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EVOLUTION OF THE FLOWSECURE ARTIFICIAL URINARY SPHINCTER

Hypothesis / aims of study

The use of the artificial urinary sphincter (AUS) for the treatment of moderate to severe stress urinary incontinence(SUI) has long been established as the standard practice when conservative measures have failed. (1,2) There has been however, the development of alternative artificial urinary sphincters which has tried to address some of the flaws in design of the 3-piece device. (1,2,3) The introduction of a "stress balloon" developed by Craggs and colleagues aimed to address two of the major deficiencies of the 3-piece device, namely the failure of the pressure regulating balloon to adapt to changes in intra-abdominal or bladder pressure and, the issues relating to revision when there is cuff atrophy. (1,3) The aim of the current study was to critically analyse the outcomes of the first generation of FlowSecure urinary sphincter in a regional, tertiary centre.

Study design, materials and methods

Within our regional, tertiary centre, twelve FlowSecure artificial urinary sphincters were implanted into eleven patients between 2013 and 2015. Patient notes were reviewed along with electronic hospital database and X-ray systems. Ten of the patients had history of SUI secondary to previous laparoscopic radical prostatectomy (one patient had two FlowSecure sphincters implanted) and one patient had a history of spina bifida with neuropathic bladder. The patients were randomly selected to have a FlowSecure sphincter fitted and all had a pre-operative video urodynamics and cystoscopy. A pre-operative 24hour pad weight test was recorded as was post-operative pad weight test if applicable. Patients were reviewed for activation at 6 weeks further reviews at eight to ten weeks for further top-up depending on the clinical picture. For those with ongoing SUI, an MRI was carried out to assess the sphincter components and if any anatomical abnormality was accounting for the failure.

Results/ Interpreation of results

Of the ten patients who had a previous radical prostatectomy, none had adjuvant radiotherapy, one patient had non-insulin dependent diabetes mellitus (NIDDM) and one patient had a previous cerebro-vascular accident (CVA). Four patients had Gleason 3+3pT2c disease, five patients had intermediate risk Gleason 3+4 or 4+3 pT3a and one patient had high risk Gleason 4+4T3b adenocarcinoma of the prostate. The average pre-operative 24hour pad weight test was 713grams (n= 8, range 200gms to 2000gms). There were no operative complications and immediate post-operative recovery was unremarkable. Two patients did have a CT abdomen/pelvis day one post-operatively because of abdominal pain but no abnormality was found and their symptoms settled. All patients attended for review and activation of sphincter at six weeks.

There was failure of the Flowsecure sphincters in seven out of twelve implanted. Four of the patient had malfunctions related to the pump, despite attempts at top-ups/withdrawal of fluid and three patients had issues with the size of cuff being used (all 3 had 4.5cm cuff size implanted). Of the seven that had malfunctioned, all had MRI's to investigate the cause of failure which was indeterminate. Six of the failed FlowSecure sphincters have been explanted and replaced with AMS 800 while the seventh is awaiting explantation and revision surgery.

Two patients with FlowSecure sphincter are under review and although still having urinary leakage, the volume is much less than before. In one patient, his 24hour pad weight test has reduced by 78% (2000gms to 428gms) while the other patient (with spina bifida) is still requiring 5 pads per day with average 24hr pad weight of 523grams.

The final three in this case series are all happy with the results of their FlowSecure implantation. The surgeons made two adjustments in these three cases. All three have 3.5cm cuff implanted rather than the bigger 4-4.5cm cuff size. The other deviation from previously was altering the position of the balloons placement intra-peritoneally. In these three patients, the pre-operative 24hour pad weight test measured 800gms, 450gms and 200gms respectively and their post-operative 24hr pad weight test measured 36gms, 0gms and 0gms respectively. All three reported to be feeling 'very much better' in their global outcome of severity score.

Concluding message

The small case series highlights that further research and development is required to devise a better artificial urinary sphincter. In this tertiary centre where surgical experience of insertion of the AMS 800 artificial urinary sphincter is high, there were noteable problems encountered with the early FlowSecure sphincter which required removal in almost 60% of cases. Issues relating to the size of cuff and the placement of the pressure regulating balloon seem to be at the forefront of these problems, evidenced by the latter success of the remaining cases It appears that the original cuff sizes were inaccurate and the size measured as 4.5cm was actually 5.5cm. the development of a fibrous capsule around the reservoir and stress relief balloon, when placed in the retropubic space, made activation difficult. Now that both these issues have been addressed by the correct sizing of the cuff and placement of the reservoir and stress balloon in the peritoneal cavity, the efficacy of the FlowSecure sphincter is greatly improved and may well rival that of the AMS 800.

References

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