likely to become even more prevalent with increasing of comorbid conditions (Huang et al., 2014). Although the most widely used medication phosphodiesterase type 5 inhibitors (PDE5-Is) have improved symptoms in most patients with ED, they cannot effectively restore the vascular lesions secondary to chronic diseases such as diabetes mellitus and hyperlipidaemia. Recently, low-intensity extracorporeal shockwave therapy (Li-ESWT) is

Yan-ping Huang and Wei Liu contributed equally to this article.

considered to be a novel effective therapeutic method for ED, and it has already been included as a first-line therapeutic option for ED in guidelines (Hatzimouratidis et al., 2010). Animal studies have shown that low-intensity shockwave can trigger neovascularisation of the cavernous tissue and subsequently improve penile blood flow and endothelial function (Li et al., 2016). Many clinical studies have shown that Li-ESWT has an improved effect on self-reported erection symptoms in patients with ED (Chitale, Morsey, Swift, & Sethia, 2010; Chung & Cartmill, 2015; Vardi, Appel, Kilchevsky, & Gruenwald, 2012).

Although Li-ESWT has been considered as an effective treatment method for ED in clinical practice, most studies were retrospective and had small sample size, and the therapeutic effect indicators were limited to the self-reported symptom scales, such as Clinical Global Impression of Change (CGIC), International Index of Erectile Function (IIEF) and Erection Hardness Score (EHS). As a matter of fact, simple self-reported symptom scales cannot accurately reflect the treatment effect, and men with failed sexual intercourse or few sexual attempts are not suitable to be evaluated by IIEF score (Rynja, Bosch, Kok, Wouters, & De Kort, 2009). The objective of this study is to evaluate the effect of Li-ESWT on objective parameters of nocturnal penile tumescence and rigidity (NPTR) and penile haemodynamics.

2 | METHODS

2.1 | Study population

The study was a prospective, nonrandomised, single-centre study. From January 2018 to March 2019, consecutive ED patients over 18 years of age were enrolled from andrology and urology outpatient in our hospital. Clinical data including general health status, sexual activity history, physical examination and cardiovascular risk factors were recorded in detail, and blood chemistry and endocrine assay were tested in all ED patients. Patients with ED must have a stable heterosexual partner and present erectile complaint more than 6 months. Patient who was taking PDE5is must cease medication for at least 1 month. Subjects were excluded from the study if they had following diseases: serious cardiac problems (unstable angina, congestive heart failure, arrhythmia, etc.); clinically noteworthy penile deformities affecting penetration; pelvic surgery or trauma of perineal region; neurogenic pathology or an addiction problem (such as narcotic drugs); and obvious psychological origin or androgen deficiency. Moreover, we also excluded patients who did not complete the Li-ESWT session.

This study had been registered on the Chinese Clinical Trial Registry (No. ChiCTR-INR-17013804), and it received institutional review board approval (Renji Hospital, Shanghai. No. 2018-119). The study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki as revised in 2000, and all patients agreed to participate in this clinical study and had signed the informed consent.

2.2 | Study design

Before the enrolment, patients were asked to stop any medication that may affect erectile function for at least one month. ED patients eventually enrolled in the study were provided erectile function scales (IIEF-5 score, EHS and self-reported erectile symptom questions), NPTR and cavernous duplex Doppler ultrasound (CDDU) test for preliminary assessment. The patients with completed evaluation underwent four weekly Li-ESWT sessions, and the specific treatment plan is detailed in the following content of this article. A follow-up visit was carried out at 1 month after Li-ESWT, and the patients were evaluated by erectile function scales, NPTR and CDDU test again.

2.3 | Subjective erectile function assessment

ED was screened according to IIEF-5 scores (IIEF-5 < 21) and EHS (EHS ≤ 3). Four self-reported erectile symptom questions were also provided to the patients for erectile function evaluation, including Q1: Do you have an erection when you watch a sex video?; Q2: Do you have an erection when you sleep or get up in the morning?; Q3: Do you have confidence in the erection?; Q4: Do you think the penile erection is hard enough? The answer to every question was set as 'yes' or 'no'.

2.4 | NPTR monitoring

Rigiscan (Timm Medical Technologies, GOTOP, USA) was used to record NPTR parameters including radial rigidity, tumescence, number and duration of erectile events (Bradley, Timm, Gallagher, & Johnson, 1985). The device is equipped with two wire loops, one placed at the base of the penis (base monitoring site) and the other placed at the coronal sulcus (tip monitoring site) respectively. The Rigiscan device mainly record penile tumescence (circumference) and radial rigidity with timed through the standardised contraction and relaxation procedures of the two loops. The patient should maintain more than 8 hr of sleep without taking alcohol and any sleeping medications during the test. The patients receiving NPTR recording must sleep in the ward for one or two consecutive nights. Due to the limitation of the number of beds in the ward of andrology centre, the NPTR test was usually arranged at one month after the follow-up registration.

2.5 | CDDU test

Patients were asked to stay in an isolated, quiet and dim light room for 15 min. A Doppler ultrasound diagnostic apparatus (Envisor, Philips, Netherlands) and a high-resolution solid-state linear array U/S transducer (7.5- to 12-MHz frequency) were used for obtaining real-time images. The patient lay in a supine position with the

dorsal penis against the abdomen, and sagittal images were acquired through the U/S probe scanning. The entire penis was scanned from the crura in the perineum to the tip, and the echogenicity, homogeneity, fibrosis, plaques or calcification of the cavernous were recorded. Cavernous arterial diameters and haemodynamics were measured at baseline before pharmaco-induced erection and commonly every 5 min afterwards up to 20 min. Pharmaco-induced erection procedure (Yang et al., 2011, 2012): patients were asked to take sildenafil (Viagra) 100mg 1 hr in advance. Audiovisual sexual stimulation (AVSS) and masturbation stimulation were synchronously given 15 min before the erection test. Erection quality was simultaneously assessed and rated after drug induction, and the erectile hardness more than III grade was considered to be a valid erection for test. Haemodynamics parameters including peak systolic velocity (PSV), end-diastolic velocity (EDV) and resistance index (RI) of bilateral cavernous arteries were recorded.

2.6 | Li-ESWT

Patients were treated by a low-energy shock waves generator (RENOVA Direx Group). The Li-ESW was set as energy 0.09 mJ/mm^2, 300 intensity waves/min (5 Hz) and 40 mm deep. Patients receive one shock wave treatment once a week and a four-week treatment session in total. Shock wave was applied at the bilateral penile crus (1,600 shocks at each area) and corpus cavernosum (900 shocks at each area). Each session lasts approximately 20 min.

2.7 | Statistical analysis

Continuous variables were expressed as the mean ± standard deviation (*SD*) or median (minimum-maximum). One-way ANOVA (normal variables), Kruskal-Wallis (non-normal variables) and chi-square tests (categorical variables) were used for analysis on all related characteristics. All statistical analyses were achieved through SPSS 22.0 software, and statistical significance was set at $p < .05$.

3 | RESULTS

A total of 35 cases (mean age 36.51 ± 11.47 years) were enrolled for analysis. Baseline characteristic data of ED patients in the study are shown in Table 1. Table 2 shows the subjective erectile function at 1-month follow-up by Li-ESWT. Subjective erectile function indicators, such as IIEF-5 score (10.60 ± 5.99 vs. 15.13 ± 6.22, $p = .003$), EHS ($p = .016$) and self-reported erectile hardness (18.5% vs. 60.0%, $p = .014$), showed significant improvement after 1-month treatment. However, we did not find the significant improvement in the other three self-reported erectile symptoms (each $p > .05$).

The comparison of NPTR parameters before and after Li-ESWT is shown in Figures 1–3. Figure 1 shows that nocturnal erection frequency (median 3.0 times vs. median 4.0 times, $p = .010$) and total duration of erection (median 30.5 min vs. median 92.5 min, $p = .017$) increased significantly compared with the baseline after treatment. The measures of improvement after Li-ESWT also included the average and best erectile rigidity at penile tip and base (Figure 2), duration of erectile rigidity ≥60% at penile tip and base and duration of the best erection at penile base (Figure 3). CDDU parameters

TABLE 1 Patients' baseline characteristics

N = 35	Median (minimum, maximum)
Age	33 (21, 68) years
BMI	24.57 (18.25, 29.38) kg/m^2
IIEF-5 score	7 (5, 21)
EHS	3 (1, 3)
Total testosterone	13.77 (10.66, 17.55) nmol/L
Fasting blood glucose	5.0 (3.91, 13.97) mmol/L
Cholesterol	4.24 (3.18, 5.67) mmol/L
Triglyceride	1.36 (0.39, 3.90) mmol/L
Smoking history	22.9% (8)
Peyronie's disease	17.1% (6)
Comorbidities (hypertension/diabetes/hyperlipidaemia)	28.6% (10)

Abbreviations: BMI, body mass index; IIEF, International Index of Erectile Function; EHS, Erection Hardness Score; Li-ESWT, low-intensity extracorporeal shockwave therapy.

TABLE 2 Analysis of self-reported parameters at 1-month follow-up by Li-ESWT cohort

Variable	Baseline	Follow-up 1 month	*p* value
IIEF-5	10.60 ± 5.99	15.13 ± 6.22	.003
EHS	3 (1, 3)	3 (2, 4)	.016
Q1 (%)	51.9 (yes) 48.1 (no)	70.0 (yes) 30.0 (no)	.322
Q2 (%)	55.6 (yes) 44.4 (no)	50.0 (yes) 50.0 (no)	.763
Q3 (%)	40.7 (yes) 59.3 (no)	30.0 (yes) 70.0 (no)	.550
Q4 (%)	18.5 (yes) 81.5 (no)	60.0 (yes) 40.0 (no)	.014

Abbreviations: Li-ESWT, low-intensity extracorporeal shockwave therapy; IIEF, International Index of Erectile Function; EHS, Erection Hardness Score.

Q1: Do you have an erection when you watch a sex video?

Q2: Do you have an erection when you sleep or get up in the morning?

Q3: Do you have confidence in the erection?

Q4: Do you think the penile erection is hard enough?

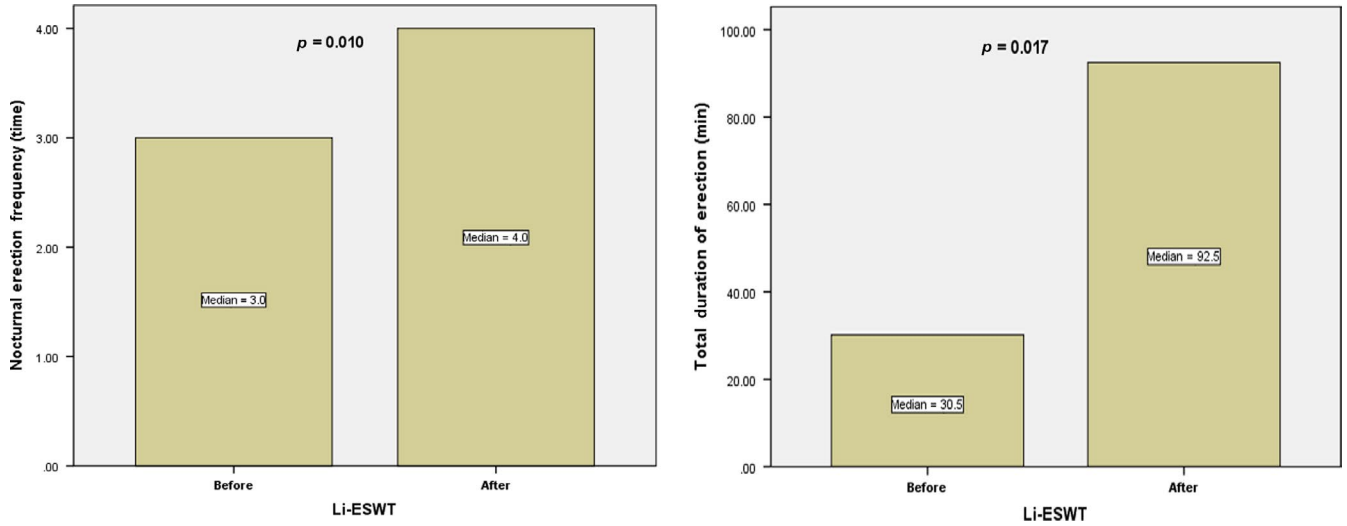

FIGURE 1 Nocturnal erection frequency and total duration of erection before and after Li-ESWT. Li-ESWT, low-intensity extracorporeal shockwave therapy

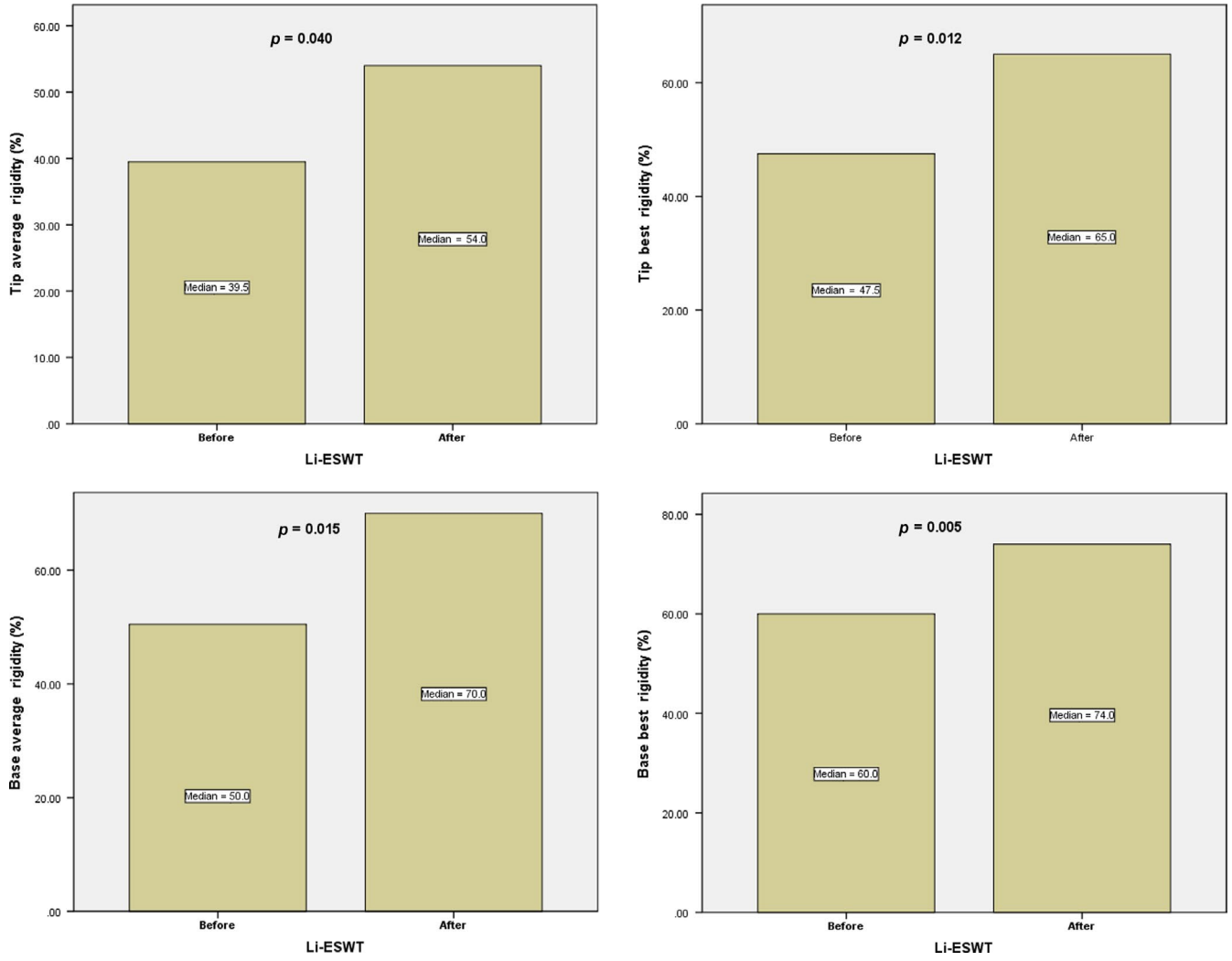

FIGURE 2 The average and best erectile rigidity at penile tip and base before and after Li-ESWT. Li-ESWT, low-intensity extracorporeal shockwave therapy

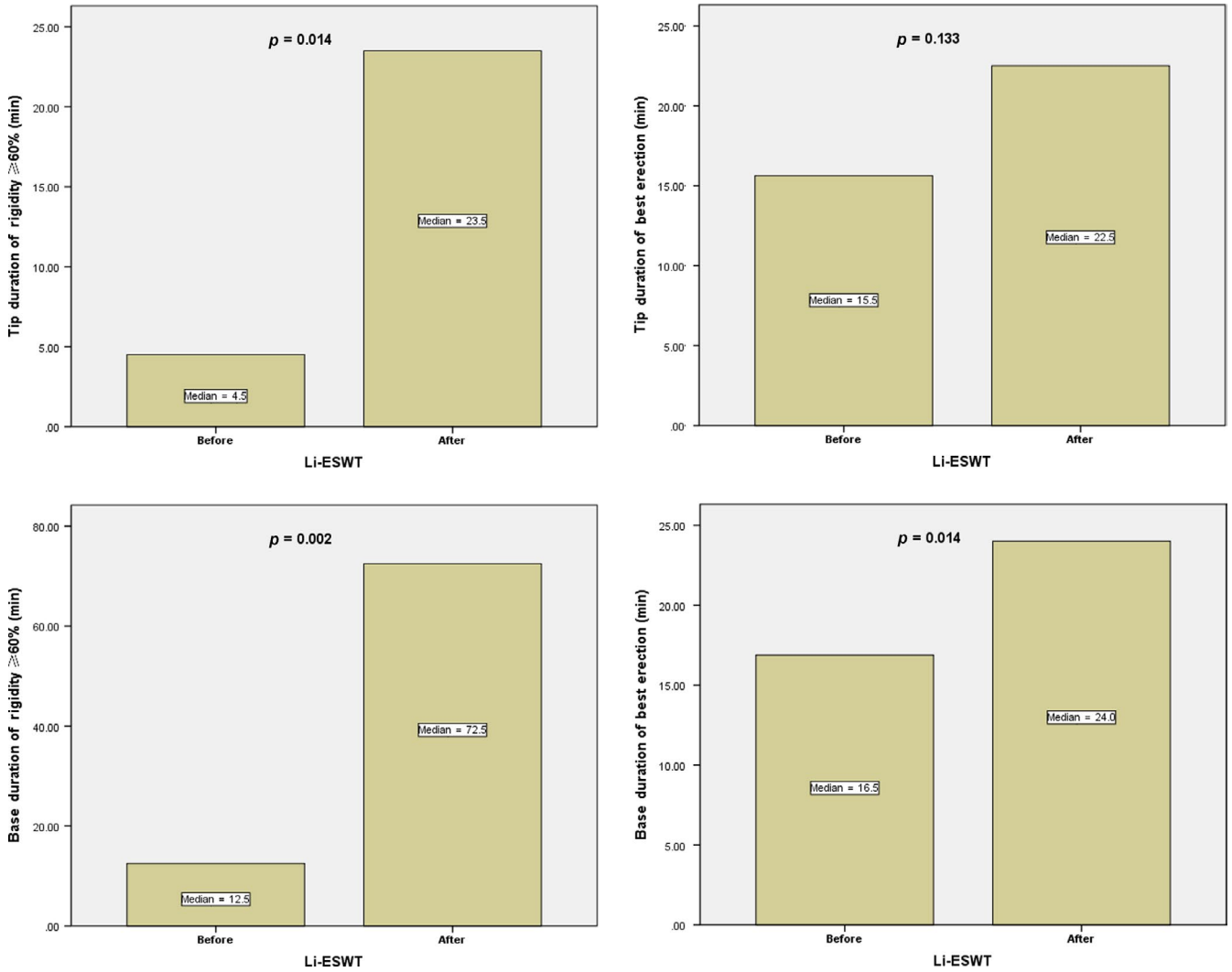

FIGURE 3 Duration of rigidity ≥60% and the best erection at penile tip and base before and after Li-ESWT. Li-ESWT, low-intensity extracorporeal shockwave therapy

before and after treatment are listed in Table 3. There were no significant haemodynamic changes of cavernous artery after Li-ESWT (all $p > .05$).

4 | DISCUSSION

These findings showed that Li-ESWT can significantly improve erectile function scores and nocturnal erectile function of ED patients. The results of EHS and self-reported erection hardness suggested that erection hardness was the most significant indicator of improvement after Li-ESWT. NPTR recording demonstrated that Li-ESWT significantly increased erectile rigidity and duration.

Li-ESWT as a treatment for ED has attracted widespread attention, more and more related studies have been carried out, and most of these studies have shown positive results. The IIEF score, the most common assessment tool for ED patients, was widely used in the evaluation of treatment effects. Three randomised controlled trials (RCTs) and one non-RCT reported that the IIEF scores increased significantly in the Li-ESWT group compared with the control group (Chitale et al., 2010; Hisasue et al., 2016; Vardi et al., 2012; Zimmermann, Cumpanas, Miclea, & Janetschek, 2009), and these studies suggested that Li-ESWT offered therapeutic benefit by 3 months. In the current study, we found that the IIEF-5 scores increased significantly at 1 month after treatment. The EHS is also a routine indicator for the evaluation of therapeutic effects. Many studies indicated that Li-ESWT increases the erectile hardness score in ED patients (Ayala, Cuartas, & Cleves, 2017; Hisasue et al., 2016; Olsen, Persiani, Boie, Hanna, & Lund, 2015; Yee, Chan, Hou, & Ng, 2014). However, some RCT findings showed that EHS did not improve as significantly after three months as it did after one month despite the therapeutic effects of both periods were statistically significant (Olsen et al., 2015; Yee et al., 2014). Our findings indicated that EHS significantly improved from 1 month after Li-ESWT, which was consistent with previous research results. Self-reported erectile symptoms are considered as the

TABLE 3 CDDU parameters at 1-month follow-up by Li-ESWT cohort

	Variable	Baseline	Follow-up 1 month	*p* value
Right CA	PSV	32.58 ± 11.40	34.39 ± 10.32	.985
	EDV	1.60(5.60, 12.00)	2.00 (5.00, 9.60)	.551
	RI	1.07 ± 0.18	1.09 ± 0.08	.690
Left CA	PSV	32.46 ± 10.72	31.74 ± 7.71	.492
	EDV	2.50(6.40, 9.60)	2.80(4.80, 4.90)	.676
	RI	1.04 ± 0.10	1.07 ± 0.08	.216

Abbreviations: CDDU, cavernous Duplex Doppler ultrasound; Li-ESWT, low-intensity extracorporeal shockwave therapy; CA, cavernous artery; PSV, peak systolic velocity; EDV, end-diastolic velocity; RI, resistance index.

important indicators for therapeutic effect evaluation in ED patients with failed sexual intercourse. In these study, we found that self-reported erectile hardness significantly improved after treatment, which supported the previous literature reports (Pelayo-Nieto et al., 2015; Ruffo et al., 2015).

The IIEF, EHS and self-reported erectile symptoms in our study and previous literature were purely subjective indicators from patient-reported assessment. However, effective treatment outcome assessment still requires more objective indicators. NPTR recording can be applied to measure the baseline of male erectile capacity (Jannini, Granata, Hatzimouratidis, & Goldstein, 2009), which also offers an objective measurement of erection potency change by a specific treatment (Bain & Guay, 1992; McCullough, Levine, & Padma-Nathan, 2008). In this study, we used Rigiscan to get an objective and reproducible NPTR recording. Vardi et al. firstly reported that Li-ESWT significant increased the duration and rigidity of nocturnal erection in ED patients at 1-month follow-up (Vardi, Appel, Jacob, Massarwi, & Gruenwald, 2010). Our results indicated that more NPTR parameters were improved at 2 months after Li-ESWT, including erection frequency, duration of total erection and erectile rigidity ≥60%, average and best erectile rigidity. These findings provide further objective evidence for Li-ESWT in the improvement of penile erectile capacity.

Kalyvianakis et al found that mean PSV at 3-month follow-up increased significantly compared with which at baseline after Li-ESWT (Kalyvianakis et al., 2018), and they also confirmed the improvement of Li-ESWT on penile haemodynamics up to 12 months (Kalyvianakis & Hatzichristou, 2017). However, we did not find any parameters of cavernous artery haemodynamics improved after Li-ESWT. These differences may be correlated with the short-term follow-up in our study (1 month), which might suggest that the cell proliferation, tissue regeneration and angiogenesis induced by Li-ESWT require longer time. Moreover, this discrepancy may also be explained by the limited cases.

The greatest strength of our study is that we confirmed the effectiveness of Li-ESWT on ED through a large number of objective NPTR parameters. However, some limitations should be mentioned in this study. First, the number of cases is relatively small. We need more cases and information to enrich the current findings. Second, the study was a pre- and post-treatment, nonrandomised and single-centre study. These results need multicentre, randomised, double-blind, placebo-controlled study to further support.

5 | CONCLUSIONS

In conclusion, Li-ESWT can improve subjective and objective indicators of erectile function in ED patients. Nocturnal erection reflected by NPTR parameters improved significantly after Li-ESWT. Large sample and long-term follow-up studies are needed to support the current findings.

CONFLICT OF INTEREST

None declared.

ORCID

Yan-Ping Huang https://orcid.org/0000-0002-3301-2847
Mu-Jun Lu https://orcid.org/0000-0002-3404-1260

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