Gallistl H¹, Huber E¹, Hubner W¹

1. Dept. of Urology Clinic Korneuburg

ABDOMINAL PRESSURE TRANSMISSION DEVICES FOR URETHRAL SPHINCTERS: IN VITRO EFFECTS AND CLINICAL OUTCOMES

Hypothesis / aims of study

AMS 800 artificial urinary sphincter has been as standard procedure for postprostatectomyincontinence –PPI for many years. Subcuff atrophy is a well known phenomenon in sphincter systems closing the urethra in the circumferential fashion. The urethral blood flow in the area covered by the cuff has shown to be of major importance for clinical continence. Therefore the goal is to reduce baseline pressures within a sphincter system and still provides stress continence. Lately a new hydraulic sphincter, Flow Secure® - FS has been introduced, providing abdomino-urethral pressure transmission as well as the possibility of postoperative adjustment of the system pressure. We compared this system to a standard AMS sphincter system that was extended by a abdominal open cuff for pressure transmission to the urethra as well as a port for percutaneous puncture to allow postoperative adjustment of the system pressure AMS 800 extended.

Study design, materials and methods

In vitro study: In order to demonstrate efficacy of the stress ballon (FS®) or open cuff (AMS 800 ext.), sudden pressure rises by 35 cm H2O were adminstered. Pressure generated by cuff closure were recorded via a rectal ballon. Simultaneously the pressures within the systems cuff pressures were recorded using a standard rectal urodynamic balloon. The same setup was used to evaluate the efficacy of the two pumps measuring the pressure decrease in the cuff per pumpstroke. 15 pts. with FS® and 5 AMS 800 ext. pts. were evaluated 6-8 weeks after activation of the system concerning initiation of voiding, uroflow and by a stresstest. Function of the trigger was demonstrated by flexible cystoskopy during valsalva.

Results

In vitro testing the demonstrated, that "abdominal" pressure was transferred to the AMS cuff by 44 % (+/- 4 %), the delay came to approximately 180 milliseconds. These numbers were practically equal in the FS®. Compressing the AMS pump resulted in a pressure decrease in the cuff by 38 (+/- 4) cm H20 per stroke, thereby emptying the cuff after a maximum of 3 strokes. In the flow secure system pressure reduction in the cuff per pumpstroke was only 3-4 cm H20, thus requiring up to 30 strokes to completely empty the cuff. In clinical practice, 5/5 AMS 800 patients needed only 3 (+/- 0,8) strokes to initiate voiding and an able normal flow rates.

Interpretation of results

All patients were dry on stresstest. All 15 FS® patients needed 8 or more pumpstrokes to initiate voiding with normal stream, whilst maintaining low flow rates. 66 % of these patients were dry at stresstest. The trigger function was demonstrated in all pats. on cystoscopy.

Concluding message

Achieving continence at the lowest possible systemic pressure appears to be desireable in order to prevent subcuff atrophy. This can be achieved by selecting low pressure balloons (AMS 800) or lowering the system pressures postoperatively by adjustment (FS®). Selective urethral pressure peaks triggered by intraabdominal pressure rises would still provide a continence even during sneezing cuffing, etc. We have shown that such pressure transmission works in both setups. However, significant problems were found emptying the flow secure cuff secondary to poor pump efficacy as well as the high volume that needs to be transferred from the distal to the proximal part of the system in order to empty the cuff. Long term studies will have to show, wether subcuff atrophy really can be prevented by using such systems. It has to be noted, that abdominal pressure triggers would be contraindicated in all patients with detrusor acontractility or neo bladders.

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| Is this a clinical trial? | No |
| What were the subjects in the study? | HUMAN |
| Was this study approved by an ethics committee? | No |
| This study did not require eithics committee approval because | yes |
| Was the Declaration of Helsinki followed? | Yes |
| Was informed consent obtained from the patients? | Yes |