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THE SPARC PROCEDURE FOR URODYNAMIC STRESS INCONTINENCE: A MULTICENTRE PROSPECTIVE STUDY WITH 1 YEAR FOLLOW UP.

Aims of Study

Minimally invasive sling type procedures, designed to provide midurethral support, have gained popularity for the treatment of female urodynamic stress incontinence. Tension free vaginal tape is the most widely utilised and in a randomised study has been shown to be as effective as colposuspension at 2 year follow up[1]. The rates of mesh infection or erosion are negligible and this has been attributed to the properties of the type of polypropylene mesh used. However some concerns regarding it's safety have been raised with complications such as major vessel and bowel injury which are thought to more common with a vaginal approach[2] it is postulated that a suprapubic approach with a similar mesh may be safer. The aim of this study was to evaluate the safety and efficacy of the AMS Suprapubic ARC procedure in women with urodynamic stress incontinence (USI).

Methods

In this ongoing study 113 women, median age 56(35-88) with USI have undergone a SPARC procedure in one of 5 European centres. The SPARC procedure involves passing two fine needles through two suprapubic incisions and out through the ipsilateral paraurethral tissue through a midurethral vaginal incision. Polypropylene tape attached to dilators is connected to each needle after cystoscopy excludes bladder injury. The tape is drawn upwards on each side and adjusted to lie in the midurethra without tension. Preoperative and 6 month postoperative evaluation included BFLUTS and Kings Health questionnaires, 1 hour pad test, uroflowmetry, cystometry, UPP and VLPP. At 1, 3 and 12 months postoperatively evaluation includes the questionnaires, uroflowmetry, urinary residual estimation and physical exam. Pre and post op haemaglobin measurements, operative blood loss, all complications and operative times were recorded in addition to post op analgesic requirements.

Results

98 women have completed 6 and 12 month follow up with complete subjective, objective and quality of life data. The median procedure time was 16mins (5-54). The median blood loss was 20mls (0-300). There was no major vessel injury or development of retropubic haematoma. The mean hospital stay was 1 day(1-4)

At 6 month follow up the subjective cure and improvement was 81% and 11% respectively. Cure or improvement in urgency was 38% and 20% respectively. At 12 month follow up the subjective cure and improvement was 83% and 11% respectively. We have not assumed women not yet followed up are all failures. 82% of women were objectively dry at 6 months(pad test and cystometry). 80% were dry at 12 months (pad test)

We found no significant change in pre and postoperative maximum cystometric capacity, VLPP, MUCP or flow rate or urinary residuals but 17% of women complained of a poorer stream. 7 women have de novo Detrusor overactivity

There were significant sustained improvements in all domains of the Kings Health questionnaire

Early complications include: 8 bladder perforations, 2 urethral perforations, 8 women had urinary tract infection and in 2 women the mesh became exposed without infection and the vaginal skin was resutured. 5 women had prolonged voiding difficulty one settled after 7 days, 2 required short term CISC and in 1 the sling was loosened and in 1 it was cut. At 1 year 1 woman has recurrent UTI and one has significant residuals and is using CISC.

Conclusions

- The SPARC sling procedure appears to be safe . There is minimal risk to vascular structures. The incidence of bladder injury, UTI and voiding difficulty appear to be similar to TVT as presented in the randomised trial[1].
- The efficacy of the procedure at 6 months and 1 year is very promising, longer term follow up will be required.

References

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