

## THE EFFICACY AND SAFETY OF COMBINATION THERAPY OF TAMSULOSIN AND SOLIFENACIN ACCORDING TO THE SEVERITY OF LOWER URINARY TRACT SYMPTOM IN MALE PATIENTS WITH CEREBRAL INFARCTION AND OVERACTIVE BLADDER

### Hypothesis / aims of study

We evaluated the efficacy and safety of combination therapy of tamsulosin and solifenacin in male patients with cerebral infarction and overactive bladder, and especially evaluated the difference of efficacy according to the severity of lower urinary tract symptom.

### Study design, materials and methods

A total of 105 male patients aged more than 50 years with cerebral infarction and overactive bladder were assessed retrospectively. Patients with IPSS score more than 8 and OAB-SS score more than 3 (especially, OAB-SS number 3 questionnaire score more than 2) were enrolled. We collected data on PSA, uroflowmetry and residual urine volume, digital rectal examination, transrectal ultrasonography and void volume chart. The patients were divided into two groups. Group 1 (moderate symptom group) included patients with moderate symptom (IPSS score 8-19) and group 2 (severe symptom group) included patients with severe symptom (IPSS score 20-35). In each group, patients group treated by combination therapy of tamsulosin and solifenacin (combined medication group) and the other patients group treated by only tamsulosin (single medication group) were compared each other. After mean 3 months, data were compared. Independent T-test and Mann-Whitney test were used for statistical methods.

### Results

Before medication, all parameters like age, IPSS, OAB-SS, prostate volume, PSA, maximal flow rate and residual urine volume were not statistically different between each group. Symptom scores were improved in each combined medication group (n=64) and single medication group (n=41) after treatment.

In moderate symptom group (n=71), the reduction of IPSS was  $5.2 \pm 4.3$  on the combined medication group (n=43) and  $3.2 \pm 5.3$  on the single medication group (n=28) ( $p=0.248$ ). And the reduction of quality of life score was  $0.8 \pm 0.8$  on the combined medication group and  $0.2 \pm 0.6$  on the single medication group ( $p=0.026$ ). And the reduction of OAB-SS was  $0.9 \pm 1.6$  on the combined medication group and  $0.3 \pm 1.8$  on the single medication group ( $p=0.036$ ). So, in moderate symptom group the reduction of IPSS was not statistically significant between subgroups, but the reduction of quality of life score and OAB-SS was statistically significant in the combined medication group compared with single medication group.

In severe symptom group (n=34), the reduction of IPSS was  $8.8 \pm 6.5$  on the combined medication group (n=21) and  $4.9 \pm 6.2$  on the single medication group (n=13) ( $p=0.023$ ). And the reduction of quality of life score was  $1.6 \pm 0.9$  on the combined medication group and  $0.5 \pm 1.0$  on the single medication group ( $p=0.009$ ). And the reduction of OAB-SS was  $2.3 \pm 1.7$  on the combined medication group and  $0.8 \pm 1.4$  on the single medication group ( $p=0.018$ ). So, in severe symptom group IPSS, quality of life score and OAB-SS were statistically significantly improved in the combined medication group compared with single medication group.

In all combined medication group 4 patients complained dry mouth (6.3%), 2 patients complained constipation (3.1%) and 1 patient complained dizziness (1.6%). In all single medication group 1 patient complained constipation (2.4%). But all side effects were mild and special treatment was not necessary.

### Interpretation of results

In the male patients who has cerebral infarction history, overactive bladder with urgency and urge incontinence is common. And considerable number of these patients have benign prostatic hyperplasia also. So many urologists encounter voiding symptom and storage symptom together in these patients.

In this study after combination medication of tamsulosin and solifenacin, no patients need catheterization. And other side effects were mild and need not special treatment. In this study IPSS, quality of life and OAB-SS of male patients with cerebral infarction and overactive bladder were improved after combination medication of tamsulosin and solifenacin. And especially in the severe symptom group (IPSS score 20-35), the efficacy of combination medication of tamsulosin and solifenacin was more significant than only tamsulosin medication.

### Concluding message

The combination therapy of tamsulosin and solifenacin in male patients with cerebral infarction and overactive bladder was more effective for the treatment of lower urinary tract symptom and quality of life compared with only tamsulosin medication. And the effect was more superior on the severe symptom group (IPSS score 20-35) than moderate symptom group (IPSS score 8-19).

### Disclosures

**Funding:** None **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of Busan Veterans Hospital **Helsinki:** Yes **Informed Consent:** Yes