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Shock wave therapy found efficacious in treating ED

Treatment success seen even in non-responders to PDE-5 inhibitors, pooled data show

October 01, 2015
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Middlebury, CT—Experience with low-intensity extracorporeal shock wave therapy (Li-ESWT) from multinational clinical trials demonstrates it is a safe, effective, and well-tolerated treatment for erectile dysfunction (ED), including in men who do not respond to an oral phosphodiesterase type-5 (PDE-5) inhibitor, reported Robert Feldman, MD, at the AUA annual meeting in New Orleans.

"Li-ESWT was associated with rapid and robust improvement in objective and subjective efficacy measures that were significantly superior to sham-treated controls. In addition, benefits were achieved among men with all severity levels of ED and were durable through follow-up to 1 year," said Dr. Feldman, who was one of the investigators and is in private practice in Middlebury, CT.

"Now, further dose-response studies are planned to define the optimal treatment protocol for select populations."

Li-ESWT for ED using the ED1000 Medispec applicator is under review by the FDA. It is currently approved in over 20 countries worldwide. Compared with extracorporeal shockwave lithotripsy, the treatment for ED involves 90% less shock wave bar pressure.

"Li-ESWT is quiet, painless, and requires no anesthesia," Dr. Feldman said.

Each Li-ESWT treatment session involves the delivery of 300 shocks to each of five sites (proximal, mid and distal along the penile shaft, and on the right and left at the level of the crura) at an energy intensity of 0.09 mJ/mm^2. In the clinical trials, men received 12 treatments administered in two 3-week cycles of twice-weekly sessions, with a 3-week rest period between cycles. Each treatment session lasts about 15 minutes.

Dr. Feldman reported data from five randomized, placebo-controlled studies conducted in the United States, Israel, Greece, and India and three single-arm, open-label studies undertaken in Israel and Japan. The pooled cohort included 440 men assigned originally to active treatment and 164 men in sham control groups. Depending on the protocol, eligible men were either responders to or had failed PDE-5 inhibitor treatment. However, all men had a baseline International Index of Erectile Function erectile function (IIEF-EF) domain score between 5 and 19. The U.S. trial also required abnormal nocturnal penile tumescence (NPT) parameters.

Considering trials enrolling PDE-5 inhibitor responders, evaluations conducted after only six treatments were administered showed a mean change in IIEF-EF of 5.4 in Li-ESWT patients. There was improvement across all levels of ED severity at baseline.

Improvements maintained at 6, 12 months

The IIEF-EF analyses also showed there was further benefit after the second cycle of treatments—mean change from baseline IIEF-EF at 1 month after the twelfth treatment was 7.4—and the improvements were fairly well maintained 6 months and 12 months after the last treatment (mean change, 6.4 and 6.9, respectively). Data from sham-treated groups showed mean change from baseline IIEF-EF scores ranged between 0.2 and 2.5.

Treatment success, defined as a minimally clinical important difference in the IIEF-EF change, was achieved by two-thirds of men at 1 month after the last Li-ESWT treatment, and this level of success was maintained at follow-up through 12 months. Success rates in the sham groups varied across the different trials and ranged from about 9% to 37.5%.

Objective efficacy assessments collected included NPT, peak systolic velocity with color Doppler ultrasound, and flow-mediated dilation. The data for these endpoints consistently showed statistically significant differences favoring the active treatment groups versus controls.

Benefits of Li-ESWT were also observed in men who were PDE-5 inhibitor treatment failures as demonstrated by improvements in IIEF-EF scores. In addition, the men became responders when rechallenged with a PDE-5 inhibitor and had improvements in both IIEF-EF domain scores and erectile hardness scores.

Adverse events occurring in men receiving Li-ESWT were infrequent (incidence, ≤0.4%), mild, and resolved without any intervention. They were limited to reports of tingling, burning, application site hypersensitivity, and skin rash related to the application gel.

Dr. Feldman is a consultant for Medispec. Several of his co-authors are consultants/advisers for Medispec, and one co-author is an employee of the company.