OBJECTIVES: To clarify the role of phosphodiesterase type 5 (PDE5) inhibitors in post-prostatectomy penile rehabilitation (PPPR). To compare nightly and on-demand use of PDE5 inhibitors after nerve-sparing minimally invasive radical prostatectomy (RP).

PATIENTS AND METHODS: We conducted a single-institution, double-blind, randomized controlled trial of nightly vs on-demand 50-mg sildenafil citrate after nerve-sparing minimally invasive RP. A total of 100 preoperatively potent men, aged <65 years, with scores on the Erectile Function domain of the International Index of Erectile Function (IIEF-EF) ≥26, underwent nerve-sparing surgery. The patients were randomized to either nightly sildenafil and on-demand placebo (nightly sildenafil group), or on-demand sildenafil and nightly placebo (on-demand sildenafil group; maximum on-demand dose six tablets/month) for 12 months. Patients then underwent a 1-month washout period. Validated measures of erectile function (IIEF-EF score and the Expanded Prostate Cancer Index Composite [EPIC]) were compared between treatment groups over the entire 13-month time course, using multivariable mixed linear regression models.

RESULTS: The treatment groups were well matched preoperatively (mean age 54.3 vs 54.6 years, baseline IIEF-EF score 29.4 vs 29.3, for the nightly vs the on-demand sildenafil groups, respectively). No significant differences were found in erectile function between treatments (nightly vs on-demand sildenafil) at any single timepoint after RP, after adjusting for potential confounding factors. When evaluated over all timepoints simultaneously, no significant effects of treatment group (nightly vs on-demand sildenafil) were found on recovery of potency, as assessed by absolute IIEF-EF scores (P = 0.765), on percentage of men returning to an IIEF-EF score >21 (P = 0.830), or on IIEF-EF score recovery to a percentage of baseline value (P = 0.778). When evaluated over all timepoints simultaneously, no significant effects of treatment group were found on secondary endpoints such as assessment of potency (including EPIC item 59 response 'erections firm enough for intercourse'), attempted intercourse frequency or confidence.
**CONCLUSIONS:** Erectile recovery up to 1 year after RP does not differ between previously potent men who use sildenafil nightly compared to on-demand. This trial does not support chronic nightly sildenafil as being any better than on-demand sildenafil for use in penile rehabilitation after nerve-sparing minimally invasive RP.

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**KEYWORDS:** erectile dysfunction; penile rehabilitation; phosphodiesterase type 5 inhibitor; radical prostatectomy; sildenafil citrate

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