

Effect of nightly versus on-demand vardenafil on recovery of erectile function in men following bilateral nerve-sparing radical prostatectomy.

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Abstract

BACKGROUND: To date, no data have been available from large, well-designed trials comparing on demand and nightly dosing of phosphodiesterase type 5 (PDE5) inhibitors on recovery of erectile function in postprostatectomy patients with erectile dysfunction (ED). **OBJECTIVE:** To investigate the effect of early postoperative dosing with vardenafil, administered either nightly or on demand, compared with placebo on recovery of erectile function in men with ED following bilateral nerve-sparing radical prostatectomy (NSRP) surgery. **DESIGN, SETTING, AND PARTICIPANTS:** A randomised, double-blind, double-dummy, multicentre, parallel group study conducted at 87 centres across Europe, Canada, South Africa, and the United States. For inclusion, patients had to be scheduled to undergo bilateral NSRP within 1 mo of screening and have a normal International Index of Erectile Function erectile function domain (IIEF-EF) score of > or =26 at screening. A total of 628 men, aged 18-64 yr, were randomised to treatment. Study design consisted of a 9-mo double-blind treatment period, a 2-mo single-blind washout period, and an optional 2-mo open-label period. **INTERVENTION:** Patients received placebo, nightly vardenafil, or on demand vardenafil. **MEASUREMENTS:** Primary outcome measure was the percentage of subjects with an IIEF-EF score of > or =22 after the 2-mo washout period. Secondary variables included mean per-patient success rates for Sexual Encounter Profile (SEP) questions 2 and 3. **RESULTS AND LIMITATIONS:** No statistically significant differences were observed among treatment groups in the proportion of patients with an IIEF-EF score of > or =22 or in SEP3 success rates after the washout period. On-demand vardenafil treatment resulted in significantly greater IIEF-EF scores and better SEP3 response rates than placebo over the entire treatment period. **CONCLUSIONS:** In this study of men with ED following bilateral NSRP, vardenafil was efficacious when used on demand, supporting a paradigm shift towards on demand dosing with PDE5 inhibitors in this patient group. **TRIAL REGISTRATION:** European clinical trials database (EudraCT; available at <http://eudract.emea.europa.eu/>). Trial registration number: 11336