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A CLINICAL GUIDELINE FOR TREATMENT OF FEMALE VOIDING DYSFUNCTION: A PROSPECTIVE, MULTI-CENTER, PHASE IV STUDY

Hypothesis / aims of study

The purposes of this study are to provides a clinical guideline for treatment of FVD patients and evaluate the clinical efficacy and safety of α-blocker in the treatment of female voiding dysfunction (FVD).

Study design, materials and methods

Functional Bladder outlet obstruction (BOO) was defined as free Q max was under 15ml/sec and PdetQmax over 20 cmH2O, and detrusor underactivity (DU) was defined as free Qmax under 15ml/sec and PdetQmax under 20 cmH20. From 2006 Oct. to 2007 Aug., 145 patients mainly complaint voiding difficulty were enrolled. Based on urodynamic study at screening and their symptoms, patients were classified into four groups: group 1, Q_{max}>15m/sec (n=29); group 2, BOO only (n=49); group 3, BOO and OAB (n=54); and group 4, DU (n=13). After 2 weeks of run-in period, we prescribed tamsulosin at 0.2 mg, qd in all groups for the first four weeks. If there is no significant symptomatic improvement after 4-week α-blocker treatment, tolterodine SR was added in group 3 and bethanechol was added in group 4.

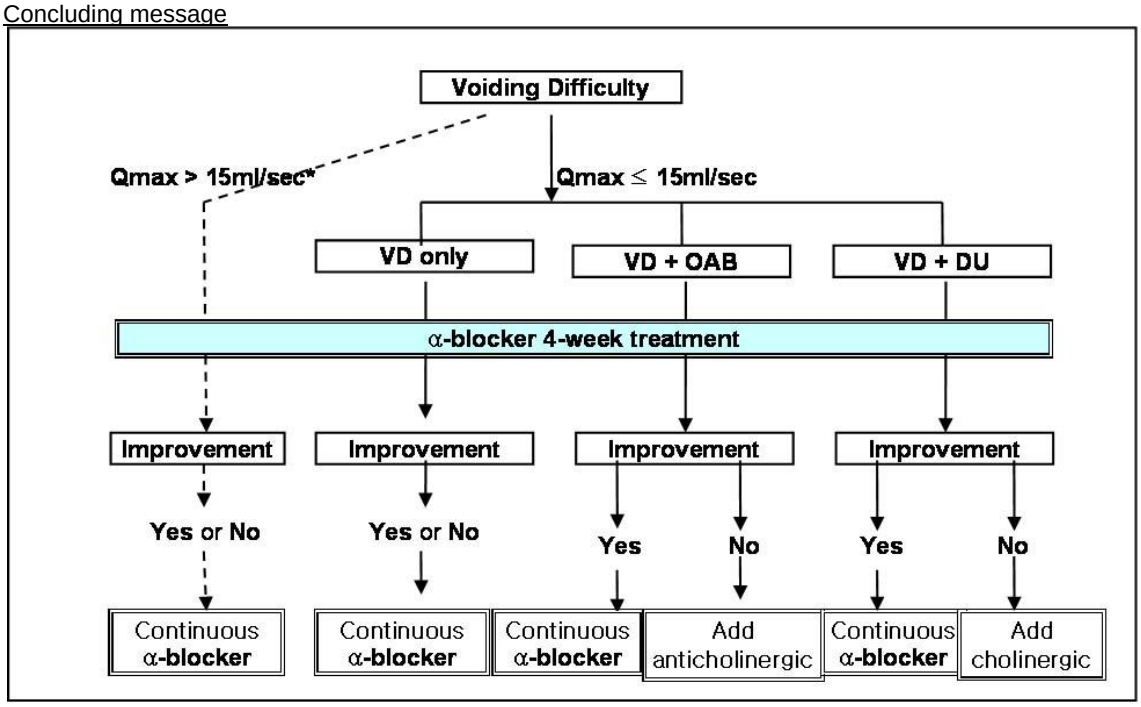
Results

In the total IPSS score, all of the groups showed statistically significant decreases four weeks after administration. At week 8, IPSS scores significantly decreased in group 3 treated concomitantly with anticholinergics. For patients with voiding symptoms, IPSS values decreased significantly at week 4 in all the groups, and at week 8 there were significant improvements in groups 2 and 3. Significant improvements in the storage symptom score were observed in groups 1 and at week 4 and in groups 1 and 3 at week 8. Q_{max} at 4 weeks after administration showed no significant change in group 1, an increase in groups 2 and 3, and a slight decrease without statistical significance in group 4. At week 8 in groups 3 and 4 with anticholinergics and cholinergics, a numerical increase in Q_{max} was observed in group 4, but in group 3 there was no change in the parameter.

Interpretation of results

Subjective parameters of voiding were significantly improved in all groups, but objective parameter was improved only in group 2 and 3 after 4-week α-blocker treatment. Storage symptoms were improved after additional 4-week combined anti-cholinergic therapy in FVD with OAB patients. Qmax was improved after additional 4-week combined cholinergic therapy in detrusor underactivity patients.

Concluding message



Specify source of funding or grant	**No**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**We wanted to see the clinical courses after treatment of Female voiding dysfunction**
Was the Declaration of Helsinki followed?	**Yes**

Was informed consent obtained from the patients?	**No**