

Where do we stand?—Recent update of shock wave therapy as penile rehabilitation for postprostatectomy erectile dysfunction

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In the United States, prostate cancer is the most common type of cancer among men. Approximately 268,490 newly diagnosed prostate cancer cases and 34,500 prostate cancerrelated deaths were estimated in the United States in 2022 (1). In South Korea, prostate cancer was documented to be the most common cancer among men for the first time in 2022, with approximately 22,391 newly diagnosed prostate cancer cases and 2,278 prostate cancer-related deaths (2).

The goal of radical prostatectomy is to secure oncologic outcome (free from cancer recurrence) as well as functional outcome [restoration of urinary continence (3) and erectile function (4)]. Despite the remarkable advances in radical prostatectomy technique such as nerve-sparing procedure and the widespread application of robotic surgical system, postoperative 1- or 2-year potency rates have been variously reported to be 54–90% or 63–94%, respectively (5). Furthermore, despite treatment with phosphodiesterase type-5 inhibitors, less than 50% of the patients returned to their preoperative baseline erectile function.

Low-intensity shock wave therapy to maximize erectile function recovery after radical prostatectomy is a new emerging therapeutic technique for erectile dysfunction with favorable regenerative effects. In 2016, Frey *et al.* (6) conducted a pilot study that included 16 patients with more than 12-month after bilateral nerve-sparing radical prostatectomy. These patients with erectile dysfunction underwent two sessions of low-intensity shock wave therapy every other week for a period of 6 weeks. They concluded that low-intensity shock wave therapy can improve erectile function, with median improvement in International Index of Erectile Function-5 scores of 3.5 (P=0.0049) and 1 (P=0.046) at 1 month and 12 months after low-intensity shock wave therapy, respectively. The use of erectogenic aids were permitted in this study. The combination of lowintensity shock wave therapy, medicated urethral systems for erections, and phosphodiesterase type-5 inhibitors was 'somewhat' beneficial for recovery of erectile function. To our best knowledge, this trial was the only study published before 2022 that focuses specifically on low-intensity shock wave therapy for postprostatectomy erectile dysfunction.

In 2022, we conducted a prospective trial comparing the efficacies of 'early' low-intensity shock wave therapy plus daily tadalafil therapy with daily tadalafil-only therapy for postprostatectomy erectile dysfunction in patients with prostate cancer who underwent bilateral interfascial nervesparing radical prostatectomy (robotic or open) (7). From April 2019 to March 2021, 165 patients were enrolled in this prospective study, with 80 of them completing it successfully. All patients were given tadalafil daily. Lowintensity shock wave therapy comprised a total of six sessions performed on days 4, 5, 6, and 7 and on the

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2nd and 4th week after radial prostatectomy. Each lowintensity shock wave therapy session consisted of 300 shocks delivered at each of the five treatment points for 15 minutes at an energy density of 0.09 mJ/mm² and a frequency of 120 shocks per minute. Thirty-nine patients were treated with tadalafil-only (group A), whereas 41 were treated with tadalafil and low-intensity shock wave therapy simultaneously (group B). At postoperative 6 months, group B had a significantly higher proportion of patients with Erection Hardness scores ≥ 3 (4/39 vs. 12/41) (P=0.034), and multivariate analysis showed that low-intensity shock wave therapy was the only independent factor for predicting Erection Hardness scores ≥ 3 (odds ratio, 3.621; 95%) confidence interval, 1.054-12.437; P=0.041). There were no serious side effects related to early low-intensity shock wave therapy. Thus, we demonstrated that early low-intensity shock wave therapy combined with daily tadalafil therapy for postprostatectomy erectile dysfunction is more effective than tadalafil alone. To the best of our knowledge, our trial is the first to compare the efficacy and safety of early lowintensity shock wave therapy plus phosphodiesterase type-5 inhibitors for erectile dysfunction in patients with prostate cancer undergoing nerve-sparing radical prostatectomy to those of oral phosphodiesterase type-5 inhibitors. The lack of a control group (no phosphodiesterase type-5 inhibitors use and no low-intensity shock wave therapy application) and an only-low-intensity shock wave therapy treatment group or a sham treatment group, however, is a major limitation of this study. The small patient cohort and nonrandomization of treatment groups could have resulted in selection bias. Short follow-up period is another drawback. In addition, imaging studies involving objective assessments, such as dynamic duplex ultrasound of the penis or nocturnal penile tumescence and rigidity tests, were not performed in this trial.

An interesting study that contradicts the results of the aforementioned papers was recently published. Bryk *et al.* (8) investigated whether 'radial wave therapy' can improve the recovery of early erectile function after nerve-sparing radical prostatectomy through a prospective, nonrandomized, open-label trial. Radial wave therapy differs from lowintensity shock wave therapy in that it generates lower pressure waves with lower peak energy. This is the first trial of radial wave therapy for penile rehabilitation after nerve-sparing radial prostatectomy. Postoperative erectile function outcomes were analyzed and compared between the radial wave therapy (6 weekly treatments started approximately 2 weeks postoperatively) plus standard of care (phosphodiesterase type-5 inhibitors) group (n=43) and the non-sham-controlled standard of care group (n=30). In the control and intervention groups, erectile function was restored in 5 (16.6%) and 11 (25.6%) patients, respectively (defined as International Index of Erectile Function-5 scores ≥ 17 and Erection Hardness scores ≥ 3), which was not a significant difference (P=0.37). The intervention arm, however, had a significantly higher median Erection Hardness scores than the control group (P=0.03). There were no serious side effects related to radial wave therapy. Nevertheless, this study has several limitations, including a small sample size, nonrandomization, no blinding, and the absence of a sham-controlled group. Furthermore, we must consider that the differences between the results of our study and the present study are that the energy intensity of shock wave therapy is different and the definition of erectile function recovery they set is slightly more stringent.

To overcome the limitations of these nonrandomized, noncontrolled studies, large-scale randomized controlled trials are required to validate their findings.

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