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COMPARISON OF THE EFFICACY OF TAMSULOSIN AND NAFTOPIDIL ON THE QUALITY OF LIFE SPECIFIC TO EACH SYMPTOM OF THE INTERNATIONAL PROSTATE SYMPTOM SCORE: A RANDOMIZED CONTROLLED TRIAL IN ELDERLY MEN WITH OVERACTIVE BLADDER

Hypothesis / aims of study

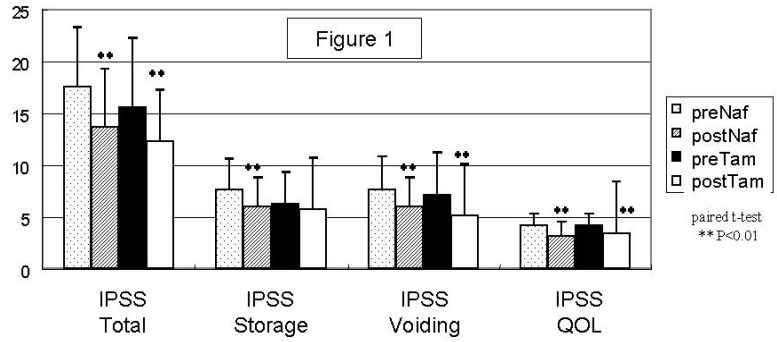
Lower urinary tract symptoms (LUTS) compatible with benign prostatic hyperplasia (BPH) and concomitant overactive bladder (OAB) cause significant bother, anxiety or morbidity in elderly men. The recent trend in treatment for male LUTS with OAB has been directed toward the alleviation of bother in both storage and voiding symptoms with prevention of disease progression to achieve a better quality of life (QOL) in the long-term. Alpha-adrenoceptor antagonists are the safe first-line treatment for older men with LUTS, and the severity and/or frequency of LUTS is most commonly quantified using the 7 symptom questions of the International Prostate Symptom Score (IPSS) (1). Although a high total score on the IPSS is likely to have great impact on QOL in patients with LUTS, the most severe symptom of the 7 items in the IPSS may not necessarily match the most significant symptom that patients want to be treated. The novel visual analog scale measure (VAS) of QOL specific to each of the 7 items on the IPSS has a significant impact on identifying the patient's chief complaint as well as on the patient specific bother/satisfaction of each symptom of the IPSS (2). In order to compare the clinical efficacy of the 2 alpha-adrenoceptor antagonists of tamsulosin hydrochloride (Tam) and naftopidil (Naf) on the bother/satisfaction specific to each symptom of LUTS, we performed a multi-center randomized controlled study with concomitant use of IPSS and VAS questionnaires in elderly men with OAB. A recent systematic review of Naf for the treatment of LUTS from randomized clinical trials (3) reported that there was only limited evidence that may suggest Naf (25-75mg/day) provides short-term improvement in LUTS from the baseline compatible to low-dose Tam (0.2mg/day) in male LUTS compatible with BPH.

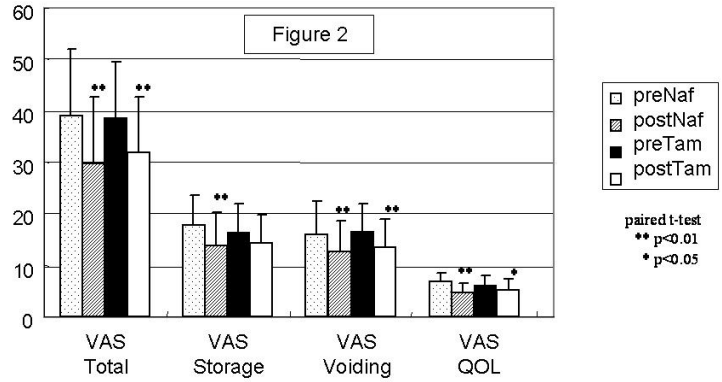
Study design, materials and methods

Eighty-two male patients complaining of LUTS with OAB symptom were randomized to receive either Tam (0.2mg) or Naf (50-75mg) for 12 weeks. Before and after treatment the patients were asked to complete the IPSS questionnaire with IPSS-QOL score and VAS questionnaires to assess bother or satisfaction regarding patient QOL specific to each of the 7 items on the IPSS. The VAS questionnaire (2) used in this study was a 10 cm line ranging from delighted at the left to terrible at the right to determine patient bother or satisfaction specific to each of the 7 questions on the conventional IPSS. Logistic regression analysis was used to identify the best predictor of pre- or post-treatment IPSS-QOL score, representing the patient's pre- or post-treatment bother.

Results

There were no significant differences in age, pre-IPSS, pre-score of IPSS-QOL, and ultrasound-determined prostate volume at the baseline between the Tam (n=43) and Naf (n=39) groups. There were statistically significant improvements in total IPSS as well as voiding symptoms in both groups (P<0.001) (Figure 1). Significant improvements in urgency episodes were noted in both groups (p<0.01). However, Naf significantly improved the sum of IPSS storage symptoms (p<0.005) and the sum of VAS storage symptoms (p<0.001), while Tam did not improve the former (p=0.14) or the latter (p=0.053) (Figures 1 and 2). Before treatment, among the 14 items of the 7 IPSS scores and 7 VAS measures, multiple stepwise linear regression analysis identified that the best predictor of pre-treatment patient's bother was VAS nocturia (F=13.3, p=0.0005), followed by VAS incomplete emptying (F=6.8, p=0.011). After treatment, interestingly, multiple regression analysis to identify the VAS measure to impact most on patient's post-treatment QOL revealed that, by the treatment with Naf, the post-treatment bother in nocturia and incomplete emptying were improved to be insignificant; on the other hand, by the treatment with Tam, the post-treatment bother in nocturia still remained as significant bother (p=0.0104).





Interpretation of results

The recent trend in treatment for male LUTS with OAB could be that an alpha-adrenoceptor antagonist should be administered first, and if monotherapy is ineffective, an anti-cholinergic agent could be added. Indeed, this study duplicated the short-term equal efficacy of both Naf and Tam to improve total IPSS, especially in voiding symptom scores and in urgency episodes. However, in consideration of the choice of alpha-adrenoceptor antagonists in patients suffering from male LUTS with BPH and concomitant OAB, this study suggested that Naf (50-75mg/day) is more likely to relieve the storage symptoms, especially leading the alleviation of the patient's bother in nocturia. A longer term study with a larger number of patients would be warranted to evaluate the compliance of Naf (50-75mg/day) monotherapy in the improvement of OAB-related storage symptoms and bother, in comparison to other treatment choices including other alpha-adrenoceptor antagonists and/or its combination with an anti-cholinergic agent.

Concluding message

In patients suffering from male LUTS with OAB, both 0.2mg of Tam and 50-75mg of Naf were equally effective in improving total IPSS, including voiding symptom scores and urgency episodes, leading to a significant improvement in QOL score in the IPSS questionnaire. Interestingly, however, assessment of the VAS questionnaire with regard to bother specific to each symptom of the IPSS revealed that Naf is more likely to relieve bother in storage symptoms, especially in nocturia

References

1. J Urol, 148: 1549, 1992
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3. Cochrane Database Syst Rev. Oct 7(4):CD007360. 2009

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	**Ethics Committee of Kyoto prefectural university of medicine**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**