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## Words of Wisdom

### Re: The Effect of Low-intensity Shock Wave Therapy on Moderate Erectile Dysfunction: A Double-blind, Randomized, Sham-controlled Clinical Trial

Kalyvianakis D, Mykoniatis I, Pyrgidis N, et al.

J Urol 2022;208:388–95

#### Expert's summary:

Kalyvianakis et al. reported their findings from a randomized clinical trial involving 70 men with moderate erectile dysfunction (ED) assessed as being purely vasculogenic [1]. On the basis of the theory that low-intensity shock wave therapy (LI-ESWT) induces endothelial damage with subsequent neoangiogenesis, patients were equally assigned to 12 sessions of either LI-ESWT or sham therapy. The authors found that 79% in the LI-ESWT group and 0% in the sham group had achieved a clinically meaningful improvement in their erectile function at 3 mo after completion of treatment. The International Index of Erectile Function score for the erectile function domain had improved in the LI-ESWT group by 4.4 points more than in the sham group (95% confidence interval 3.4–5.4;  $p < 0.001$ ). No significant side effects were observed in the study.

#### Expert's comments:

LI-ESWT has emerged as a potentially curative treatment for ED. In the latest European Association of Urology guidelines, the modality has received a weak recommendation for use in vasculogenic ED. The authors' group is well respected and the positive results will be used to promote the treatment further and may help in moving it up as a first-line option for ED. However, caution is still warranted. Notably, the results from randomized controlled trials are heterogeneous, with the largest studies showing no clear benefit over sham treatment [2,3]. Furthermore, trials have been hampered by high dropout rates, potential issues with blinding, and a surprising lack of placebo responses in the sham groups [4]. The latter issues could also play a role in the trial by Kalyvianakis et al. The authors report that the sham probe generated noise and vibrations without delivering any shockwave energy. As in other trials on LI-ESWT, it is difficult to understand how this was not noticed by participants and personnel. As previous trials on ED showed clinical benefits in approximately one-third of men assigned to placebo, the lack of response should at least raise some

eyebrows [5]. However, the varying results may also be caused by use of different devices and different treatment protocols in different patient populations. If it can be convincingly shown that a specific LI-ESWT protocol leads to a long-term improvement in erectile function, this would be a major leap forward and create a paradigm shift in andrology. Considering the discrepancies and unanswered questions in published studies, it is imperative that the positive results are reproduced before LI-ESWT is moved to the first line for ED. Finally, it should be noted that while LI-ESWT does not seem to have any side effects, it is time-consuming and costly for patients.

**Conflicts of interest:** The author is a speaker for Boston Scientific and Astellas Pharma.

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