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Sildenafil Improves Sleep-Related Erections in Hypogonadal Men: Evidence From a Randomized, Placebo-Controlled, Crossover Study of a Synergic Role for Both Testosterone and Sildenafil on Penile Erections

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To study the effects of sildenafil on human sleep-related erections according to the state of androgenization, we evaluated the effects of sildenafil on sleep-related erections in hypogonadal men before and during testosterone replacement treatment and in control subjects. We enrolled 24 hypogonadal men and 24 healthy men as a control group. All hypogonadal subjects had very low testosterone levels (<200 ng/dL [8.93 nmol/L]). All subjects underwent nocturnal penile tumescence and rigidity monitoring (NPTRM) for 3 consecutive nights and were randomly assigned to consume either 50 mg of sildenafil or placebo 1 hour before bedtime on the second or third night of nocturnal penile monitoring. The hypogonadal subjects were tested twice, first without replacement treatment (H-T) and then after at least 6 months of testosterone replacement therapy (H+T). The subjects of the control group (C) were tested once. The following parameters of sleep-related erections were analyzed: total number of valid erections, total duration of both rigidity greater than or equal 70% and increase in penile circumference greater than or equal 30 mm, maximum rigidity, and maximum increase in penile circumference. NPTRM parameters were reduced in hypogonadal men before testosterone treatment (H-T+P) when compared with control subjects taking placebo (C+P). NPTRM parameters after testosterone (H+T+P) and sildenafil (H-T+S) administration were similar to that of control subjects taking placebo (C+P). When the statistical analysis was restricted to the hypogonadal men before testosterone treatment, sildenafil alone significantly increased NPTRM parameters when compared with placebo (H-T+S vs H-T+P). Testosterone restored normal erections when administered to hypogonadal subjects (H+T+P vs H-T+P); in hypogonadal men, however, the combined treatment (sildenafil plus testosterone) resulted in the maximum positive effect on NPTRM parameters. When the increase from baseline was analyzed, the effects of testosterone plus sildenafil were greater than the sum of the effects of each

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drug used alone. In conclusion, sildenafil administered at bedtime improves sleep-related erections in hypogonadal men, suggesting that the nitric oxide pathway may be pharmacologically enrolled and enhanced despite low serum testosterone. Furthermore, these data strongly support the idea of a synergic effect on sleep-related erections of sildenafil and testosterone.

Key words: Nitric oxide pathway, androgen, hypogonadism, penile rigidity and tumescence, nocturnal erection, PDE5, NPT

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