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ORIGINAL RESEARCH

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Comparative effectiveness of focused shockwave therapy and radial wave therapy for erectile dysfunction: a two center prospective cohort study

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Abstract

Background: Focused shockwave therapy (fSWT) has now taken its place in the algorithm for the treatment of vascular erectile dysfunction (ED) in current guidelines. Radial wave therapy (rWT) has started to be applied with the same indication in recent years and positive results have been reported. We aimed to compare the long-term effectiveness of fSWT and rWT in ED. **Methods**: A two-center study enrolled 200 patients aged 40 to 70 years with ED complaints. Patients were non-randomly allocated to either fSWT or rWT groups based on the clinic they visited. **Results**: After 3 months, the mean International Index of Erectile Function (IIEF) score for patients in the fSWT group was significantly higher compared with the baseline (13 ± 2.9 *vs.* 20.4 ± 4.7, $p < 0.001$), and the same trend was observed at 1 year (13 ± 2.9 *vs.* 18.1 ± 4.9, $p < 0.001$). Similarly, in the rWT group, the mean IIEF score was significantly higher at 3 months (13.1 ± 3 *vs.* 22.8 ± 4.6, $p < 0.001$) and 1 year (13.1 ± 3 *vs.* 19.4 ± 4.9, $p < 0.001$) compared with the baseline. However, there was no significant difference in the mean IIEF score changes between the two groups at both 3 months and 1 year. The proportion of patients giving a positive response to the Sexual Encounter Profile-2 (SEP-2) question was 81% at 3 months and 63.2% at 1 year in the fSWT group, and 88.9% at 3 months and 71.6% at 1 year in the rWT group, with no significant difference between the groups. **Conclusions**: Both fSWT and rWT are effective treatments for vascular-related ED, showing comparable efficacy in improving IIEF scores. **Clinical Trial Registration**: The study was retrospectively registered with https://www.isrctn.com/ as: ISRCTN14000407.

Keywords

Erectile dysfunction; Focused shock wave; Non-focused; Radial wave

Efectividad comparativa de la terapia de ondas de choque focalizadas y la terapia de ondas radiales en la disfunción eréctil: estudio de cohorte prospectivo multicéntrico

Resumen

Antecedentes: Nuestro objetivo fue comparar la efectividad a largo plazo de la terapia con ondas de choque focalizadas (fSWT) y la terapia con ondas radiales (rWT) en la disfunción eréctil. **Métodos**: En este estudio bicéntrico se incluyeron 200 pacientes de entre 40 y 70 años con quejas de disfunción eréctil. Los pacientes fueron asignados de forma no aleatoria a los grupos fSWT o rWT según el centro al que acudieron. **Resultados**: A los 3 meses, la puntuación media del Índice Internacional de Función Eréctil (IIEF) en el grupo fSWT fue significativamente superior a la basal (13 ± 2.9 *vs.* 20.4 ± 4.7; $p < 0.001$), manteniéndose esta mejoría al año (13 ± 2.9 *vs.* 18.1 ± 4.9; $p < 0.001$). De forma similar, en el grupo rWT la puntuación media del IIEF fue significativamente mayor a los 3 meses (13.1 ± 3 *vs.* 22.8 ± 4.6; $p < 0.001$) y al año (13.1 ± 3 *vs.* 19.4 ± 4.9; $p < 0.001$) en comparación con el valor basal. No se observaron diferencias significativas en los cambios medios del IIEF entre ambos grupos ni a los 3 meses ni al año. La proporción de pacientes con respuesta positiva a la pregunta el Perfil de Encuentro Sexual-2 (SEP-2) fue del 81% a los 3 meses y del 63.2% al año en el grupo fSWT, y del 88.9% a los 3 meses y del 71.6% al año en el grupo rWT, sin diferencias significativas entre los grupos. **Conclusiones**: Tanto la fSWT como la rWT son tratamientos eficaces para la disfunción eréctil de origen vascular, con una eficacia comparable en la mejoría de las puntuaciones del IIEF. **Registro del Ensayo Clínico**: Este estudio fue registrado retrospectivamente en https://www.isrctn.com/ con el identificador: ISRCTN14000407.

Palabras Clave

Disfunción eréctil; Terapia con ondas de choque focalizadas; Terapia con ondas radiales; Ondas de choque no focalizadas

1. Introduction

Erectile dysfunction (ED) is the inability to achieve and maintain an erection sufficient for sexual intercourse [1]. It is known to affect nearly 50% of men between the ages of 40 and 70 [2]. Treatment is tailored to the etiology and severity of the disease [3]. In vascular-related cases, shockwave treatment (SWT) can be tried if it is not improved with phosphodiesterase type 5 inhibitors (PDE5i) or if PDE5i has not been tried at all [3]. Shockwave therapy is divided into two types according to its type: focused shockwave therapy (fSWT) and unfocused radial wave therapy (rWT). The energy profile of a focused shockwave is characterized by a rapid rise and fall of the pressure wave, which occurs over a timescale of 10 nanoseconds; these mechanisms create a unique pressure wave that can be directed at a focal point and these waves can reach up to 10–12 cm in human tissues [4]. Radial waves have their maximum energy point at the tip of the device. These acoustic waves then disperse radially away from the tip of the device, with rapid energy attenuation. The energy profile of a radial wave has a slower rise and fall of pressure than a focused shockwave, taking place over a timescale of 5–10 microseconds. Radial waves are generated by a mechanical concussion, in which a ballistic projectile repeatedly strikes an endplate, generating the dispersive acoustic wave. The depth of penetration of radial waves varies depending on the energy input, but can reach up to 3.5 cm in human tissues [5].

We aimed to compare the effectiveness of fSWT and rWT on ED at one year follow-up.

2. Materials and methods

This is a prospective, non-randomized, two-center cohort study. Patient recruitment was conducted between January 2024 and June 2024. The allocation of patients to each group was based on the clinic they visited. As the study was conducted in two different cities, so randomization was not performed. Patients who visited our clinic in one clinic were treated with fSWT, while those who visited the other clinic received rWT. Patients who underwent fSWT were classified as the first group, and those who received rWT were classified as the second group.

2.1 Eligibility criteria

Patients with complaints of ED, lasting at least 3 months, aged between 40 and 70 years, and having an International Index of Erectile Function (IIEF) score between 6 and 21 were included in the study.

Patients with untreated hypogonadism, history of pelvic surgery (such as radical prostatectomy), receiving other treatments for ED (such as oral PDE5 inhibitors or intracavernosal injections), using medications that could aggravate ED (such as metoprolol or thiazides), having neurologic conditions suggestive of neurogenic ED (uncontrolled or long-standing diabetes, multiple sclerosis, *etc.*), or having psychogenic ED were excluded from the study. Patients were prohibited from taking PDE5-inhibitor drugs or herbal extracts containing them for one year, and it was confirmed that the patients included in the study did not use them.

2.2 Study design

Prior to treatment, all patients completed the IIEF-5 questionnaire. After ensuring that patients met the inclusion and exclusion criteria, IIEF and Sexual Encounter Profile-2 (SEP-2) forms were completed.

Patient's age, body mass index (BMI), duration of ED, presence of vascular risk factor diseases (such as diabetes, hypertension, dyslipidemia, ischemic heart disease), baseline

IIEF scores, IIEF scores and responses to SEP-2 question were recorded at 3 months and 1 year after treatment.

2.3 Treatment protocol

Patients in the first group received three consecutive weekly treatments, and 12 sessions, using a low-energy shockwave generator (ED1000™, manufactured by Medispec in Gaithersburg, MD, USA). The treatment protocol consisted of two initial sessions. This was followed by a three-week period with sessions twice a week. After this initial phase, a three-week break was incorporated. Subsequently, the treatment resumed with another three weeks of twice-a-week sessions. fSWT was applied to five specific penile sites, including three sites on the penile shaft and both crura. Each site received 300 shockwaves at an intensity of 0.09 mJ/mm^2, delivered over a 3-minute period (equivalent to a frequency of 120 shocks per minute). Treatment was administered only on one side of the penile shaft, as the shockwave depth was sufficient to reach both corpora. It was performed on both sides of the midline on the dorsal penis, not laterally or on the dorsum.

Patients in the second group underwent the rWT procedure with the radial device (Zimmer enPuls Pro, Zimmer Medizin Systeme GmbH, Neu-Ulm, BY, Germany). This device utilizes an electromagnetically generated radial pulse. The rWT regimen involved administering 10,000 shocks per session at a frequency of 15 Hz and an energy level of 70 mJ. Patients received three consecutive weekly treatments. The treatment protocol consisted of two initial sessions. This was followed by a three-week period with sessions twice a week. After this initial phase, a three-week break was incorporated. Subsequently, the treatment resumed with another three weeks of twice-a-week sessions. To deliver the shockwaves, manual and gentle stretching of the penis was performed, targeting six treatment sites: one at each cruse (1000 shocks) of the penis on the perineum, and two locations on the shaft bilaterally (2000 shocks).

2.4 Data synthesis

Pre- and post-treatment IIEF scores were compared, and the objective benefit based on IIEF score change was noted. Minimal clinically important differences (MCIDs) were used for this purpose. The MCIDs in the EF (Erectile Function) domain were determined based on the baseline severity of ED. For mild ED, a difference of two points was considered clinically significant, while for moderate ED, it was five points, and for severe ED, it was seven points [6]. Responses to the SEP-2 question were noted as “positive” or “negative”.

2.5 Statistical analysis

The minimum number of patients required for final analysis was calculated as 78. To address multiple testing, we prespecified a two-tier inferential strategy. The primary confirmatory comparison was the between-group difference in IIEF change at 3 and 12 months, for which familywise Type I error was controlled using the Holm procedure ($\alpha = 0.05$). Secondary analyses (MCID proportions, SEP-2 responses, subgroup comparisons) were considered exploratory, and false discovery rate (FDR) control using the Benjamini-Hochberg method was applied. Within-group pre–post comparisons were retained only as descriptive supportive analyses, not for inferential claims, the primary analysis was reformulated as a between-group comparison using analysis of covariance (ANCOVA) with baseline IIEF as a covariate. As sensitivity analysis, we additionally performed a longitudinal mixed-effects model including time, treatment, and time $\times$ treatment interaction. The distribution of data was measured using the Kolmogorov-Smirnov test. Since the distribution was normal, parametric tests (Student-*t*) were used for comparing parametric data, and non-parametric data were compared using the chi-square test. The Wilcoxon test was used to compare each group before and after treatment. A *p*-value less than 0.05 was considered statistically significant. All analyses were performed using the Statistical Package for the Social Sciences (SPSS for Windows, version 17.0., IBM Inc., Chicago, IL, USA).

3. Results

A total of 100 patients were included in each group. All patients completed the 12 treatment sessions; however, some could not be reached at the 12-month follow-up. This is particularly due to the rWT group being located in an area with many summer houses, making it susceptible to seasonal effects. The number of patients who completed the one-year follow-up was 95 in the fSWT group and 81 in the rWT group. Both groups had similar average age, BMI, symptom duration, and the proportion of patients with vascular risk factors (Table 1).

In the ANCOVA analysis comparing the two groups, only the effect of treatment modality on the one-year outcomes was statistically significant. Therefore, the two groups can be considered comparable (Table 2).

The baseline average IIEF scores were similar in both groups (13 ± 2.9 *vs.* 13.1 ± 3, $p = 0.594$). After 3 months, the mean IIEF score for patients in the fSWT group was significantly higher compared with the baseline (13 ± 2.9 *vs.* 20.4 ± 4.7, $p < 0.001$), and the same trend was observed at 1 year (13 ± 2.9 *vs.* 18.1 ± 4.9, $p < 0.001$). Similarly, in the rWT group, the mean IIEF score was significantly higher at 3 months (13.1 ± 3 *vs.* 22.8 ± 4.6, $p < 0.001$) and 1 year (13.1 ± 3 *vs.* 19.4 ± 4.9, $p < 0.001$) compared with the baseline. However, there was no significant difference in the mean IIEF score changes between the two groups at both 3 months and 1 year (Fig. 1).

The mean IIEF score changes at 3 months and 1 year were similar between the groups. According to the MCIDs, the proportion of patients benefiting from treatment in the fSWT group was 80% at 3 months and 59% at 1 year, while in the rWT group, it was 85.2% at 3 months and 65.4% at 1 year, and there was no significant difference between the two groups. The proportion of patients giving a positive response to the SEP-2 question was 81% at 3 months and 63.2% at 1 year in the fSWT group, and 88.9% at 3 months and 71.6% at 1 year in the rWT group, with no significant difference between the groups (Table 3).

TABLE 1. Comparison of the patients' baseline characteristics.

	Focus	Radial	*p* value
Patients number (n)	95	81	
Mean age (yr) ± sd	47.5 ± 8.5	48.7 ± 9.2	0.255
Mean Body-Mass Index (kg/m^2)	27.3 ± 2.5	27.5 ± 2.5	0.698
Erectile dysfunction duration (mon) ± sd	5.02 ± 2.6	6.2 ± 4.3	0.357
Presence of the vascular risk factors (%)	48 (50.5%)	42 (51.9%)	0.861

sd: standard deviation.

TABLE 2. ANCOVA analyze of groups.

Source	Type III Sum of Squares	Sig.	Partial Eta Squared
Corrected Model	161.856	0.092	0.054
Intercept	101.840	0.015	0.034
Comorbidity	25.392	0.221	0.009
Age	31.371	0.174	0.011
Body Mass Index	0.604	0.850	0.000
ED interval	4.493	0.606	0.002
Treatment modality type	72.287	0.040*	0.025
Error	2856.593		0.000
Total	8621.000		
Corrected Total	3018.449		

**: is significant p value under 0.05. ED: Erectile dysfunction; Sig.: significance.*

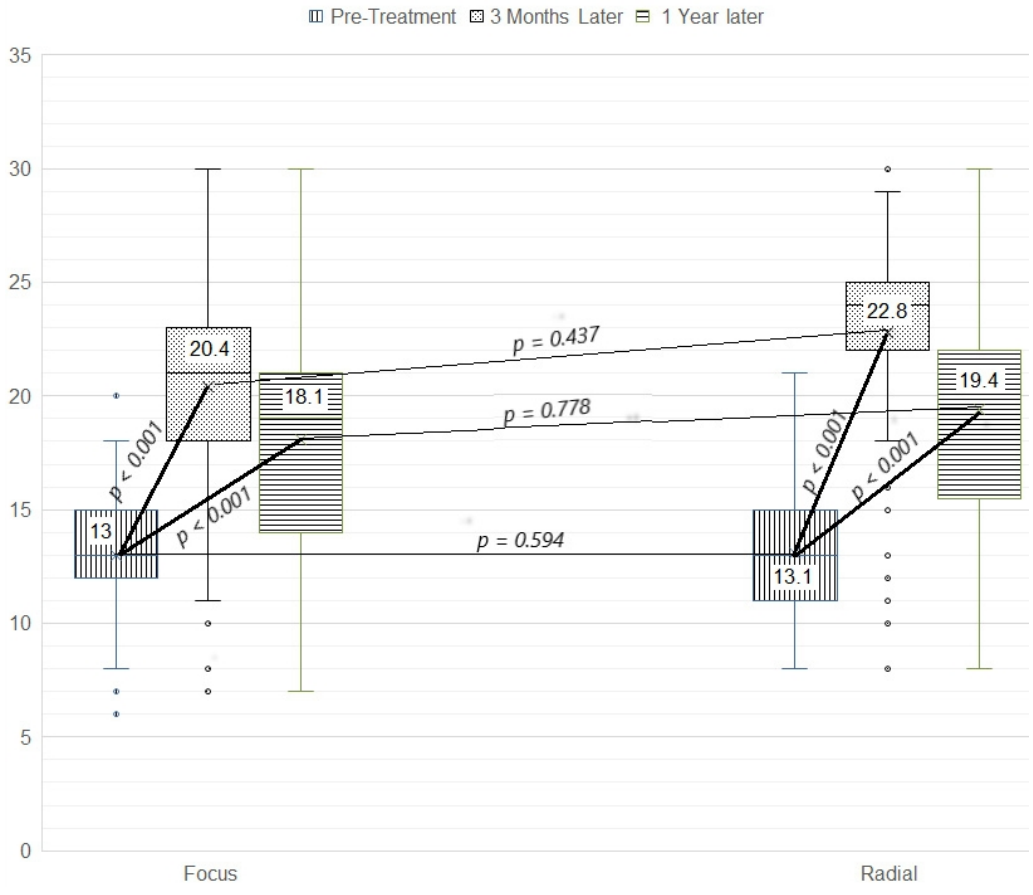

FIGURE 1. Mean IIEF scores changing in terms of time and wave type (*p* value is significance under 0.05).

TABLE 3. Comparison of the groups in terms of results.

	Focus	Radial	*p* value
Mean IIEF score changing three months later ± sd	7.4 ± 3.6	9.6 ± 3.9	0.216
Mean IIEF score changing one year later ± sd	5.1 ± 3.9	6.3 ± 4.4	0.138
Three Months Later MCIDs	76 (80.0%)	69 (85.2%)	0.368
One Year Later MCIDs	56 (58.9%)	53 (65.4%)	0.377
Positive SEP-2 Three Months Later	77 (81.0%)	72 (88.9%)	0.150
Positive SEP-2 One Year Later	60 (63.2%)	58 (71.6%)	0.235

IIEF: International Index of Erectile Function; MCIDs: minimal clinically important differences; SEP-2: Sexual Encounter Profile-2; sd: standard deviation.

4. Discussion

SWT for ED was first introduced by Vardi *et al.* [7] in 2010. Since then, it has become widespread worldwide and has been accepted as an effective treatment [8]. It has also now taken its place in the ED treatment algorithm [3].

Focal shock waves and radial waves are two distinct forms of acoustic waves utilized in various medical and therapeutic applications. The primary disparity between these waves lies in their maximum pressure levels and pulse durations. In the case of radial waves, the maximum pressure typically ranges from 0.1 to 1 megapascal (MPa). These waves exhibit a pulse duration of 1 to 5 milliseconds, with a characteristic outward or radial propagation [9].

Despite being occasionally mislabeled as shock waves, radial waves function as sound waves rather than true shock waves. Importantly, they operate at significantly lower maximum pressures and possess a slower rise time, preventing them from achieving the shock effect. Additionally, their propagation lacks a focal point, dispelling any shock effects and focal characteristics [4].

Conversely, focal shock waves exhibit a substantially higher maximum pressure, reaching up to 100 MPa. The pulse duration for focal waves is notably shorter, not exceeding 2 milliseconds. Unlike radial waves, focal shock waves are capable of concentrating their energy at a specific focal point. This concentration of pressure at the focal point is crucial for inducing the shock effect, differentiating them from radial waves. It is essential to clarify that radial waves, being sound waves, do not share the same shock-inducing properties as true shock waves. The slower rise time and absence of a focused point in radial waves contribute to their inability to generate the shock effect. Furthermore, there is a notable distinction in the biological effects of these waves, particularly in terms of cavitation. While focal shock waves are known to produce cavitation effects, it remains unverified whether radial waves can elicit similar effects [10].

SWT is a treatment method that applies high-level sound waves to the body, and is thought to work by stimulating angiogenesis, which is the growth of new blood vessels [11]. This can improve blood flow to the affected area and promote healing. SWT has been shown to improve erectile function in men with ED by boosting neovascularization, which is the growth of new blood vessels in the erectile tissue and stimulate angiogenesis [12]. SWT does this by promoting regeneration and repair of damaged tissue [13]. We could not find any article examining focused and non-focused in the same study. However, in two different studies, it was stated that two different techniques improved angiogenesis through the same mediators, endothelial Nitric oxide Synthase and Vascular Endothelial Growth Factor (eNOS and VEGF) [14, 15].

Although rWT and focused shockwave therapy fSWT differ substantially in their physical characteristics with rWT generating low-pressure, non-focused acoustic waves and fSWT producing high-pressure waves with a defined focal zone, both modalities may still induce overlapping biological responses at the tissue level [16]. Current evidence suggests that mechanical stimulation above a certain energy threshold, regardless of the wave's focality, can trigger similar downstream effects, including transient hyperemia, modulation of nociceptor activity, and mechanotransductive signaling, leading to improved tissue perfusion and pain reduction [17]. Chawla *et al.* [18] demonstrated that in rats treated with radial wave therapy (rWT), VEGF expression was increased and penile microperfusion was doubled via the nitric oxide/cyclic guanosine monophosphate (NO/cGMP) pathway.

In our study, there was an average increase of 7 points in the IIEF score in the fSWT group after 3 months. The average change in the IIEF score in the studies in the literature is between 5–12.5 points, which is parallel to our study [3, 19–22]. The average change in the IIEF score at the end of one year was between 3.5–8.7 points, and it was found to be 5.1 in our study [22–26]. Similarly, the percentage of patients who benefited according to MCIDs in the literature is between 71–86% for 3 months after, and it was found to be 80% in our study [19, 20, 27]. Spivak *et al.* [28] found that the percentage of patients who benefited according to MCIDs decreased from 79.5% to 65.9% at the end of one year. A decrease from 80% to 59% was detected in our study.

The average increase in the IIEF score after rWT in the literature is between 5–6.3 points [26–30]. The average increase in the IIEF score after rWT 1 year is around 5 points [29]. It was found to be 6.3 points in our study, which is similar to the literature.

Sramkova *et al.* [24] found that patient's age, baseline IIEF value, ED duration, and presence of vascular risk factors did not affect treatment success. However, Oginski *et al.* [31] reported that patients with vascular risk factors responded positively to treatment and did not benefit in other cases. In our

study, both groups were similar in terms of age, BMI, symptom duration, and average baseline IIEF score.

Wu *et al.* [32] found that the percentage of patients who responded clinically according to MCIDs was 54% in the fSWT group and 75% in the rWT group in their comparative study; however, they stated that there was no significant statistical difference between them. Eryılmaz *et al.* [29] reported that the average change in the IIEF score was very close between the two groups; although the success rate was found to be 50% in the fSWT group and 65% in the rWT group, there was no significant statistical difference between the two groups. In our study, we could not detect a significant statistical difference between the two groups, although the average change in the IIEF score, MCIDs success and the percentage of patients who responded "positively" to SEP-2 were slightly better in the rWT group. In their meta-analysis, Ramadhani *et al.* [33] included 15 studies with heterogeneous designs, including both sham-controlled and non–sham-controlled trials, rather than uniformly comparing fSWT and rWT against sham groups. Therefore, any assumption that all included studies were based exclusively on sham-controlled comparisons would be inaccurate. With regard to individual studies, Eryilmaz *et al.* [29] reported that the unfocused SWT group demonstrated a "far larger" improvement in IIEF-5 scores compared to the focused group; however, no detailed between-group statistical analysis was provided for this comparison, and thus these findings should be interpreted with caution. In contrast, Wu *et al.* [32] reported higher success rates in the rWT group (75% *vs.* 54%), although this difference was not statistically significant ($p = 0.42$), reflecting variability in treatment effects across studies. Nevertheless, the meta-analysis demonstrated that both modalities were associated with improvements in erectile function outcomes. Specifically, the pooled analysis showed a statistically significant difference favoring fSWT over rSWT (SMD (Standardized Mean Difference) = 0.45, 95% CI (Confidence Interval): 0.04–0.86; $p < 0.005$), while both treatment groups exhibited positive mean differences compared to their respective control conditions (rSWT: MD = 0.96, 95% CI: −0.37–2.29; fSWT: MD = 1.41, 95% CI: −0.42–3.23), indicating overall therapeutic benefit . These findings support the notion that both fSWT and rWT are clinically effective treatment options, which is consistent with and reinforces the results of our study.

As a limitation, the non-randomized allocation based on clinical site introduces the possibility of baseline socioeconomic or disease-severity imbalances between centers. Although major demographic variables were statistically comparable, unmeasured confounders cannot be excluded. Second, the study relied exclusively on patient-reported outcomes (IIEF, SEP-2). No objective physiological measures—such as penile duplex Doppler ultrasound, nocturnal penile tumescence monitoring or endothelial function testing—were collected. Therefore, improvements should be interpreted as subjective functional gains rather than physiologically confirmed recovery. Third, the attrition rate was notably higher in the rWT group (19%) compared with the fSWT group (5%). The treatment completion rates were the same; however, there were difficulties reaching some patients during follow-up. This was due to the rWT group being located in an area with many summer houses and experiencing substantial migration after the earthquake. Finally, the absence of a sham-control arm prevents exclusion of placebo effects, which are known to be substantial in ED interventions. Accordingly, our conclusions focus on comparative effectiveness rather than absolute efficacy.

5. Conclusions

Both focused shockwave therapy (fSWT) and radial wave therapy (rWT) resulted in significant and sustained improvements in erectile function over a one-year follow-up in men with vascular-related erectile dysfunction. No significant differences were observed between the two modalities in terms of IIEF score changes, MCID achievement, or SEP-2 responses. Despite their differing physical characteristics, both treatment approaches demonstrated comparable clinical effectiveness. These findings suggest that rWT may serve as an effective alternative to fSWT in the management of erectile dysfunction. However, given the non-randomized design, reliance on patient-reported outcomes, differential follow-up rates, and the absence of a sham-control arm, the results should be interpreted with caution. Future randomized, sham-controlled trials incorporating objective vascular assessments and longer follow-up durations are warranted to better define the comparative and long-term efficacy of these modalities, as well as the optimal treatment protocols and need for maintenance therapy.

ABBREVIATIONS

fSWT, Focused shockwave therapy; rWT, Radial wave therapy; ED, erectile dysfunction; IIEF, International Index of Erectile Function; MCIDs, minimal clinically important differences; SEP-2, Sexual Encounter Profile-2; PDE5i, phosphodiesterase type 5 inhibitors; BMI, body mass index; MPa, megapascal; eNOS, endothelial Nitric oxide Synthase; VEGF, Vascular Endothelial Growth Factor; cGMP, cyclic guanosine monophosphate; NO, nitric oxide; EF, Erectile Function; FDR, false discovery rate; ANCOVA, analysis of covariance.

AVAILABILITY OF DATA AND MATERIALS

The data are contained within this article.

AUTHOR CONTRIBUTIONS

GB, YO, CY—research conception and design. YO, IB, AY—data acquisition; statistical analysis. CY, AY, IB—data analysis and interpretation; administrative, technical, or material support. GB, AY, CY—drafting of the manuscript. YO, CY, AY—critical revision of the manuscript; supervision. GB, IB, AY—approval of the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study and all experimental methods were authorized by Samsun University Local Ethics Committee. Registration

number: SUKAEK-2023 12/24. Written informed consent was obtained from all the patients for study participation.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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