Review Article

Comparative effectiveness radial shockwave therapy versus focused linear shockwave therapy as an erectile dysfunction treatment systematic review and meta-analysis

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Abstract

Low-intensity shockwave therapy (SWT) is a promising non-invasive treatment for vasculogenic erectile dysfunction (ED). Two primary modalities, focused linear shockwave therapy (fSWT) and radial shockwave therapy (rSWT), differ in energy delivery and tissue penetration. While fSWT is well-studied, rSWT remains less explored for ED despite its growing use. This study compares the effectiveness of fSWT and rSWT in improving erectile function. A systematic review and meta-analysis were conducted following PRISMA 2020 guidelines. Relevant studies published between 2009 and 2024 were identified through searches in PubMed, ScienceDirect, and Cochrane Library. Studies assessing erectile function using the International Index of Erectile Function (IIEF-5), Sexual Health Inventory for Men (SHIM), or Erection Hardness Score (EHS) were included. A random-effects model was applied to analyze standardized mean differences (SMD) and address heterogeneity. Fifteen studies met the inclusion criteria. Meta-analysis revealed that fSWT demonstrated superior efficacy compared to rSWT, with an SMD of 0.45 (95% CI: 0.04–0.86; $P < 0.005$). High heterogeneity was observed ($I^2 = 80\%$ for rSWT; $I^2 = 99\%$ for fSWT). fSWT and rSWT improved erectile function, but fSWT consistently produces better outcomes across IIEF-5, SHIM, and EHS scores.

Keywords: Erectile dysfunction, focused linear shockwave therapy, radial shockwave therapy, shockwave therapy

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Received: 18.01.2025, **Accepted:** 17.02.2025, **Published:** 17.04.2025.

INTRODUCTION

One new method of treating vasculogenic erectile dysfunction (ED) in males is low-intensity shockwave therapy (SWT). Numerous randomized trials with differing degrees of benefit have assessed the effectiveness of SWT in this context. Meta-analyses of these studies show that vasculogenic ED males had a considerable increase in the function of the erectile following SWT, despite significant variation in treatment regimens and devices.[1] Focused SWT (fSWT) has been employed in all preclinical and clinical investigations to date.[2]

Access this article online	
Quick Response Code:	Website: www.urologyannals.com
	DOI: 10.4103/ua.ua_13_25

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How to cite this article: Ramadhani T, Warli SM, Nasution R, Kadar DD, Warli MH. Comparative effectiveness radial shockwave therapy versus focused linear shockwave therapy as an erectile dysfunction treatment systematic review and meta-analysis. Urol Ann 2025;17:84-91.

The acoustic wave of energy known as an extracorporeal shockwave, which is applied in medicine, passes through tissues and causes a sudden increase and decrease in pressure at the interfaces of tissues. There are two distinct methods: focused shockwaves and nonfocused radial waves and acoustic waves can reach tissues. The two forms of shockwaves vary significantly in terms of how quickly pressure rises and falls, how well they can focus, and how deeply they can penetrate tissue (shockwave shape). Although the biological consequences of the various waveforms might differ, it is still unclear how these variations will affect particular indicators.

Extracorporeal Shock Wave Lithotripsy (ESWL) employs energy reflected from an acoustic source to produce focused shockwaves, which can be precisely targeted to specific tissue depths, ranging from 10 to 12 cm, for the treatment of urolithiasis This minimize energy dispersion and collateral harm to nearby tissues by enabling the waves to gather at a focal point for maximum energy.[3] The pressure wave rises and falls quickly (10 ns) as a focused shockwave. There are three different ways to start a pressure wave that can produce focused shockwaves: Piezoelectric, electrohydraulic, and electromagnetic. A region of interest can be targeted by the unique pressure wave they create.[4]

On the other hand, a radial wave, also called a dispersive shockwave, has its maximum energy point near The device's tip.[5] Subsequently, these acoustic waves disperse widely in all directions from the device's tip, rapidly losing energy. Human tissues can be penetrated by radial waves up to 3.5 cm in depth, depending on the energy intake. Compared to a concentrated shockwave, the energy profile involves a slower increase and decrease in pressure (5–10 μs). When a ballistic projectile repeatedly contacts an endplate, it creates a mechanical concussion that produces radial waves and dispersive acoustic waves. The bullet is forced against the endplate using two different mechanisms: an electromagnetic system and pneumatic air compression.

Although it is frequently used in physical therapy, dermatology, and orthopedics, radial wave therapy (rWT) is an alternate technique for producing acoustic waves that have not been widely used and tested for use with men who have ED.[6-9] Although rWT is frequently promoted as an evidence-based ED therapy option, its impact on men with vasculogenic ED is uncertain. Therefore, this study is sought to analyze the difference in efficacy between fSWT and rWT in clinical studies.

MATERIALS AND METHODS

Search strategy

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis 2020 guidelines were followed in the methodology and reporting of this meta-analysis. Using ScienceDirect, PubMed, and the Cochrane Library, a comprehensive search of the literature was conducted. The predefined keywords used in the literature search were "(Focused Linear Shockwave Therapy OR FSWT OR Focused Shockwave Therapy) AND (Erectile Dysfunction OR Impotence)" and "(Radial Shockwave Therapy OR RSWT OR Radial Wave Therapy OR Radial Wave) AND (Erectile Dysfunction OR Impotence)." Articles with relevant titles and abstracts would be included in this process so they may be evaluated in full and subjected to additional qualitative and quantitative analysis. All the studies that were considered in this review had to be published between 2009 and 2024, written in English, and have full-text accessibility. The specifics of the study search approach are displayed in Figure 1.

Inclusion and exclusion criteria

The primary goal of the research selection criteria was to identify studies that provided accurate information regarding the impact of fSWT and radial SWT (rSWT) on individuals with ED. Only studies meeting these criteria were considered for inclusion, ensuring an exhaustive analysis of the efficacy of rSWT and fSWT. We ensured the reliability and validity of the findings by applying the following exclusion criteria: (1) Unavailable full-text articles and (2) study that omitted important results.

Data extraction and risk of bias assessment

The name of the author, the publication year, the study design, and the erectile function scores obtained before and after the intervention – measured by the Erection Hardness Score (EHS), the Sexual Health Inventory in Men (SHIM), or the International Index of Erectile Function (IIEF-5) – were all extracted.

After that, we took data out of the publications we had chosen. The quality of the articles was also evaluated using Consolidated Standards of Reporting Trials (CONSORT) for clinical trials and The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) for observational studies. Every reviewer worked together to analyze the quality until a consensus was reached.

Outcome measure

The primary outcome measures assess the effectiveness of rSWT in enhancing erectile function relative to fSWT, utilizing standard deviations and 95% confidence intervals (CI) for statistical analysis. Mean difference (MD) or standardized mean difference (SMD) is employed to facilitate a thorough comparison of the therapeutic approaches. Using the DerSimonian and Laird approach,

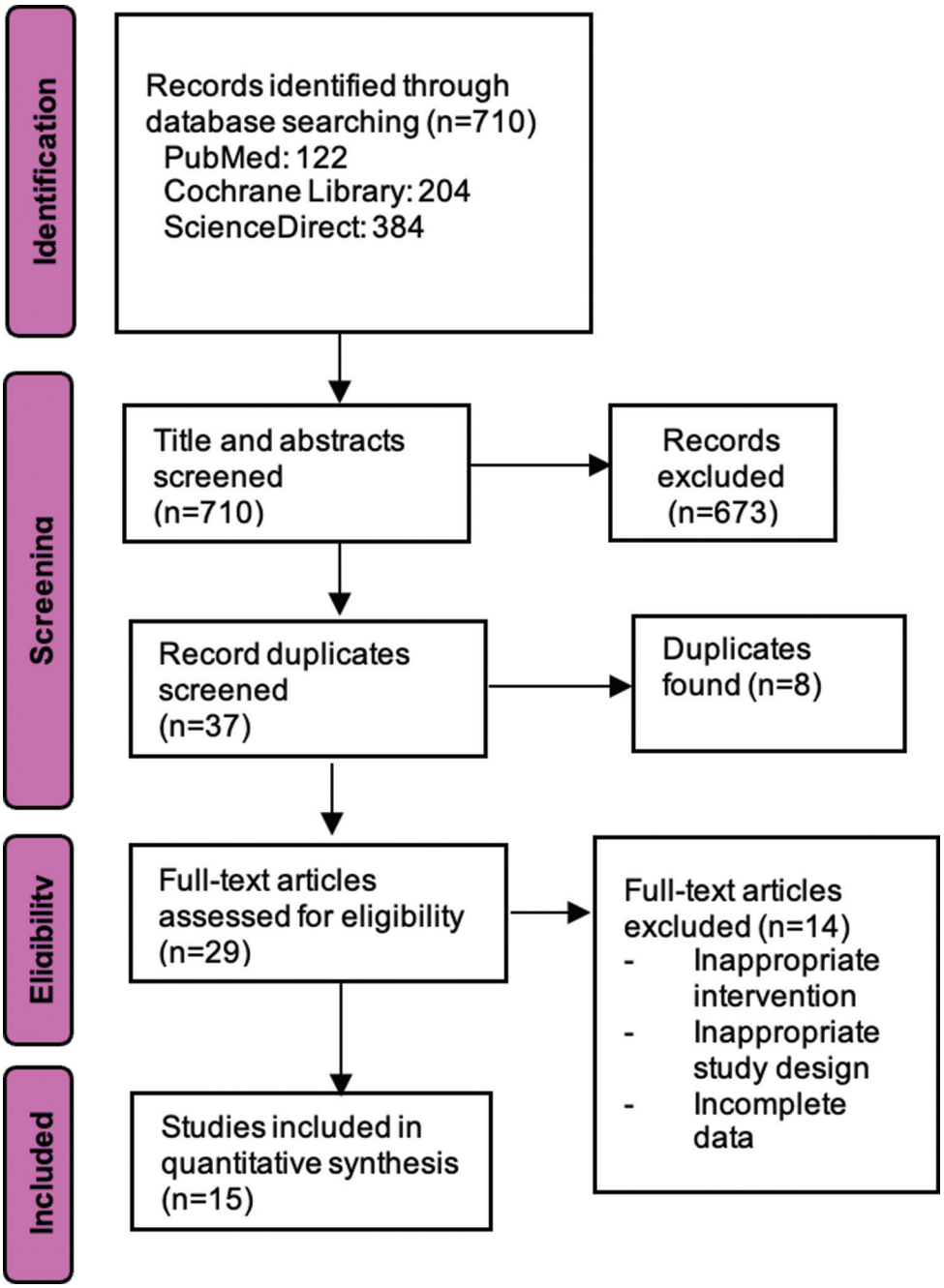

Figure 1: Diagram flow of literature search strategy for this meta-analysis

a random-effects model was employed because population differences between the studies might exist. The analysis was conducted in two phases. All continuous variables were initially evaluated to get the 95% CI for the SMD. Next, the standard errors (SE) of the respective SMDs were calculated. A Forest plot provided a comprehensive visual representation of the impact sizes and variability for each trial, including the SMDs and 95% CIs. The Forrest plot helps identify variation within the studies when comparing the overall efficacy of rSWT with fSWT. To provide an overview of the total effect estimate across all included studies, the Forrest plot additionally included the pooled SMD and its 95% CI from the random-effects model. Using the Higgins *I*-squared (I^2) statistical model, heterogeneity was examined. The results of the heterogeneity test were categorized as low (25%–50%), moderate (50%–75%), high (<75%), and negligible (0%–25%).

RESULTS

Included studies

From all databases, 710 studies were found in the first search. After the titles and abstracts were screened, 673 of

Table 1: Study characteristics

Author	Year	Study design	Intervention group (*n*)	Control group (*n*)	Patient characteristics	Intervention	Control	Outcome
Wu *et al*.[21]	2020	Retrospective observational	24	24	Men with ED	rSWT	fSWT 3000 shocks at 0.09 mJ/mm^2 each session	Between fSWT (6.2) and rWT (6.8) in SHIM score (*P*=0.42). 54% of males managed with fSWT demonstrated a notable enhancement in clinical outcomes (≥ grade 2 response) (*P*=0.42), as opposed to 75% of the rWT group's men. There were no known negative effects of any tools
Bryk *et al*.[22]	2023	Prospective nonrandomized trial	43	30	Men who had NS radical prostatectomy and had good preoperative EF	rSWT	Nonsham-controlled standard of care	The intervention arm did had a significantly higher median EHS than the control arm. With five patients (17%) and eleven patients (26%), respectively, within the control and intervention groups, No statistically significant variation was noted in the recuperation of EF (*P*=0.37)
Salinas *et al*.[20]	2022	RCT	40	40	Men with mild ED, free of comorbidities, sickle cell anemia, anticoagulant medication, or secondary ED-related problems	rSWT	Sham therapy	The IIEF-EF score changed by an average of RW group: 3.4 (95% CI 1.5–5.2) and control group: 4.2 (95% CI 2.5–5.9). There was no difference between the groups from one another (*P*=0.742). The median EHS score did not change, according to the evaluations. There were no notable adverse effects in one patient (2.5%) who underwent sham therapy and two patients (5%) who received radial wave therapy
Yamacake *et al*.[33]	2018	RCT	10	10	Men who have had ED for 6 months or longer	rSWT	Sham therapy	With a *P*<0.0001 (between the periods), After 4 months, the mean IIEF scores for sham therapy were 16.5±5 and 17.2±5.7 for Li-EWST. In 70% of cases, The improvement in the IIEF score was greater than five (from 0 to 10) of the Li-ESWT group and 10% (ranged from 1–14) of the Sham group. After a year, the Li-ESWT group's mean IIEF score change was 4.8
Fojecki *et al*.[17]	2017	RCT	63	63	Men who score <25 points on the IIEF-EF and have ED	fSWT	Sham therapy	The IIEF-EF score showed that the ESWT group had a success rate of 37.9% (OR = 0.95, 95% CI = 0.45-2.02, *P* = 0.902)compared to 38.3% for the sham group. The ESWT group's success rate was 3.5%, but the sham group's was 6.7%, based on the EHS score (OR = 0.44, 95% CI = 0.08-2.61, *P* = 0.369)
Sramkova *et al*.[23]	2019	RCT	30	30	Men who have had ED for 6 months or longer	fSWT	Sham therapy	At 4 and 12 weeks after therapyThe IIEF-5 erection quality scores showed statistically significant variations between the groups. EHS after week 12 (*P*=0.049 and *P*<0.001, respectively), and following week 12 (*P*<0.001), and a rise within the EHS following 4 and

Contd...

Table 1: Contd...

Author	Year	Study design	Intervention group (*n*)	Control group (*n*)	Patient characteristics	Intervention	Control	Outcome
								12 weeks (*P*=0.030 and *P*<0.001, respectively)
Rayegani *et al*.[24]	2020	RCT	16	15	Men with ED and chronic pelvic pain syndrome	fSWT	Pharmacotherapy with 4 sessions of sham-ESWT	The two group's IIEF scores did not differ statistically
Eryilmaz *et al*.[25]	2019	RCT	20	20	Men with ED	fSWT	Unfocused SWT	The mean IIEF-5 score of the unfocused group rose from 9.6±2.9 to 15.0±5.0 during the course of the 3-month follow-up, an increase of 6.3±3.3 (*P*<0.05). The IIEF-5 score of the targeted group increased by an average of 5.34 points, between 10.01±2.5 and 15.4±3.1. In conclusion, the IIEF-5 score of the unfocused ESWT group was far larger than the concentrated ESWT group
Kitrey *et al*.[26]	2016	RCT	37	18	Men with vasculogenic ED whose use of PDE5i was discontinued since it was ineffective	fSWT	Sham therapy	Forty-five percent of the males who got low intensity shock wave treatment saw an improvement in their IIEF-EF scores, although none of the sham group did (*P*=0.001)
Vardi *et al*.[27]	2012	RCT	40	20	Men with ED	fSWT	Sham therapy	Between visit 1 and follow-up 1, the group receiving treatment's IIEF-EF domain score improved significantly higher than the sham-treated group's
Yee *et al*.[28]	2014	RCT	30	20	Men with ED	fSWT	Sham therapy	EF index: ED domain scores for the sham arm and the arm of extracorporeal SWT with low intensity were 15.8±6.1 and 17.8±4.8, respectively, in week 13 (*P*=0.156). In week 13, Erection Hardness values were 2.7±0.5 and 2.4±0.9 on average, respectively (*P*=0.163)
Ladegaard *et al*.[30]	2021	RCT	20	18	Men who have had RARP and have ED	rSWT	Sham therapy	At 4 and 12 weeks, group A (the intervention group) showed a significant rise in IIEF-5 and EHS. The average EHS score rose by 12 weeks 0.5 points (*P*=0.019) and the average IIEF-5 score increased by 3.45 points (*P*=0.026)
Olsen *et al*.[31]	2014	RCT	51	54	ED-afflicted men of organic origin	rSWT	Sham theraphy	Following treatment, 29 men (57 percent of the active group) were capable of having sex and achieving an erection without the use of drugs. Only five males (9%) in the placebo group exhibited comparable outcomes (*P*=0.0001). After 5 weeks, the EHS revealed that males in the active group had significantly less ED; however, the IIEF, or EF domain, did not yield any noteworthy results
Kalyvianakis *et al*.[29]	2018	RCT	21	22	Patients with vasculogenic ED responding to PDE5is	fSWT	fSWT with fewer treatment session	MCIDs were attained by 71% of group B and 62% of group A., whereas 47% of group A and 65% of group B responded "yes" to SEP3 (*P*=0.02). Baseline mean peak systolic velocity for Group A

Contd...

Table 1: Contd...

Author	Year	Study design	Intervention group (*n*)	Control group (*n*)	Patient characteristics	Intervention	Control	Outcome
								and at the 3-month follow-up was 29.5 cm/s, while group B's was 29.6 cm/s and 35.4 cm/s (*P*=0.06)
Patel *et al*.[32]	2020	RCT	45	42	Men with ED	fSWT	fSWT with different treatment session	The IIEF-EF showed statistically significant (*P*<0.05) improvements at 6 months, with mean increases of 2.7 (95% CI=1.2–4.2) Groups A and B had respective scores of 2.7 points (95% CI=1.4–4.1) and 0.6 points (95% CI=0.3–0.8) and 0.5 (95% CI=0.2–0.8)

ED: Erectile dysfunction, RCT: Randomized controlled trial, IIEF: International Index of EF, RARP: Robotic nerve-sparing radical prostatectomy, PDE5: Phosphodiesterase type 5 inhibitor, fSWT: Focused SWT, rWT: Radial wave therapy, SWT: Shockwave therapy, EHS: Erection Hardness Score, Li-ESWT: Low-intensity extracorporeal SWT, OR: Odds ratio, CI: Confidence interval, EF: Erectile function, SHIM: Sexual Health Inventory in Men, MCID: Minimal clinically important differences

them were disqualified. Furthermore, eight of them were eliminated because they were duplicates. Subsequently, 14 further studies were eliminated due to their irrelevant outcomes or participants for this study. In the end, a quantitative synthesis was performed using 15 researches. Features of every study that was included are presented in Table 1.

Study characteristics and outcomes

Out of all the included studies, one had a STROBE score of 19.00/22.00, and the lowest CONSORT score (range: 18.00–22.50) was 18.00/25.00 in terms of risk assessment. The fact that almost two-thirds of the criteria were met in every study suggests that there was less chance of bias and generally high quality in all of the included research.

Quantitative synthesis

Figure 2a presents the MD of the improvement in outcome, measured between the control and rSWT groups. We discovered that the MD was 0.96 (95% CI; −0.37–2.29; $P = 0.16$). This analysis revealed a high heterogeneity with an I^2 of 80%; therefore, a model of random effects was applied. While the MD of the improvement in the outcome, measured among the control group and the fSWT group as presented in Figure 2b was 1.41 (95% CI; −0.42–3.23; $P = 0.13$) with an increased heterogeneity with an I^2 of 99% hence the random effect model was used again. As depicted in Figure 2c, the mean difference (MD) between rSWT and fSWT was further calculated, yielding a value of 0.45 (95% CI: 0.04–0.86; $P < 0.005$).

DISCUSSION

For men with vasculogenic ED, low-intensity SWT is becoming a more viable noninvasive choice or supplement to PDE5 medications. To date, shockwaves have been delivered using fSWT in preclinical and clinical research. The growing prevalence of rWT use, even in the lack of clinical research, could be attributed to the devices' user-friendliness and the lax FDA regulations surrounding them. With strong evidence to back its application, rWT is frequently employed in other sectors for conditions such as plantar fasciitis and venous ulcers.[10,11]

Microtrauma is one of the theorized modes of action of SWT, which promotes neuron regeneration, angiogenesis, and stem cell proliferation.[12,13] In ED rat models, SWT leads to increased release of vascular endothelial growth factor and endothelial nitric oxide synthase in the corpus cavernosum.[12] The biological consequences of rWT are not well-known because focused shockwaves were used in this research. However, it is plausible to suppose that The reaction to harm would be separate from the source of energy for waves In the event that the radial wave enters the target tissue and stresses the target cells in a way that is not fatal, particularly if a comparable clinical reaction is observed. The mild side effects of fSWT and rWT include paresthesia, edema, bruising, and discomfort in the treated area.[13]

Several meta-analyses have revealed the therapeutic benefits of concentrated SWT in ED patients.[14,15] Clavijo *et al*. found that following fSWT, participant's SHIM improved by 6.4 points, as opposed to 1.65 points in those receiving sham therapy in seven sham-controlled studies that were meta-analyzed, randomized studies.[14] According to a later meta-analyses, men receiving fSWT showed SHIM improvements ranging from 2.0 to 4.23.[15] On the other hand, the application and awareness of rWT in nonurological domains are growing. rWT has been widely employed in the orthopedic sector to treat a

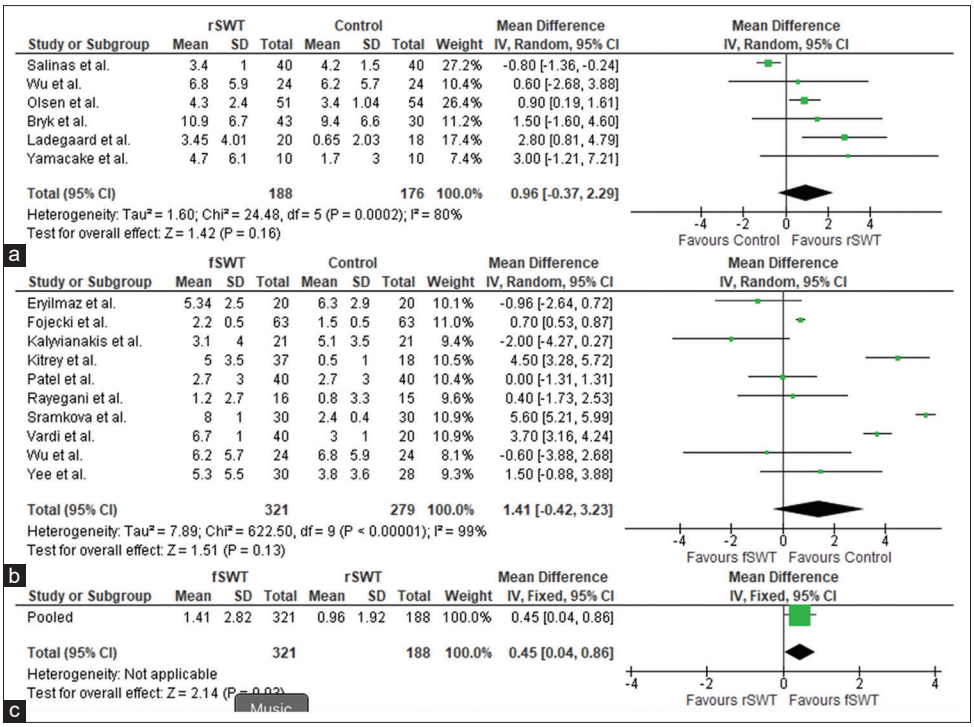

Figure 2: Forrest plot of (a) the effect of radial shockwave therapy (rSWT), (b) the effect of focused shockwave therapy (fSWT), and (c) the pooled effect between rSWT and fSWT

variety of disorders, including plantar fasciitis,[8,16] biceps tendinopathy,[16] and knee tendinopathy.[8] In soft-tissue musculoskeletal injuries, a meta-analysis of fSWT and rWT revealed that all therapy techniques are similarly safe; however, their effectiveness varies depending on the kind of injury. The meta-analyses predominantly comprised studies that restricted the use of PDE5 inhibitors during fSWT administration, thereby demonstrating the efficacy of fSWT as a monotherapy in patients likely unresponsive to PDE5 inhibitors. According to this research, fSWT may be useful for treating ED in nonresponders to PDE5i or in conjunction with PDE5i. Our meta-analysis showed that when comparing between rSWT and fSWT, fSWT showed a better and significant result than rSWT. The SMD between rSWT and fSWT was 0.45 (95% CI; 0.04–0.86; $P < 0.005$) suggesting a significantly better result reported and showed by the fSWT intervention in comparison to rSWT. This result was in line with the previously described studies in which there have been conflicting findings about the effectiveness of fSWT and rSWT in treating ED. The divergent rates of success of fSWT and rSWT[17-30] in such investigations are mostly attributed to patient co-existing illnesses and device characteristics. The shockwave distribution applied to the corpus cavernosum is one of the device's parameters. These findings show that the therapeutic efficacy is significantly impacted by various installation characteristics and treatment regimens. The surface area impacted by the shockwaves and the energy provided to the unit target area is directly correlated with the clinical outcomes of both interventions.

CONCLUSION

For ED patients, fSWT showed a significantly better result than rSWT. This approach has been shown to produce better improvements in terms of erectile function scores as measured by IIEF-5, EHS, and SHIM. We postulate that fSWT should be considered as one of the treatment modalities in treating patients with ED; either as a single or combined treatment with medication and exercises.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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