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COMPARISON OF DIFFERENT DOSES OF NAFTOPIDIL FOR OVERACTIVE BLADDER ASSOCIATED WITH BENIGHN PROSTATIC HYPERPLASIA: A PROSPECTIVE, RANDOMAIZED CONTROLLED STUDY.

Hypothesis / aims of study
The aim was to investigate the efficacy and safety of alpha 1D/A adrenoceptor antagonist, naftopidil, at 25, 50 or 75mg/day in men with overactive bladder symptoms (OAB) associated with benign prostatic hyperplasia (BPH).

Study design, materials and methods
Men aged more than 50 years who had a total International Prostate Symptom Score (IPSS) of 8 or higher, an IPSS Quality-of Life (QOL) index score of 3 or higher, Overactive Bladder Symptom Score (OABSS) of 3 or higher with an urgency score of OABSS of 2 or higher and maximal flow rate of 15ml/sec or less were enrolled. They were randomized to receive 25mg/day (group LD), 50mg/day (group MD) or 75 mg/day (group HD) of naftopidil for 8 weeks. Endpoints included changes in OABS, IPSS and QOL index score. The changes in maximum flow rate on free uroflowmetry and post-void residuals (PVR) and bladder diary were also analyzed.

Results
Of the 156 patients enrolled, 148 were eligible for the efficacy analysis (group LD: 46, group MD: 52, group HD: 50). There was no significant difference in any parameter at baseline among the groups. There were significant improvements in OABSS, IPSS and QOL index score in all groups. Additionally maximal flow rate and urgency episodes were improved in all groups, but urge incontinence episodes were significantly reduced in the group HD alone. However, there was no significant intergroup difference in the improvement of all parameters among the three groups. The incidence of adverse effects did not differ significantly among the three groups.

Interpretation of results
This study suggested that different doses of naftopidil have similar efficacy in the treatment of OAB associated with BPH. However, high dose administration of naftopidil is recommendable for men with urge incontinence.

Concluding message
Alpha 1D/A adrenoceptor antagonist, naftopidil significantly improves OAB symptoms and other lower urinary tract symptoms in men with the OAB associated with BPH.

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Hokkaido University Hospital Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**