

EARLY RESULTS ON THE PREPUBIC APPROACH TO THE PLACEMENT OF A SYNTHETIC MIDURETHRAL SLING FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

While generally safe and effective the retropubic and trans-obturator routes of midurethral sling placement may result in devastating complications resulting from the blind passage of trocars through body compartments, namely major vascular, bowel, and neurologic injury. In 2003 Ulmsten reported on a technique of prepubic placement of a synthetic midurethral sling as an equally efficacious and potentially safer method of mesh placement. [1] We herein report on our series of women with stress urinary incontinence (SUI) treated via the prepubic placement of a woven prolene midurethral sling.

Study design, materials and methods

Thirty-five women with urodynamically confirmed stress incontinence were enrolled in an open label prospective trial at three medical centers. Human studies committee approval was obtained from the Institutional Review Boards at the respective institutions prior to enrollment. Women with significant urge incontinence, low sensory capacity, elevated post void residual, prior pelvic radiation, and previous stress incontinence surgery were excluded from participation. Preoperative evaluation included urodynamics, focus physical exam, voiding diary, pad test, and subjective questionnaires. The sling was placed under regional or general anesthesia via a 2-4 centimeter vaginal incision with trocars guiding the sling material through the prepubic space to the skin surface. Tension was adjusted per surgeon preference. No intraoperative stress test or was performed. Patients were followed at 10-days, 3, 6, and 12 months postoperatively by pad weight after provocative maneuvers (jumping 10 times in place), physical examination, and quality of life questionnaires including the Pelvic Floor Distress Inventory (PFDI) and Short-form Sexual Questionnaire (PISQ-12). Cure was defined as less than 1 gram of urine loss on pad testing with no leakage of urine reported on subjective questionnaire.

Results

Thirty women underwent the prepubic sling procedure. Mean age of those enrolled was 56 years (range 35-83). Subjects had a mean body mass index (BMI) of 30 (range 21-51). The mean time to perform the procedure was 31 minutes (range 5-103 minutes). Follow-up on 29 subjects at the 3-month post-operative visit showed cure in 15 (65%) and improvement in 11 (21%). Failure was observed in 3 subjects (13%). Transient urinary retention was reported in 2 patients (6.7%). No cases of bladder penetration were noted. There were no other intraoperative or postoperative complications.

Interpretation of results

The placement of a synthetic midurethral sling via a prepubic approach shows similar efficacy at 3-month follow-up as retropubic and trans-obturator techniques with a minimum of intraoperative and postoperative morbidity.

Concluding message

Early results of the prepubic midurethral sling procedure are promising. This route of mesh placement is potentially safer as it avoids blind passage of trocars through the retropubic space and obturator foramen minimizing the risks of bladder, bowel, nerve, and major vascular injury.

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Federal Food and Drug Administration, Institutional Review Board at the respective institutions and followed the Declaration of Helsinki Informed consent was obtained from the patients.