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CUFF PRESSURE VS CONTINENCE: LONG TERM CLINICAL RESULTS OF A PROTOTYPE ARTIFICAL URINARY SPHINCTER WITH CONDITIONAL OCCLUSION FOR THE TREATMENT OF GENUINE STRESS INCONTINENCE (GSI)

Aims of Study

The safety and efficacy of the prototype artificial urinary sphincter with conditional occlusion has been evaluated with a follow up of up to one year. The aim of this study was to investigate the relationship between urethral pressure and continence in patients with the prototype device. The prototype AUS consists of a bulbar urethral cuff, a pump unit with self-sealing port, a regulation balloon and a stress relief balloon. The stress relief balloon transmits intra-abdominal pressure rises transiently to the cuff providing conditional occlusion during periods of stress, this enables the device to operate at lower regulation pressures. This device has been designed to overcome some of the problems associated with the existing AMS-800 AUS such as urethral atrophy which has been attributed to high occlusion pressures [1]. The device is implanted as one-piece and the pressure is set post-operatively and optimised to give continence without compromising urethral tissue viability.

Methods

Seven male patients (mean age 66.4 (60-77) years) with post prostatectomy GSI have been implanted with the prototype artificial urinary sphincter. Activation was carried out between 2-4 weeks post operation by percutaneous injection of sterile saline into the base of the pump unit. Implant pressure was set in the range 0-70 cmH_2O and urethral pressure beneath the cuff (P_{UC}) was monitored simultaneously using perfusion profilometry techniques. Continence was assessed in the laboratory using standardised stress tests; Valsalva manoeuvre, coughs and squats. Continence was also assessed in the home environment using patient voiding and leakage diaries which were completed for 7 days prior to attendance at the clinic. A new index of continence was derived from the reported leaked volume (V_L) and voided volume (V_V) over the seven day diary entry period. The 'Continence Index' was calculated using the following formula :

Continence Index = $[100*V_V / (V_L + V_V)]$

Patients were followed up at one, three, six and twelve months post activation. At each visit a number of additional procedures were carried out including standard cystometrogram, flowmetry and stress tests. Magnetic Resonance Imaging (MRI) was also carried out to visualise position of urethral cuff in all patients.

Results

We have demonstrated that the prototype artificial urinary sphincter provides a significant improvement in genuine stress incontinence following prostatectomy. The graph in Figure 1 shows the Continence Index for the seven patients at each follow up visit as calculated from patient voiding diaries. Prior to implantation the mean continence index was 55.1 ± 30.8% and at 12 months the mean index for 2 patients to date is 98.7 ± 1.8%. Patient JV002 had the device removed following activation, as a sufficient degree of continence could not be achieved, the cuff fixation was found to be faulty during investigation by MRI. The mean urethral pressure beneath the cuff P_{uc} was 43 cmH_2O, the lowest pressure AMS800 balloon is 51-60 cmH_2O. Laboratory stress tests demonstrated that the stress relief facility provided good continence even though device pressures were low. The relationship between urethral pressure and continence demonstrates that above a threshold of 40cmH_2O in P_{UC} there is no significant improvement in Continence Index. Follow up cystometry and flowmetry showed no incidence of detrusor instability and insignificant changes in flow rate following implantation.

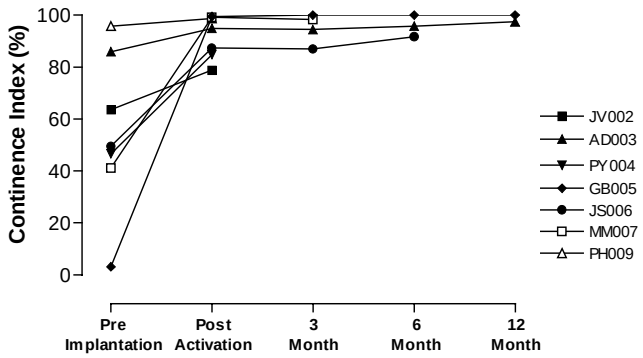

Figure 1. Continence Index as indicator of continence following insertion of the prototype artificial urinary sphincter with conditional occlusion.

Conclusions

The results of this investigation suggest that the prototype artificial urinary sphincter significantly improved post-prostatectomy incontinence as measured using the Continence Index and standardised stress tests. The urethral pressures measured beneath the cuff show that the device can be successfully operated at low regulating pressures due to the action of the conditional occlusion facility. This should potentially reduce long term problems associated with urethral tissue atrophy [2].

References

1. Journal of Urology. 2000 Sep;164(3 Pt 1):702-6

2. European Urology.1998;33(Suppl 1):97.