Hypothesis / aims of study
To quantify the rate of different complications following the TVT-O (Gynaecare®) procedure and to study the effect of these complications on recovery pattern.

Study design, materials and methods
Between July 2007 and February 2008, 40 patients underwent a TVT-O procedure for urodynamic stress incontinence. Patients were asked to fill in a Proforma at the 6-8 weeks follow up appointment. SPSS was used to analyze the data. Chi² test was used for most calculation. Fisher’s exact test was used where expected individual cell value was less than 5.

Results
24/40 (60%) patients had the procedure as a day case; the majority of the rest (10/16) had other procedures in addition to TVT-O. 29/40 (73%) felt that the procedure cured their symptoms, 9/40 (23%) felt that there symptoms improved after the procedure and only one patient felt that her symptoms got worse after the procedure. There was a trend for the cure rate of the procedure to be negatively affected by having another procedure simultaneously, but this did not reach statistical significance (p=0.26). There were no major complications. 30/40 patients had one or more minor complications; the most frequent complication was groin pain (16/40) which lasted anything from one day up to few weeks, but invariable resolved by 8 weeks. Other complications included: suspected urinary tract infection (UTI) 3/40 (7.5%), confirmed UTI 6/40 (15%), urinary retention 1/40 (2.5%), voiding difficulty 2/40 (5%), new overactive bladder symptoms 7/40 (18%), vaginal discharge or bleeding 6/40 (15%), vaginal pain 3/40 (7.5%), dysparunia 1/40 (2.5%), buttock numbness 1/40 (2.5%) and other complications 2/40 (5%). only one patient required readmission for vaginal bleeding. The rest of the complications resolved either spontaneously or with medical advice. Recovery from the TVT-O procedure for the patients who did not have other procedures was as follows: By day 3, 24/30 (83%) had had their first bowel motion. Activities such as mobilising, driving, shopping and hoovering were generally resumed within a week of the procedure (figure 1), while other activities such sexual intercourse and returning to work took longer to recover (figure 2). There was no significant association between groin pain and resumption of mobility (going upstairs p=0.36, going outside the house p=0.52), driving (p=0.51), sexual life (p=0.96) or work (p=0.07). 23/30 (77%) patients felt that they were back to normal level of activity within 4 weeks of the procedure. 38/40 patients were satisfied with the procedure, two patients did not comment on their level of satisfaction.

Interpretation of results
The incidence of groin pain (40%) and new overactive bladder symptoms (18%) are higher than what has been reported in the literature (1). All cases of groin pain, however, resolved by 6-8 weeks and did not affect recovery. It has been suggested that the inside-out approach for inserting a trans-obturator mid-urethral tape is associated with lower risk of urinary tract injury as compared to the outside-in approach (2), but it may be associated with a higher risk of groin/ thigh pain. The latter is proposition is debatable, though (1). The only way to resolve this issue is a randomised controlled trial. Most of the new overactive bladder symptoms are short lasting and self limiting, but we did not have enough affected cases to examine this further. Recovery from the TVT-O procedure is impressive; however there is a need to stress the importance of delaying sexual activity until hospital review at 6-8 weeks, 68% of those who were sexually active had had sexual intercourse before their post-operative hospital visit which, theoretically, might increase the risk of tape erosion or increase the risk of infection of an eroding tape.

Figure 1: Percentage of patients resuming different activities at different points in time during recovery

![Figure 1: Percentage of patients resuming different activities at different points in time during recovery](image-url)
Concluding message
The quick recovery of patients following a TVT-O procedure may lead patients to resume their sexual life before complete healing had taken place. This issue needs to be brought to the attention of patients. Also, there is a need for an appropriately powered randomised controlled trial to compare the complication rate of the two approaches for inserting trans-obturator mid-urethral tapes.

References

Specify source of funding or grant
No funding was received for this project

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
it was part of a service evaluation exercise and it did not entail any change to patients' care

Was the Declaration of Helsinki followed?
Yes

Was informed consent obtained from the patients?
Yes