SURGICAL AND PATIENT REPORTED OUTCOMES OF ARTIFICIAL URINARY SPHINCTER IMPLANTATION - A MULTICENTRE PROSPECTIVE OBSERVATIONAL STUDY

Hypothesis / aims of study
The AMS 800TM artificial urinary sphincter (AUS) remains the gold standard for the treatment of stress urinary incontinence in men. However, there have been few prospective observational studies using validated classifications of complications or standard questionnaires to assess changes in continence status and quality of life (QOL) after surgery. We conducted a multicenter, prospective, observational study to assess outcomes, including QOL, after AUS implantation.

Study design, materials and methods
A total of 135 patients who underwent primary AUS implantation at 5 institutions between 2011 and 2015 were prospectively registered. Perioperative complications that occurred within 90 days after surgery were classified according to the Clavien-Dindo classification. The number of patients who underwent AUS revision surgery during the observation period and the rate of patients who did not undergo revision surgery (revision-free rate) were estimated. Multivariate analysis was performed to identify patient risk factors for revision surgery. The numbers of pads needed per day, the ICIQ-SF and King’s health questionnaire (KHQ) were assessed prospectively to estimate continence status and QOL preoperatively and at 1, 3 and 12 months after surgery. All research protocols were approved by the ethics committee of our institution.

Results
Median age of the 135 patients at the time of surgery was 73 (range, 30-84) years. A total of 13 (10%) patients had perioperative complications (wound infection, 5; urinary retention, 4; others, 4) that were equal to or less than grade 3b in the Clavien-Dindo classification. Sixteen patients finally underwent AUS revision surgery during the median observation period of 24 (3-53) months. Revision-free rates at 1-, 2- and 3-years after AUS implantation were 94%, 88% and 81%, respectively. Diabetes mellitus and poor preoperative ASA physical status classification were significant risk factors for revision surgery. The median number of urinary pads used decreased from 6 (1-20) to 1 (0-5) after surgery. The scores in both ICIQ-SF and KHQ were markedly improved after surgery. However, the ICIQ-SF and some items from KHQ showed slight but significant deterioration at 12 months compared with scores at 1 month after surgery.

Interpretation of results
Same as previous publications, AUS implantation was safe and durable surgery. However, revision surgery was needed in a certain percentage of patients. AUS implantation substantially improves patient continence status and QOL soon after surgery, however, pad numbers needed per day and scores of ICIQ-SF and KHQ showed slight but significant deterioration from relatively early, within one year, after surgery.

Concluding message
AUS implantation is safe, durable and effective surgery. AUS implantation markedly improves patient continence status and QOL soon after surgery, however, patients started to experience slight, but noticeable, deterioration in continence status and QOL from relatively early after surgery. This finding might be helpful in appropriate counselling patient undergoing AUS implantation.
Disclosures
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