EFFICACY AND SAFETY OF THE SINGLE INCISION SUB-URETHRAL SLING PROCEDURE FOR STRESS URINARY INCONTINENCE

Hypothesis / aims of study
Among the various minimally invasive procedures for treatment of female stress urinary incontinence, single incision slings offer less invasiveness with presumed less morbidity. This is a study to assess the efficacy, safety and patient satisfaction rates for single incision sling.

Study design, materials and methods
A cohort of 92 patients with a mean age of 61.55 years, who underwent MINIARC sling (American Medical Systems) between March of 2008 to December of 2009 by a single surgeon, were reviewed retrospectively. Pre operatively, all patients filled out a questionnaire, underwent a physical exam, cough test and a complete urodynamic study. Postoperatively the patients filled out questionnaire regarding their subjective continence status and satisfaction rates. All patients had a post operative physical exam and cough test. Patients who claimed to have recurrent or persistent stress urinary incontinence underwent a complete urodynamic study. Subjective cure rate was defined as no use of pads and objective cure rate was negative cough test and/or negative leak on urodyamics.

Results
On urodynamic testing 20 (21.74%) patients had a low leak point pressure (LPP) (less than 50) and 31 (33.70%) had moderate LPP (50 to 90) and 41 (44.57%) had high LPP (above 90). 37 (40.2%) patients had a Minarc procedure alone while the rest had concomitant pelvic floor prolapse surgery, which includes 23 (25%) with concomitant cystocele repair, 13 (14%) with concomitant rectocele repair, 17 (18%) with Antero-Posterior repair and 3 with other vaginal surgeries. All patients were done as outpatient procedures. There were no unanticipated events or complications. Follow up ranged from 2 weeks to 126 weeks. 76 (82.6%) patients with a follow up of more than six weeks (mean 28 weeks), were included in the study. The subjective cure rate was 93.5% and objective cure rate was 97.4%. 24% had persistent urge incontinence which was mild to moderate and managed by behavioral modifications and medications except one who did well with interstim test stim and is awaiting permanent Interstim placement. None had de novo urge incontinence. 94.7 % were pleased or delighted with the results of the surgery and a similar number would recommend it to their friend. The two patients had complained of persistent stress urinary incontinence on post operative follow up visit and two developed stress incontinence on follow up visit at 6 weeks and 3 months respectively. Three out of four patients gave the history of being continent admitted to some episode of increased intra-abdominal pressure which they attribute to causing the recurrence. Four failures showed objective improvement in their LPP on urodynamics. Three patients underwent a follow-up retropubic sling procedure and were very satisfied post-operatively, making the final satisfaction rates 98.7%. 

Interpretation of results
MiniArc procedure is a single incision sling system for female urinary incontinence, which has gained widespread acceptance since its launch. This might be on account of the simplicity of the procedure and minimal morbidity to the patient with resultant early return to normal activities. This study highlights that this procedure can be done in all severities of incontinence, with a high success rates. This study also shows that the patients undergoing this procedure are very satisfied with the outcome.

Concluding message
MINIARC sling is an effective and a safe procedure and has a high patient satisfaction rates. The failures can be easily and effectively managed.

Specify source of funding or grant None

Is this a clinical trial? No

What were the subjects in the study? HUMAN

Was this study approved by an ethics committee? No

This study did not require ethics committee approval because

This is a retrospective chart review of FDA approved procedure with no reference to individual patients. A blanket consent has been obtained from all patients for data collection and use for paper presentation or research purposes without revealing any personal identity.

Was the Declaration of Helsinki followed? Yes

Was informed consent obtained from the patients? Yes