



Letter to the Editor

Reply to Giacomo Novara and Vincenzo Ficarra's Letter to the Editor re: Francesco Montorsi, Gerald Brock, Jay Lee, et al. Effect of Nightly versus On-Demand Vardenafil on Recovery of Erectile Function in Men Following Bilateral Nerve-Sparing Radical Prostatectomy. *Eur Urol* 2008;54:924–31

We would like to thank Dr Novara for his interesting and insightful comments regarding our article, “Effect of Nightly versus On-Demand Vardenafil on Recovery of Erectile Function in Men Following Bilateral Nerve-Sparing Radical Prostatectomy” [1].

We presented results from a randomised, double-blind, double-dummy, multicentre, parallel group study which investigated the benefits of vardenafil, administered nightly or on demand, on the recovery of erectile function in men following nerve-sparing radical prostatectomy (NSRP). This study consisted of three phases: (1) a 9-mo double-blind treatment phase, initiated within 14 d of surgery, in which patients were randomised to treatment with on-demand vardenafil and nightly placebo, on-demand placebo and nightly vardenafil, or on-demand placebo and nightly placebo; (2) a 2-mo washout period; and (3) a 2-mo open-label phase in which all participants received on-demand vardenafil. Results from the study support the use of on-demand vardenafil in post-NSRP patients, as demonstrated by the significant improvements in erectile function seen in this patient group during the double-blind phase of the study. Importantly, the study findings did not support the use of nightly vardenafil post-NSRP, with no demonstrable long-term benefit of nightly dosing beyond that achieved with on-demand vardenafil following the washout period.

In his letter, Dr Novara raised the question of how many tablets were taken by patients in the on-demand group versus those in the nightly group

during the double-blind treatment phase, stating that “the differences in vardenafil doses between the two active arms might be very small in the case of patients with a high on-demand intake.” We would agree that access to these data offers the reader a better opportunity to critically evaluate the results of our study, and we are happy to provide them. During the double-blind phase of the study, patients receiving on-demand vardenafil and nightly placebo took an average of 1.28 vardenafil tablets per week. This highlights the effectiveness of vardenafil for the treatment of erectile dysfunction (ED) in men following NSRP, even when taken relatively infrequently.

Another important point highlighted by Dr Novara was the favourable efficacy of vardenafil observed during the open-label phase of the study, in which all patients took vardenafil on-demand regardless of their previous treatment group. During this phase, we observed no reduction in the efficacy of on-demand vardenafil among patients who were randomised to placebo treatment during the double-blind phase of the study. Therefore, we would agree with Dr Novara's interpretation that during the 12-mo interval between surgery and the start of the open-label phase, the fibrosis and veno-occlusive dysfunction in cavernosal tissues which has been hypothesised to take place [2,3] did not have a detrimental effect on treatment success with a phosphodiesterase type 5 (PDE5) inhibitor. Consequently, for those patients who do not wish to undergo treatment for ED during the postsurgical period, PDE5 inhibitors may be initiated with good effect after a delay of up to 1 yr, with no significant reduction in efficacy.

Conflicts of interest: Professor Montorsi, Dr Brock, Dr Lee, and Professor Stief have acted as paid consultants or investigators for Bayer Schering Pharma AG.

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management, analysis, and interpretation of the data; and the preparation, review, and approval of the manuscript.

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