FPIN's Help Desk Answers

Shockwave Therapy for Erectile Dysfunction

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Clinical Question

Is shockwave therapy an effective treatment for erectile dysfunction?

Evidence-Based Answer

Shockwave therapy, a noninvasive treatment that applies extracorporeal shock waves to the penile shaft, can provide mild to moderate improvement in patients with erectile dysfunction of varying etiologies, including vascular, neurogenic, and procedural causes. It can also benefit patients for whom previous medical therapies were not effective. (Strength of Recommendation: A, meta-analysis of randomized controlled trials [RCTs] and four RCTs.)

Evidence Summary

A 2019 meta-analysis of 10 RCTs (N = 872) evaluated the effectiveness of shockwave therapy vs. sham treatment for erectile dysfunction in patients with a mean age of 58 years (range = 27 to 81 years).[1] Most participants had vasculogenic erectile dysfunction, and phosphodiesterase inhibitors were effective in most patients. Participants received shockwave therapy or sham treatment once or twice per week for three to six weeks. Erectile function was measured by the International Index of Erectile Function (IIEF), which is self-assessed and scored from 6 to 30, with higher scores indicating better function. In eight trials (n = 519), shockwave therapy resulted in greater improvement (mean difference [MD] = 4.0; 95% CI, 2.1 to 5.8) and higher scores (MD = 3.7; 95% CI, 0.29 to 7.1) at follow-up compared with the control group. More patients receiving shockwave therapy gained a minimal clinically important difference in IIEF score of greater than 4 points (seven trials; n = 556; odds ratio = 8.5; 95% CI, 2.6 to 28). No significant adverse effects were reported. Eight of the 10 studies were considered to have a low risk of bias based on the Cochrane risk of bias assessment, but the two studies with higher risk of bias were among the largest (n = 264).

A 2022 RCT (N = 60) examined the effectiveness of shockwave therapy for erectile dysfunction among patients for whom pharmacologic therapy was not effective.[2] The mean age of participants was 56 years (range = 42 to 68 years), and patients had mild to moderate vascular erectile dysfunction for at least six months that did not improve with oral phosphodiesterase inhibitors or intracavernosal therapy. Other etiologies for erectile dysfunction were excluded. Patients received shockwave therapy or sham treatment twice per week for six weeks. The primary outcome measures were erectile function at one, three, and six months after treatment according to the abridged five-item IIEF (self-assessed and scored from 5 to 25, with higher scores indicating better function) and the Erection Hardness Score (EHS; single-item self-assessment scored from 1 to 4; scores greater than 2 indicate erection adequate for penetration). Compared with sham treatment, shockwave therapy resulted in higher five-item IIEF scores at one month (MD = 2.8; P = .028), three months (MD = 3.6; P = .029), and six months (MD = 4.0; P = .028). At six months, 21 of 30 patients (70%) in the treatment group had improved five-item IIEF scores greater than 5, compared with 3 of 30 patients (10%) in the sham treatment group (P = .028). Shockwave therapy also led to a higher EHS compared with sham

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treatment at one month (MD = 1.2; $P = .029$), three months (MD = 1.2; $P = .035$), and six months (MD = 1.3; $P = .033$). This RCT did not provide 95% CIs. No adverse effects were reported. The study was limited by a lack of blinding of the shockwave technician, although all patients and investigators were blinded.

A 2021 RCT (N = 76) examined shockwave therapy effectiveness among patients for whom phosphodiesterase inhibitors were not effective.[3] Participants (median age = 60 years) had vascular erectile dysfunction of any severity for at least six months; those with erectile dysfunction of nonvascular etiologies were excluded. Patients received weekly shockwave therapy or sham treatments for four weeks. Erectile function was measured with the IIEF and the EHS at one, three, and six months after treatment. The shockwave therapy group had improved IIEF scores compared with the sham treatment group at three months (mean change = 3.5; interquartile range, 0 to 10 in the shockwave group vs. mean change = −0.5; interquartile range, −11 to 1 in the control group; $P = .004$). No differences were noted between the groups at one or six months. Shockwave therapy resulted in a higher percentage of patients with an EHS greater than 2 at six months (21 of 40 [53%] vs. 10 of 36 [28%] in the control group; $P = .028$). No adverse effects were reported.

A 2021 RCT (N = 42) examined shockwave therapy effectiveness for erectile dysfunction in patients with diabetic neuropathy.[4] Patients (mean age = 48 years) had well-controlled diabetes mellitus with neuropathy and mild to moderate erectile dysfunction for at least six months. Patients with other likely causes of erectile dysfunction and those for whom phosphodiesterase inhibitors were not effective were excluded. Participants received shockwave therapy or sham treatment twice weekly for six weeks, with a three-week rest period halfway through. All patients were trained to perform Kegel exercises three times per day for six weeks. The primary outcome was the score on the five-item IIEF. The treatment group had significant improvement at three months (from 12.8 ± 3.2 to 17.5 ± 2.7 after treatment; $P < .001$), whereas the sham treatment group did not significantly improve (from 12.8 ± 2.6 to 13.4 ± 2.9 after treatment; $P = .19$). Shockwave therapy had a higher percentage of patients achieving erections sufficient for intercourse compared with sham treatment (15 of 21 [71%] vs. 2 of 21 [9.5%]; $P < .001$). No adverse effects were reported. The study was limited by a lack of clarity on whether the shockwave technician and researchers were blinded.

A 2021 RCT (N = 38) examined shockwave therapy effectiveness for erectile dysfunction after radical prostatectomy.[5] Patients had erectile dysfunction for at least six months, with onset after prostatectomy. The mean age of participants was 62 years, and 90% had previously used oral phosphodiesterase inhibitors; a mean of 61% had treatment that was considered effective. Patients received shockwave therapy or sham treatment weekly for five weeks and measured erectile function using the five-item IIEF and EHS at four and 12 weeks. The treatment group had improved five-item IIEF scores at four weeks (MD = 2.4; standard deviation [SD] = 3.3) and 12 weeks (MD = 3.5; SD = 4.0), whereas the control group improved at four weeks (MD = 1.3; SD = 1.9) but not at 12 weeks (MD = 0.65; SD = 2.0). No adverse effects were reported. This study was limited by a relatively short follow-up and small sample size.

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