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THE ARTIFICIAL URINARY SPHINCTER FOR STRESS INCONTINENCE AFTER PROSTATE CANCER THERAPY IN MEN WITH OR WITHOUT HISTORY OF NEO BLADDER NECK STENOSIS - EFFICACY, QUALITY OF LIFE AND SATISFACTION

Hypothesis / aims of study

We aim to study the outcome in a contemporary series of bulbar artificial urinary sphincter (AUS; AMS800) implantations in men with stress urinary incontinence (SUI) after prostate cancer therapy. We also aim to compare the outcome in men without and with significant neo bladder neck stenosis (NBNS). The latter had required one or more incision(s) and/or dilatation(s) before AUS implantation.

Study design, materials and methods

This retrospective study reports on 48 consecutive men with SUI after prostate cancer therapy, that were treated with an AUS between [oct] 2005 and [jun] 2010. Out of 48 patients, 14 were treated for NBNS first. They all underwent radical prostatectomy (of which 5 laparoscopic). Three underwent additional radiotherapy (RT) for local recurrence.

Out of the 34 men without previous NBNS, one patient was primarily treated with external RT followed by a transurethral resection of the prostate. 33 had undergone radical prostatectomy (of which 15 laparoscopic). Of these, 8 received RT for local recurrence. In both groups 25% had undergone RT.

The pre-operative work-up included a detailed history. Severity of incontinence was evaluated by 24-hour pad counts (or the use of a condom catheter in case of total incontinence). All men underwent an urethrocystoscopy: in case the NBN was not passable with a 16 F flexible cystoscope, the patient underwent deep incisions of the NBN (preferably untill fatty tissue was seen) at 3 and 9 'o clock. The NBN was re-evaluated 3-4 months later, and if patent (>16F) the patient was considered a candidate for AUS implantation pending urodynamic evaluation. In case of early restenosis the incision and reevaluation was repeated once. In case of a 2nd restenosis, a 3rd incision was performed and the patient was taught self-dilatation (18-20F).

An urodynamic study consisting of a filling cystometry and pressure-flow study was performed in all patients. Patients were only considered candidates for implant if there was no detectable detrusor overactivity below a filling of 250 ml (with filling speed of 20 ml/min); additionally, no decreased bladder compliance had to be present until 250 ml. Patients were evaluated 6 weeks after activation and in October 2010. At those time points we noted 24-hour pad counts. All patients received a mailed questionnaire in October 2010. At that time, patients also completed a patient global perception of improvement (PGP-I) on a scale from 0-100% and the validated International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI-SF). Additionally, a survey to measure patient satisfaction with AUS by an additional set of 6 questions, was completed. The Mann-Whitney and Wilcoxon tests were used for the statistical analysis

Results

Of the 48 patients, 14 were treated for NBNS first and underwent 1 or more NBN-incisions (mean 1.4;range 1-5). Three patient[s] had to be started on self-dilatation. Of the 48 questionnaires, 46 were returned (95.8%). One questionnaire was returned but not completed due to the death of the patient, unrelated to prostate cancer or the AUS. This leaves 45 patients for analysis (12 with and 33 without NBN-incisions, before AUS implant). The follow-up ranged from 4-59 (median 27) months.

Table I - Baseline data of patients grouped according to the presence or absence of previous NBNS.

	Total (45)	**NBNS (12)**	**No NBNS (33)**	**p value**
Age (yrs;mean ± SD)	67 ± 5.0	68 ± 5.3	67 ± 4.9	N.S.
Severity of incontinence				
Pad use (mean ± SD) in 37 pts	4.5 ± 1.5	4.6 ± 1.5	4.4 ± 1.6	N.S.
Total incontinence in 8 pts (no. pts. Using condom catheter)	8	2	6	N.S.

Table II - Results at last follow-up.

	Total (45)	**NBNS (12)**	**No NBNS (33)**	**P value**
Follow-up duration (mos;[mean and range])	27.0 [4-59]	29.5 [4-59]	26.2 [4-56]	N.S.
Complications				
Revision/re-operation (n)	3	2	1	N.S.
Superficial wound infection (n)	1	0	1	N.S.
Pad use at last follow-up				
Using pads at baseline (median, range)	1.1 (0-5;n=37)	1.5 (0-5) (n=10)	0.9 (0-3) (n=27)	N.S.
Using condom catheter at baseline [Total incontinence] (median, range)	1.6 (0.5*-4;n=8)	2.2 (0.5-4)(n=2)	1.3 (0.5-3)(n=6)	N.S.
Patient Global Perception of Improvement of urinary condition (n)				
>90%	27	5	22	N.S.
75-90%	15	5	10	N.S.
50-75%	3	2	1	N.S.
25-50%	0	0	0	N.S.
<25%	0	0	0	N.S.
ICIQ-SF score (mean, range)	6.8 (0-17)	8.6 (0-17)	6.1 (0-16)	N.S.

**For pad counts a value of 0.5 was chosen in case of use of 1 pad for security.*

Preoperatively, the mean pad use was 4.5 per day (range 1-8) in 37 men; in these men the mean pad use dropped to 1.1 per day. Of these men only 9 used more than 1 pad per day at last follow-up. 8 patients (16.7%) reported to be totally incontinent and used condom catheters; these men used 1.6 pads per day at last follow-up. Of them 3 used more than 1 pad per day at last follow-up

Symptoms and Impact on quality of life were assessed with the ICIQ-UI-SF The mean summed score was 6.8; for a possible range of 0-21 points, this indicates a low impact on quality of life.

Of the men, 48.9% were cured (no pads or a pad for security only) at last follow-up. The cure rate in men without treatment for NBNS was 51.5% as opposed to 41.7% in those with previous NBNS-treatment. Most patients (42; 93.3%) reported an improvement of >75% in their urinary condition, while 27 (60%) reported >90% improvement. There were no patients reporting less than 50% improvement. Patient global perception of improvement was >75% in 97% of the men without previous treatment for NBNS and 83.3% in those who underwent treatment for NBNS. Satisfaction with treatment was also better in men without previous treatment for NBNS, with 90.9% being satisfied or very satisfied as opposed to 58.3% in those with previous treatment for NBNS. All patients would recommend the procedure to a friend. Also, 44 patients would be willing to undergo the procedure again, 1 was undecided.

Interpretation of results

The outcome in men without or with a history of NBN-incisions before AUS implantation is different; ICIQ-UI-SF scores, the percentage of men reporting >75% improvement on the global perception of improvement scale and the percentage of men who were satisfied or very satisfied were all worse in the group with a history of NBNS-treatment.

Concluding message

Artificial urinary sphincter implantation is a safe and effective treatment for male incontinence due to prostate cancer therapy. Overall, treatment is very successful with 93.3% reporting more than 75% improvement in their urinary condition. Although results in men with a history of treatment for NBNS are less good, all men would recommend the procedure to a friend and would not refrain from undergoing this type of surgery again, had they known the result beforehand.

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