

## THE REAL-WORLD DISCONTINUATION RATE OF SILODOSIN IN MALE LOWER URINARY TRACT SYMPTOMS

### Hypothesis / aims of study

It was well known that the main side effect of silodosin was ejaculation disorder. Retrograde ejaculation was the most common drug-related adverse event but rarely resulted in discontinuation (1.3-2.9%) of treatment in randomized, double-blind, placebo-controlled trials. In the real-world, the discontinuation rate (exchange to other  $\alpha$ -blockers) will be different with studies. We want to know the discontinuation rate of silodosin in the real-world.

### Study design, materials and methods

From January 2009 to March 2012, medical records of 401 male LUTS (lower urinary tract symptoms) who received with silodosin 8mg per day at least three week treatment were reviewed. We examined the kinds of adverse events, an exchange to other  $\alpha$ -blockers and previous  $\alpha$ -blocker treatment history. Patients who had an adverse event of ejaculation disorder were divided either as discontinuation group or maintenance group. Discontinuation was defined as a condition that the patients were treated with other  $\alpha$ -blocker due to adverse event. The factors were compared between discontinuation and maintenance group.

### Results

Of the total subjects, 303 (303/401, 75.6%) patients were able to maintain silodosin treatment during follow up whereas 98 (24.4%) patients had the adverse events. Of adverse events, 76 (76/98, 77.55%) patients had an ejaculation disorder and 51 (51/76, 67.1%) patients discontinued silodosin and exchanged with other  $\alpha$ -blockers. Alfuzocin (27/51, 52.9%) was most frequently chosen. 25 (25/76, 32.9%) patients were maintained silodosin in disregard of ejaculation disorder. The patients that had no history of  $\alpha$ -blocker treatment in discontinuation group (39/51, 76.5%) was significantly higher than the patients (12/25, 23.5%) in maintenance group ( $p=0.013$ ).

Parameters	Discontinuation group (n=51)	Maintenance group (n=25)
Age (years)	60.4±11.6	56.5±14.8
Previous treatment history		
No	39 (76.5%)	12 (48%)*
Yes	12 (23.5%)*	13 (52%)

\*: significantly higher ( $p<0.05$ )

### Interpretation of results

Previous RCTs reported a very low discontinuation rate (1.3-2.9%) due to ejaculation disorder. But real world discontinuation rate was 12.7% (51/401) in our study. 76.5% of patients who had no history of  $\alpha$ -blocker treatment changed silodosin to other  $\alpha$ -blockers.

### Concluding message

When the patient had adverse event of ejaculation disorder and no history of  $\alpha$ -blocker treatment, the discontinuation rate was raised.

### References

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2. Marks LS, Gittelman MC, Hill LA, Volinn W, Hoel G. Rapid efficacy of the highly selective  $\alpha_1$  A-adrenoceptor antagonist silodosin in men with signs and symptoms of benign prostatic hyperplasia: Pooled results of 2 Phase III studies. *J Urol* . 2009;181:2634–2640.

### Disclosures

**Funding:** none **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review Board of Seoul Paik hospital **Helsinki:** Yes **Informed Consent:** No