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Re: Effect of Nightly versus On-Demand Vardenafil on Recovery of Erectile Function in Men Following Bilateral Nerve-Sparing Radical Prostatectomy

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Experts' summary

This multi-institutional, double-blind, placebo-controlled, randomized study examined the efficacy of a phosphodiesterase type 5 inhibitor (PDE5-I) for penile rehabilitation after nerve-sparing radical prostatectomy. Men were randomized to (1) nightly vardenafil with on-demand placebo for intercourse, (2) nightly placebo with on-demand vardenafil for intercourse, or (3) placebo nightly and on demand. Men in the on-demand-vardenafil group fared significantly better relative to the other two groups with respect to capacity for satisfactory erections at 9-mo follow-up. Interestingly, after the 2-mo washout period and during the open-label phase, there were no significant differences in erectile function between groups.

Experts' comments

Penile rehabilitation after radical prostatectomy has been a topic of interest for well over a decade [1]. PDE5-Is have emerged as the simplest and most popular medical regimens for accomplishing this goal [2]. In animal models of chronic-dose PDE5-Is after cavernous nerve injury, beneficial effects including improved erectile hemodynamics, preservation of smooth muscle-to-collagen ratio, decline in apoptosis, and improved endothelial function have been reported [3]. Several small human studies of routine-dose sildenafil after radical prostatectomy have also demonstrated significantly better erectile function in treated men versus controls [3].

Although the complex design of the current study has been criticized [4], the results are quite compelling in that men who received the treatment on demand fared better at the 9-mo follow-up, with all groups equalizing during the washout period and during the open-label extension. It may be inferred that the superior erectile results observed in the treatment-on-demand arm during the study were driven by acute effects of the drug on erectile hemodynamics during attempts at intercourse.

No evidence has suggested that PDE5-Is have neurotrophic or neuroprotective properties; however, the hemo-dynamic changes that accompany even nerve-sparing radical prostatectomy have been implicated in the penile tissue changes often observed after radical prostatectomy and may play an important role in neuronal regeneration and preservation [5].

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Conflicts of interest: Tom F. Lue is a consultant to Pfizer, Lilly, Bayer, Medtronic, UroDYNIX, and Auxilium; has received research grants from American Medical Systems, Rinat/Pfizer, Biopharm, and Astellas; is a board member of Genix; and is a medical advisor to GeneBio. Alan W. Shindel has received salary support from the American Urological Association Foundation and grant support from the California Urologic Foundation and the Sexual Medicine Society of North America.

It is our *opinion* that any means to promote cavernosal blood flow (and, by extension, oxygen, nutrients, and serum vasculogenic and neurotrophic factors) may be helpful in preventing apoptosis, promoting vascular integrity, and supporting nerve regeneration. This can be achieved by PDE5-Is, by intracavernous injection, by transurethral therapy, or by vacuum erection device use.

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