



## 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 read with great interest the randomized controlled trial published by Montorsi et al in the October issue of *European Urology* comparing the efficacy of nightly and on-demand treatments with vardenafil following bilateral nerve-sparing radical prostatectomy (NSRP) [1]. The study addressed a really important clinical problem, namely, the efficacy of rehabilitation and on-demand therapies for erectile dysfunction after NSRP. Only two randomized controlled studies had previously been published on the same issue [2,3], the former evaluating the efficacy of intracavernous injection of alprostadil and the latter of sildenafil (50 mg or 100 mg once daily at nighttime). Despite the fact that both studies were of poor methodologic quality, rehabilitation therapy with phosphodiesterase type 5 inhibitors (PDE5-Is) and/or intracavernous injections became a standard clinical practice in many urologic centers.

The present study was a randomized, double-blind, double-dummy, multicenter parallel-groups study that randomized 628 patients after NSRP to a 9-mo treatment with nightly vardenafil plus on-demand placebo, on-demand vardenafil plus nightly placebo, or nightly plus on-demand placebo. After the 9-mo double-blind treatment period, the patients entered a single-blind placebo washout period, which was followed by a 2-mo open-label treatment with on-demand vardenafil. According to the primary end point of the study, the percentages of subjects with an International Index of Erectile Function–Erectile Function (IIEF-EF) score  $\geq 22$  after the end of the 2-mo washout period were similar in the three treatment arms (28.9%, 24.1%, and 29.1% of patients for placebo, vardenafil nightly, and vardenafil on demand groups, respectively) [1].

Briefly, nightly vardenafil was not shown to be more effective than vardenafil on demand, as theoretically hypothesized.

The trial was a high-quality randomized controlled study, providing a Ib level of evidence in favor of the on-demand treatment with vardenafil of the erectile dysfunction which followed NSRP and, consequently, supporting the on-demand use of any PDE5-I in the same clinical setting. However, very critical data such as the number of tablets taken during the double-blind period in the on-demand arm is lacking in the study report. Clinically speaking, it is clear that the differences in vardenafil doses between the two active arms might be very small in case of patients with a high on-demand intake, which might provide an explanation of the study's results. For the external validity of the study, physicians and patients should be aware of the minimal number of tablets to be taken to achieve such results.

The study results raise a second consideration on the need to suggest that patients have early therapies to improve recovery of erectile function after NSRP. The efficacy of vardenafil on demand in the open-label phase of the study was similar in the three study arms regardless of the previous treatments, indicating that, even in patients who did not take any PDE5-Is during the first 12 mo after NSRP, the efficacy of the drug was not reduced due to fibrosis within the corpus cavernosa and to cavernous veno-occlusive dysfunction, as previously suggested [4]. Consequently, it might be hypothesized that we could delay the beginning of PDE5-I therapy, which could ultimately increase patients' acceptance—usually not very high in the first months after surgery [5].

**Conflicts of interest:** The authors have nothing to disclose.

## References

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