

SHAPE-MEMORY NICKEL-TITANIUM ALLOY STENT FOR MANAGING BENIGN PROSTATIC HYPERPLASIA.

Hypothesis / aims of study

The patients whose surgery deemed a high risk because of their complication with urinary retention due to benign prostatic hyperplasia, previously had been forced to indwelling urethral catheter. But now, they can select the minimally invasive treatment, such as urethral stents. Shape-memory nickel-titanium alloy stent MEMOKATH® can be easily removed and inserted. The aim of study is to examine the indications and limitations of the urethral stent by investigating long-term clinical outcome.

Study design, materials and methods

The 48 cases with urinary retention due to benign prostatic hyperplasia enrolled. Eligibility criteria was urinary retention, surgery was deemed a high risk with their complications, and they were able to void themselves if they were without lower urinary tract obstruction. Mean age was 83 ± 5.9 years old (range:67-97). Complications were cerebral infarction 20cases, ischemic heart disease 10cases, chronic obstructive pulmonary disease 6cases, chronic renal failure 2cases and severe dementia 10cases. We evaluated IPSS, QOL, prostate volume, residual urine volume, durability of MEMOKATH®, and complications.

Results

Prostate volume was 70.8 ± 41.1 g (33-180) and mean MEMOKATH® length was 5.7 ± 1.3 cm (range:3-8). Pre-treatment IPSS was 25.4 ± 5.4 and Post-treatment IPSS was 12.3 ± 5.3 . Pre-treatment QOL was 5.1 ± 1.2 and Post-treatment QOL was 2.0 ± 0.5 . Initial success rate of voiding was 92% (44/48). About the durability of MEMOKATH®, the average indwelling period was 21.4 ± 17.7 month (2-75). And 1 year stent indwelling rate was 92.2%, 2 year stent indwelling rate was 70.5% and 3 year stent indwelling rate was 54.0%.

Complication was stone formation was 38.0% (18/48), gross hematuria was 8.3% (4/48), pyuria (>10/hpf) was 58.3% (28/48), and OAB (urgency, urgency incontinence) was 67% (32/48).

Interpretation of results

Because stent failure may occur within 2 years after the placement of Memokath®, the expected treatment period of Memokath® is seemed to be about 2 years. The main reason of the stent failure is stone formation which is related with UTI. There is a possibility that we can extend the treatment period of Memokath® with controlling UTI.

Concluding message

Memokath® is a useful device for managing BPH patient whom surgery is deemed a high risk, in spite of many complications.

Specify source of funding or grant	No founding or grant.
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Yamagata University Ethics Committee.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes