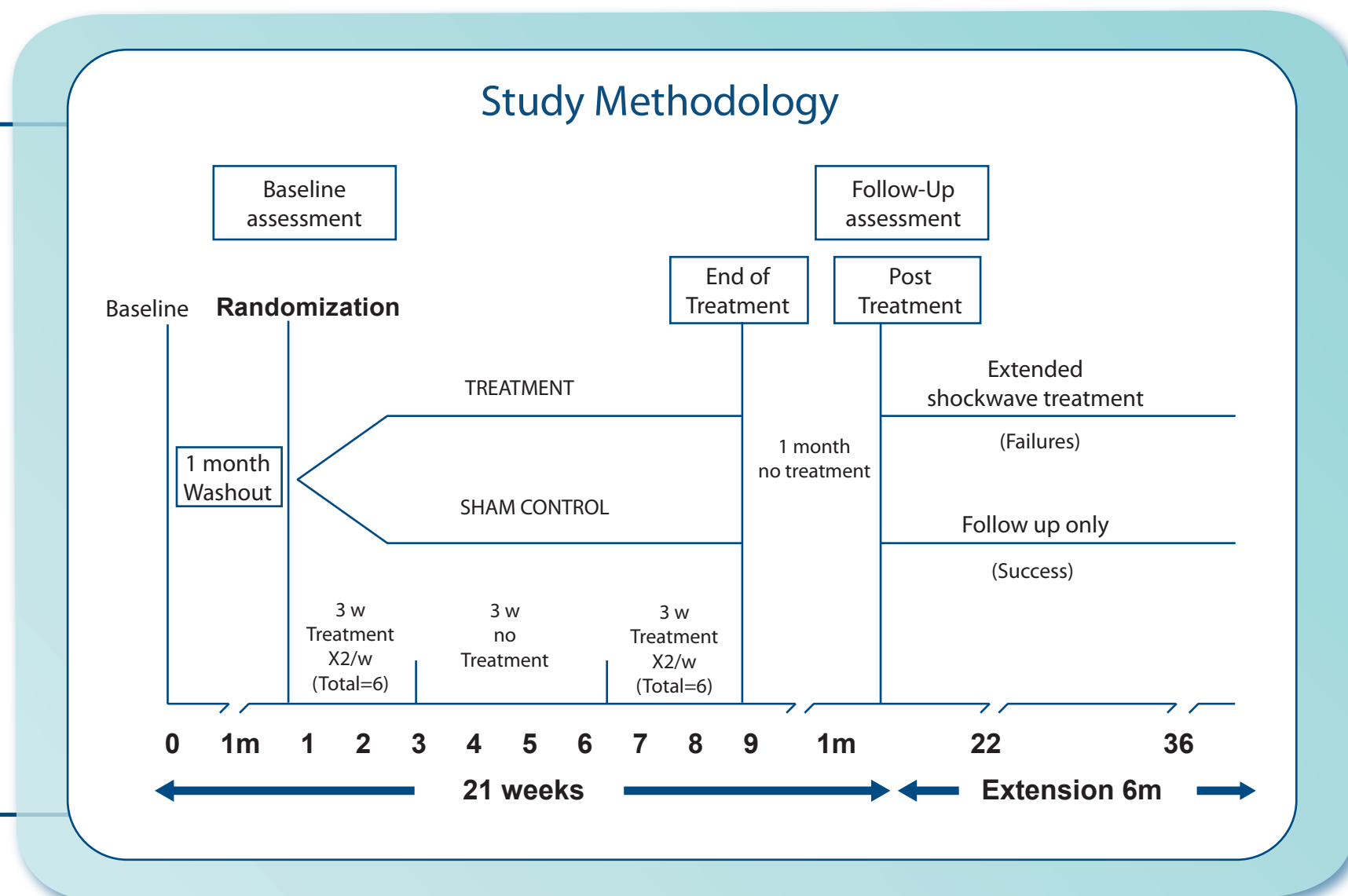


Objectives and Aim:

In a preliminary pilot study we have been able to show that Low Intensity Shock Wave Therapy (LI-ESWT) has a valuable effect on erectile function in patients responding to PDE5i's. The aim of this study was to validate these results in a double-blind sham-controlled manner on a larger group of ED patients.

Design and Methods:



We screened 84 subjects from whom 66 were randomized, 6 dropped out during the study. Data from 60 vasculogenic ED patients were analyzed who at screening were responders to PDE5i therapy (SHIM score >21). Age range was 27-77 (mean age 56.5y). After a one-month washout (visit 1), they underwent a baseline assessment of erectile function using validated questionnaires and objective penile endothelial function testing (using the flow mediated dilatation technique (FMD)). At this visit a blinded randomization to treatment (2/3) and sham (1/3) was performed. The treatment protocol included 12 LI-ESWT sessions, twice a week for 3 weeks, repeated after a 3-week no-treatment interval. During the whole period of the study no PDE5i was allowed and re-evaluation of erectile function was performed at the last visit (one-month post treatment).

RESULTS & CONCLUSIONS

Results

The initial average IIEF-ED at visit 1 was 12.3 with no significant difference between the groups. When comparing results of erectile function parameters between visit 1 and the last follow up visit (4 months from first treatment session), we found that the average increase in IIEF-ED score for the treatment group was 6.7 ± 5.5 vs. 2.2 ± 6.2 for the sham ($P=0.0098$). 26/40 (65%) of the treated had an increase of ≥ 5 points compared to 20% of the sham $P=0.0007$. Moreover, according to the EDITS questionnaire, the treated patients were significantly more satisfied with treatment vs. sham (28.9 ± 10.2 vs. 35.7 ± 10.8 respectively, $p=0.0025$). All FMD parameters significantly increased only in the treatment group ($P=0.0009$). No adverse events were reported.

Conclusions

In this first randomized sham controlled double blind study we have demonstrated that applying LI-ESWT directly to the penis has a clinical significant effect on the erectile mechanism and hemodynamics. This study requires further investigation in a larger scale of ED population and needs more basic science research in order to fully understand its mechanism of action.

