767

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A MULTI CENTRE PROSPECTIVE COHORT STUDY OF SINGLE INCISION TRANSOBTURATOR TAPE (SI-TOT) FOR THE TREATMENT OF STRESS URINARY INCONTINENCE (SUI) UNDER LOCAL ANAESTHESIA

Hypothesis / aims of study:

- To establish the feasibility and acceptability of new adjustable single- incision transobturator tape (SI-TOT) to be done under our Local anaesthesia (L.A) protocol.
- To assess the safety and short-term success of SI-TOT procedures.
- To establish the appropriate "Learning Curve" cases for this new technique.

Study design, materials and methods: A multicentre, prospective cohort study involving 3 urogynaecologists and 4 gynaecologists from 6 units in Scotland. All eligible women admitted for sub-urethral tapes in the period between August 2009 and March 2010 were invited to participate in the study. Women would have had urodynamics stress incontinence (USI) or Mixed Urinary Incontinence (MUI) with predominant stress component, with failed or refused pelvic floor muscle training. Women with neurological conditions, concomitant surgery or prolapse (POP-Q II) were excluded. Women were informed of the lack of long-term data on this procedure and that surgeons are within their learning curve; informed consent obtained.

All surgeons attended a formal training session by an experienced urogynaecologist and subsequently performed at least 8 cases under general anaesthesia (GA) before offering the procedure under LA. The SI-TOT used was the 'Ajust'© (C. R. Bard, Inc., Murray Hill, New Jersey, USA) and procedures were done as originally described and Cystoscopy was performed for all cases. L.A protocol included preoperative analgesia: Diclofenac 50-100mg PR and/or Paracetemol 1g PR and optional 10mg morphine. Intra-operative IV midazolam (1-10mg titration) and infiltration of 20-40 mls of L.A using a spinal needle of gauge 22 (Levo-Bupivacaine 0.25% only or Bupivacaine with adrenaline).

Pre-operative assessment included detailed history and examination. Women completed validated symptom severity questionnaires: International Consultation on Incontinence Questionnaire (ICIQ-SF) and the Urgency Perception Scale (UPS) pre and 3 month postoperatively. In addition they completed Patient Global Impression of Improvement (PGI-I) and underwent cough stress test (CST), and vaginal examination at follow-up. Patient reported success was defined as "Very Much/ Much Improved" while objective success was defined as negative cough stress test with comfortably full bladder. Operative data were prospectively collected: blood loss, operative time (including anaesthetic time), operative pain scores (on a10 point scale) at end of dissection, trochars insertion and postoperatively at 30 minutes and 3 hours. All patients underwent standardised postoperative voiding assessment. Length of postoperative stay and time to return to normal activities was recorded.

Data was analysed using SPSS 17.0 (Chicago, Illinois) using descriptive/frequency analysis. Categorical variables tested with Chi-square test and fisher's exact test for the two independent variables. Independent t test was used to test differences in ICIQ-SF scores pre to post-operation. Mann-Whitney tests used to compare between different groups. For learning curve analysis; the procedures were arranged chronologically and assigned a rank based on their position in that surgeon's 'order of procedures'. This was then plotted against the procedure time/ difficulty, success rates & pain scores in order to establish a relation with surgeon experience if any. All statistical tests evaluated a significance level of 5%.

Results: 89 patients underwent SI-TOT during the study period: G.A (n=54) Vs. L.A. (n=35)

(a) Feasibility and acceptability of SI-TOT to be done under our developed LA protocol:

35/ 41 women (85%) approached to have the procedure under L.A. agreed. Only one woman had to be changed to G.A intra-operatively due to pain score (7/10) at end of dissection. Of the successful 34/35 women under LA: most women received a pre-operative combination of two or more of Diclofenac (Median dose: 100mg), Paracetamol (1gm) and Midazolam titration (Median dose 4.0 mg). 3 women (9%) also received Morphine (Median dose: 5 mg).

Mean pain score at the end of dissection was 0.65 ±SD 1.50 (Range: 0-7, median 0.00) and 2.82 ±SD 2.68 (Range 0-8, Median: 2.00) at end of "trochar insertion". Mean post operative pain scores at 30 minutes was 0.47± SD 1.35 (Range 0-3; Median 0.00) and at 3 hours was 0.44 ±SD 1.04 (Range: 0-3; Median 0.00). There was no significant difference with postoperative pain in women done under GA (P= 0.894 & P= 0.612 respectively).

The mean operative time was significantly shorter in the GA group 19.04 ±SD 7.80 vs. 22.56 ± SD 6.06; p= 0.027, while significantly more women in the LA group had satisfactory voiding within 24 hours of the procedure (97% vs. 84%; P= 0.019). The mean length of postoperative hospital stay in the LA group was 4:05 hours ±SD 1:39 with no statistical difference with the GA group (p=0.863, 95%CI -0:50, 0:42).

(b) The safety and short term success of the SI-TOT procedure:

At the time of writing 89% (n=79) women had completed 3- month follow-up: the patient reported success rate was 84% (n=66), additional 8% reported "improvement". 95% (n =75) had a negative cough stress test. The mean pre-operative ICIQ-SF scores was 14.02 ±SD3.51 (Range: 5-19) compared to postoperative mean 2.37±SD 4.52 and these were statistically significant (p<0.001). Pre-operative urgency was cured in 48% (n=26) of women and an additional 21% (n=11) reported improvement of at

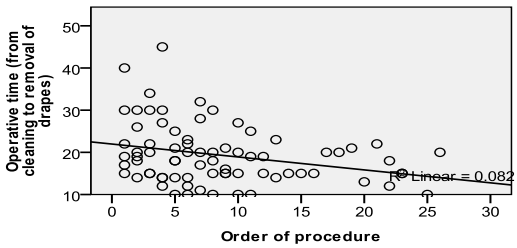
least one point on UPS. 22% (n=12) had no change in their urgency while 9% (n=5) had worsening of at least one point on UPS. 3% (n=2) women developed mild –moderate de novo urgency.

There were no cases of bladder or urethral injuries. Bleeding (>100ml) was reported in 4% (n=4) of cases. 2 cases of voiding dysfunction (3%): 1 woman had surgical division of tape and one woman was on CISC at follow-up. Surgeons reported temporal difficulty in inserting the trochars (mainly left) in 11% (n=10) of procedures; 2% (n=2) tapes were reported as faulty and new ones were successfully applied. Vaginal erosion was reported in 2% (n=2) cases.

(c) Describing the surgical Learning Curve:

Graph 1 shows a significant reduction in operative time with surgeon experience on correlation analysis (p=0.013). However there were no correlation between the surgeon experience and postoperative pain scores (p=0.96), length of hospital stay (0.86), reduction in ICIQ-SF scores (p=0.624) or surgical

Graph 1: Showing relationship between surgical experience against operative time



Interpretation of results: This is a multicentre prospective study for a new adjustable SI-TOT and the learning curve cases for surgeons. The majority of women (85%) are prepared to undertake SI-TOT under L.A. and the protocol seemed to be successful with 97% of cases completed. Some patients have a low pain threshold and extra intra-operative analgesia may be required such as Morphine or preferably Fentanyl. Further studies are recommended into the main reasons for L.A being un-acceptable to some women and to help patient selection.

This the largest study to date reported on this new adjustable SI-TOT; 2 previous small studies of 30(1) & 17(2) patients showed objective success rates of 100%. While 95% of our women had a negative CST, the use of the validated PGI-I and ICIQ-SF score are more reliable in reporting patient reported outcomes and highlight a number of women who have seen little/no improvement. The use of urgency perception scale was clinically useful in identifying that 48% of women were cured of their urgency while only 9% experienced worsening of urgency. There were no significant complications in our series, we have performed cystoscopy to all cases and there were no instances of bladder /urethral injury. Interestingly, while operative time significantly decreased with surgeon experience surgical difficulty in trochar insertion was not related.

Concluding message: The new adjustable single incision transobturator tape is feasible to be done under local anaesthesia and the procedure under LA is acceptable to the vast majority of women. Our results show this procedure to be safe and successful on the short term. Larger studies with long-term follow-up are required to confirm these initial promising results and ideally comparing to the current standard surgery.

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Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**www.clinicaltrials.gov**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**North of Scotland Research Ethics Committee, NOSRES Ref: 09/S0802/34**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**