

## ESTABLISHMENT OF THE NEW THERAPEUTIC STRATEGY FOR URINARY RETENTION DUE TO BENIGN PROSTATIC HYPERTROPHY BY 5 $\alpha$ REDUCTASE INHIBITOR UNDER THE URETHRAL STENT PLACEMENT

### Hypothesis / aims of study

Urethral stent treatment is indicated for the patients with urinary retention due to benign prostatic hypertrophy (BPH) who are at high operative risk. But due to the complications of urethral stent, as a result, indwelling urethral Folly catheter is rather selected instead of urethral stent for those cases. And this selection leads to a decline of [activity of daily living](#) (ADL) and quality of life (QOL). To prevent the complications of urethral stents may shorten the duration of stent placement. In addition to the urethral stent treatment, the administration of 5-alpha-reductase inhibitor dutasteride is expected to reduce the volume of prostate and be able to void without indwelling the urethral stent.. Early removal of the urethral stent may lead to minimize the complications of the urethral stent without impairing the QOL and ADL.

The aim of this study is the establishment of the new therapeutic strategy for urinary retention due to BPH by 5 $\alpha$  reductase inhibitor administration under the urethral stent placement.

### Study design, materials and methods

Study design: Single arm, prospective, clinical trials.

A total 32 men with BPH who were hard to be operated by complications between April 2012 and March 2014 were enrolled in this study. Inclusion criteria were over 50 years old, prostate volume  $\geq 30$ ml, urinary retention or maximum flow rate (Qmax)  $\leq 5$ ml/sec and residual urine (RU)  $\geq 100$ ml, PSA  $\leq 10$ ng/ml and no prostate cancer. All patients inserted the thermo-expandable metallic Memokath (PNN Medical, Denmark) urethral stent at least one year duration. At the same time of insertion of the stent, dutasteride administration was started and was administered continuously at least for one year. After stent removal, it was defined as a treatment success if urination was possible and it was defined as a treatment failure if urination was impossible. The primary endpoint was percentages of the possibility of urination after the stent removal. Secondary endpoints were prostate volume, Qmax and RU, international prostate symptom score (IPSS), and adverse events. Statistical analysis were used unpaired student t-test and Wilcoxon's rank-sum test.

### Results

In all patients the stents were placed successfully. All men were able to void after inserting stent. But 4 of 32 cases were dropped out during the protocol. (stent migration 1 case, stent obstruction 1 case, urethral stricture 1 case and death 1 case.) The mean age was 81 years. Mean prostate volume was 64.5 ml. Mean residual urine volume was 409 ml. Mean PSA was 4.9 ng/ml. Mean total IPSS score was 21.8. 20 of 28 (71.4%) patients treatment success.

Except the drop out cases, there were no serious adverse events.

	Treatment Success Group (n=20)	Treatment Failure Group (n=8)	P value
Age	79.9 $\pm$ 9.0	83.8 $\pm$ 8.7	0.31
Prostate Volume (ml)	63.6 $\pm$ 19.2	66.5 $\pm$ 34.3	0.78
Residual Urine Volume (ml)	341.6 $\pm$ 232.1	428.7 $\pm$ 338.2	0.02
IPSS	24.1 $\pm$ 7.3	15.4 $\pm$ 10.5	0.04
QOL	5.2 $\pm$ 1.1	4.9 $\pm$ 1.7	0.58

### Interpretation of results

71.4% patients were treatment success and no serious adverse event. Compared with treatment success group and the unsuccessful group, there was no significant difference in age and prostate volume, but IPSS score was significantly high and residual urine volume was significantly low in the success group. It is considered that the patients who were matched to this protocol were maintained the bladder sensation and detrusor contractility. If "underactive bladder" was defined with impaired bladder sensation and detrusor contractility, such cases should be excluded.

### Concluding message

It has been to select the indwelling urethral Folly catheter for the patients with urinary retention due to BPH who are at high operative risk. Except the "underactive bladder" cases, 5 $\alpha$  reductase inhibitor administration under the urethral stent placement is considered the new therapeutic strategy for urinary retention due to BPH.

### References

1. BJU Int, 98; 806-810, 2006.
2. BJU Int, 103; 626-629, 2008.

### Disclosures

**Funding:** Non Profit Organization (NPO)/ Non Government Organization (NGO) Japanese Urological and Nephrological disease research network (JUN-net) **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Yamagata University Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes