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SELECTIVE A1A-BLOCKER "SILODOSIN" SAFETY IMPROVES FEMALE LOWER URINARY TRACT DYSFUNCTIONS

Hypothesis / aims of study

Female lower urinary tract dysfunction, in particular voiding disorder, is often experienced. It can have a serious impact on the physical, social and psychological aspects of life of the sufferers, including pelvic discomfort, urinary retention, overflow incontinence, recurrent urinary tract infection, the consequent risk of upper urinary tract damage, and the potential need for self-catheterisation. However, unfortunately there is a paucity of published literature on the aetiology and management of this condition,and it is poorly understood and difficult to treat. On the other hand, male voiding disorders are common and the therapeutic role of α-blockers in the treatment of male voiding disorders due to benign prostatic hyperplasia or hypertrophy has been extensively examined. Recently, there were a few reports showed that α-blockers for the treatment of male voiding disorders improved female voiding symptom and if associated with storage symptom. These reports suggest that α-blockers would be a new treatment option for female lower urinary tract dysfunctions including voiding disorders. Thus, to evaluate the safety and efficacy of α-blockers for lower urinary tract dysfunction in females with neurogenic and non-neurogenic voiding disorders, we conducted a clinical trial using silodosin.

Study design, materials and methods

In a prospective, longitudinal open-label study, 10 females with neurogenic and non-neurogenic voiding dysfunction were treated with selective α1A-blocker silodosin. Inclusion criteria were: age >18 years, complaining of voiding symptoms (intermittent stream, hesitancy, straining and/or a feeling of incomplete emptying) and/or presence of 50ml or more of postvoid residual. Exclusion criteria were: patients receiving physical/surgical treatment for lower urinary tract dysfunction, pelvic organ prolapse, during pregnancy and lactating, or severe systemic diseases. After observation period for at least 30 days, silodosin was randomly administered in a daily dose of 4 mg for 12 weeks or in a daily dose of 4 mg for 4 weeks followed by 8 mg for 8 weeks. Primary outcomes were clinical efficacy and Q(max) improvement; secondary outcomes were tolerability and safety. Voiding and storage symptoms (IPSS, OABSS and ICIQ-SF), QOL (IPSS-QOL, KHQ), uroflowmetry results and Schellong test results (blood pressure before and 0, 5, 10 minutes after active standing) were assessed before and after observation period, and 2, 4, 8, 12 weeks after the silodosin therapy.

Results

Silodosin therapy was well tolerated and all patients finished this study. Compared with the data during observation period, after the treatment, voiding symptoms improved in all and total obstructive score in IPSS was significantly reduced at 8 and 12 week. Storage symptoms also improved in 90% of patients and total OABSS was significantly reduced at 4, 8 and 12 week. Total ICIQ-SF score did not change in all. Uroflowmetry parameters improved in most patients. Postvoiding residue improved in all significantly. IPSS-QOL and a part of KHQ scores also improved. Silodosin therapy was safety, and basal blood pressure and blood pressure oscillation after active standing did not change in all and other adverse effect related to medication was not shown.

Interpretation of results

Selective α1A-blocker silodosin improved female storage symptom 4 weeks after the treatment, followed by female voiding symptoms and voiding efficiency 8 weeks after the treatment, resulting in improvement of QOL of the sufferers. And adverse effect related to medication including influences to blood pressure and (stress) urinary incontinence was not shown.

Concluding message

Silodosin safety improved lower urinary tract dysfunction in females with neurogenic and non-neurogenic voiding disorders, and improved their QOL. These results suggest that a part of α-blockers for the treatment of male voiding disorders may be an effective treatment option in females with neurogenic and non-neurogenic lower urinary tract dysfunctions including voiding disorders.

Specify source of funding or grant	**no funding or grant**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Commitee of Chiba University Hospital**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**