

## Publication

Clinically relevant changes in sexual desire, satisfying sexual activity and personal distress as measured by the profile of female sexual function, sexual activity log, and personal distress scale in postmenopausal women with hypoactive sexual desire dis

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**INTRODUCTION:** Transdermal testosterone patch (TTP) treatment produced statistically significant improvements in a satisfying sexual activity (SSA), sexual desire, and personal distress in postmenopausal women suffering from hypoactive sexual desire disorder (HSDD), but clinical significance of these changes was not determined. **AIM:** To quantify the magnitude of change in three principal outcomes measures determined by HSDD patients as associated with the perception of meaningful benefit with TTP therapy. **METHODS:** The criteria for defining responders were determined using anchoring methodology and receiver operating characteristics analysis to establish minimum important differences (MIDs) in a representative subsample of 132 patients in two randomized, controlled trials in surgically menopausal women with HSDD (N = 1,094). Perceived benefit was established based upon the question "Overall, would you say that you experienced a meaningful benefit from the study patches?". These data defined responders and established MIDs for changes in sexual desire, SSA, and personal distress. The MIDs were applied to the two trials to establish responder rates in each treatment group. **MAIN OUTCOME MEASURES:** Changes in score that correspond to the MID for sexual desire, SSA, and personal distress, and responder rates in each treatment group based upon these values. **RESULTS:** Increases in frequency of SSA of greater than 1 activity/4 weeks, increases in sexual desire score of  $\geq 8.9$ , and decreases in the personal distress score of  $\geq 20.0$  were identified as threshold improvements best able to differentiate responders and nonresponders. The responder rate was significantly higher ( $P < 0.001$ ) in the testosterone group vs. placebo for all three outcomes measures (sexual desire, 50% vs. 34%; SSA, 44% vs. 30%; personal distress, 51% vs. 39%). **CONCLUSIONS:** Changes in sexual desire, SSA, and personal distress observed with TTP treatment in surgically menopausal women with HSDD were clinically significant and were associated with a meaningful treatment benefit.

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