

Administration of Tamsulosin with Udenafil does not Induce Clinically Significant Hypotension in Healthy Subjects

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Background/Aims: Udenafil is a phosphodiesterase type-5 (PDE-5) inhibitor used for treatment of erectile dysfunction by prolonging the biologic activity of cyclic guanosine monophosphate and decreasing peripheral vascular resistance. When PDE-5 inhibitors are coadministered with alpha-adrenergic receptor blockers such as tamsulosin, there is the possibility for a pharmacodynamic interaction that may result in clinically significant hypotension.

Methods: This was a randomized, double-blind, double-dummy, three-period, three-treatment, three-way crossover study. Twenty seven healthy male subjects were hospitalized for measuring baseline blood pressure (BP) from Day 1 to 2 (placebo lead-in period, administration of tamsulosin matching and udenafil matching placebos) at Clinical Trial Center, Seoul National University Hospital. Then they received tamsulosin 0.4 mg or placebo orally according to predefined sequences once daily from Day 2 to 4, Day 9 to 11, and Day 16 to 18. Supine, standing, and ambulatory BP were measured after administration of tamsulosin 0.4 mg or placebo followed by udenafil 200 mg or placebo 3 hours later on Day 5, 12, and 19. The maximal change of standing BP from supine baseline BP at each period was evaluated. In addition, supine BP and ambulatory BP were used for further safety evaluation.

Results: The mean maximal percent change from baseline systolic BP was -14.5% and -11% in subjects receiving tamsulosin with udenafil and tamsulosin alone, respectively. The difference between these treatments was -3.4% ($-6.7\sim 0.2\%$, 95% confidence interval), which corresponded to 4 mmHg in absolute values. The mean absolute differences between these treatments in systolic and diastolic BP were 1 and 2 mmHg, respectively, regarding ambulatory and supine BP. Five subjects receiving tamsulosin with udenafil and one subject receiving tamsulosin alone experienced a standing SBP drop of 30 mmHg or more. Three subjects receiving tamsulosin with udenafil and one subject receiving tamsulosin alone exhibited SBP less than 85 mmHg.

Conclusion: In healthy subjects, no evidence was found that coadministration of tamsulosin and udenafil show more clinically significant BP decrement than administration of tamsulosin alone.