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EVALUATION OF SAFETY AND EFFICACY OF SINGLE INCISION MID-URETHRAL SHORT TAPE PROCEDURE (MINI ARC TAPE) FOR STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Mid-urethral tapes or tapes have become widely used for the surgical treatment of women with stress urinary incontinence. First described in 1995, the systems were soon formatted as kits and marketed worldwide. The initial system, the tension-free vaginal tape(TVT), was passed retropubically, and more than 1 million of these procedures have been done worldwide. Despite its relative safety, the original tension free vaginal tape procedures require the blind passage of needles through 2 small incisions in the abdomen just above the pubic bone. The retropubic space that the needle has to pass through to get to these abdominal incisions is also a very vascular space with venous plexuses and the potential for injury to large blood vessels in the pelvis. Secondary to this and the areas that the needle has to pass to place the mesh tape, there is potential for complications such as injury to the bladder, intestines, or nerves in the pelvis and/or abdomen. All of these injuries have been reported in the literature.

In 2001 transobturator (TOT) passage of a mid-urethral tape was introduced. The rationale for transobturator passage was the restoration of hammock-like support and the avoidance of the bladder as well as of rare but serious complications such as injury to major vessels or the bowel. Despite its improved safety profile and excellent cure rates, the procedure still involves passing needles through the groin, which in certain patients can result in groin pain. Although the risk is very low, especially with the outside-in approach like the TOT tape, the risk still exists.

Miniarc™ tape involving only one incision vagina, and NO incisions in the abdomen or groins and NO needle passages through the abdomen or groins has been developed. The aim of this study was to assess complications and short term results (3 months to one year) from Miniarc™ tape for stress urinary incontinence.

Study design, materials and methods

Between August 2007 and November 2008, 76 women underwent single incision mid-urethral tape (Miniarc™). The mean age was 61, with a range 32-92 years. Mean BMI was 32.9±7. Of the 76 patients, 50 (66%) suffered pure stress urinary incontinence (positive stress test with no urge incontinence or urodynamic evidence of stress incontinence), while 26 (34%) presented with mixed urinary incontinence (confirmed on urodynamics). As part of the preoperative workup, a case history was compiled for all patients, together with a physical examination and urodynamic evaluation in the case of mixed urinary incontinence. The International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) was completed in the context of the case history preoperatively and at postoperative follow up. The duration of follow-up ranged from 91-466 days.
Objective healing was defined when physical examination of the patient with the full bladder yielded a negative stress test, while subjective healing was assessed based on the ICIQ-SF and patient perception of improvement in symptoms (dry, significantly improved, slightly improved, same, worse). Surgery was carried out under local anesthesia or with sedation in 76% (n=58) of the women and in remaining cases general anesthesia was used (10/18 women had associated prolapse repair).
Antibiotic prophylaxis (IV 1.2 g of Co-Amoxiclav) was given prior to placement of the patient in the gynaecological position with 90-degrees thigh-abdominal flexion. After emptying the bladder with Foleys catheter, 20-60ml (median dose 30ml) of 1% lignocaine mixed with 1: 200000 adrenaline was injected on the incision site and the tape trajectory to the internal obturator muscle. The patient was finally returned to the ambulatory adult surgical unit without a bladder catheter (except in cases with prolapse repair when catheter was inserted for 12-24 hours), followed by two post-micturition residue measurements. Discharge with a bladder catheter was decided when the residues were over 150 ml.
Follow-up was conducted in the outpatient clinic after 2 months with the urogynaecology nurse specialist and three months, and one year with the consultant. The case history and ICIQ-SF were documented. A physical examination with Cough stress test was also made. The pre operative and post operative ICIQ-SF scores were analysed statistically using SPSS inc., release 16.0.
Results

	At 3 months follow up				At 1 year follow up			
Subgroup	Total	No follow up	Stress test negative	Subjectively dry or significantly improved	Total	No follow up	Stress test negative	Subjectively dry or significantly improved
Pure SUI	50	3	31(66%)	33/47(70%)	25	nil	18(72%)	18(72%)
Mixed UI	26	2	13(54%)	14/24(58%)	3	nil	2(67%)	2(67%)
Total	76	5	44(62%)	47/71(66%)	28	nil	20(725)	20(72%)

On using the ICIQ-SF questionnaire a statistically significant improvement in the Pre operative scores (Mean 17±3.17) and postoperative scores (Mean 9.63±6.28) was found ($p<0.0001$-Wilcoxon signed ranks test).

90% (n=69) of the women did not require bladder drainage. 6 (8.5%) women required bladder drainage for 12-24 hours all had associated prolapse repair and were done under GA. One woman required suprapubic catheter for more than 24 hours for urinary retention this was the woman with SUI with partial outflow obstruction on urodynamics. 90% (n=69) of the women were discharged home the same day and remaining (n=7) were discharged home on day 1 (<24 hrs), one was a diabetic and the remaining had associated prolapse repair under GA. 98% (n=75) of the patients had residual volume <150ml post operatively. No intra-operative complications were reported. One (1.4%) woman each had vaginal tape erosion at incision site, one (1.4%) had vaginal synechiae

causing obliteration of vagina, she had a prolapse repair done along with Miniarc™. One woman had chronic retention requiring intermittent self catheterisation. 9 (13%) women reported de-novo urgency symptoms of which 3 required anticholinergic treatment.

Interpretation of results

Treatment of Pure SUI with Miniarc™ tape resulted in 66% objective and 70% subjective improvement at 3 months follow up and 72% subjective and objective improvement at 1 year. The subjective and objective improvement was lower in women with mixed incontinence at 3 months (54% and 58%) at 3 months follow up. Our results of success are lower than reported by (Ref.2), but comparable with published evidence for TVT secur for which 1 year follow up data exists (Ref.1 -78% subjective and 81% objective improvement). The major complications noted in our study were one vaginal tape erosion and one vaginal synechiae.

Concluding message

At short term follow-up, single-incision mid-urethral tape procedure is an effective option in the treatment of stress urinary incontinence. The major advantage of this procedure when compared to TVT or TOT procedures is the possibility of performing this procedure under local anaesthesia on an ambulatory basis with less post operative pain and intra operative complications. However, a long term follow-up is required to confirm these findings.

References

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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 eithics committee approval because	**In our centre, Miniarc sling has been approved by the Clinical Governance committee. Therefore IRB or LREC approval is not required.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**