

## Improvement in sexual quality of life of the female partner of men with erectile dysfunction following vardenafil treatment: a randomised, double-blind, placebo-controlled study

Antonio Martín-Morales, Alessandra Graziottin, Gilbert Bou Jaoudé, Frans Debruyne, Jacques Buvat, Manfred Beneke, Dieter Neuser

**Objectives:** To assess the efficacy of vardenafil in men with erectile dysfunction (ED) and determine the effects of treatment of the man on the female partner's sexual quality of life.

**Design and methods:** Study participants comprised men aged 18–64 years with ED and their female partners. Eligible men had ED of  $\geq 6$  months' duration, and a female partner who was motivated to support their ED treatment. Eligible female partners had a total Female Sexual Function Index (FSFI) score  $>23.55$ , indicating an absence of significant sexual dysfunction. Following a 4-week screening period, the man was randomised to treatment with vardenafil 10 mg or placebo, which could be titrated to 20 or 5 mg after 4 weeks. Primary efficacy measures (assessed at week 12/last observation carried forward [LOCF]) were: (1) Sexual Encounter Profile Question 3 (SEP3); and (2) improvement in female partners' sexual quality of life, assessed using the quality of life domain of the modified Sexual Life Quality Questionnaire (mSLQQ-QOL).

**Results:** The intent-to-treat population included 343 couples, with 168 and 175 men randomised to receive vardenafil and placebo, respectively. Vardenafil treatment significantly improved rates of successful intercourse and the female partners' sexual quality of life. Least squares (LS) mean SEP3 success rates after 12 weeks of treatment were 67.2% (9.5% baseline) vs 24.2% (12.4% baseline) in the vardenafil and placebo groups, respectively ( $p < 0.0001$ ). In female partners, LS-mean mSLQQ-QOL scores were 68.2 (28.8 baseline) for vardenafil vs 40.5 (24.6 baseline) for placebo ( $p < 0.0001$ ).

**Conclusions:** Vardenafil treatment of men with ED improves rates of successful intercourse and the sexual quality of life of the female partner, including women with mild sexual dysfunction.