

TENSION FREE VAGINAL TAPE (TVTTM) VS LESS INVASIVE FREE TAPE (LIFTM) - A RANDOMIZED MULTICENTRIC STUDY OF SUBURETHRAL SLING SURGERY

Hypothesis / aims of study

Since the introduction of TVT by Ulmsten in 1996 numerous modified tapes and surgical methods were developed. Most of the new tapes have not yet been the subject of detailed studies. We conceived a comparative study of two different tapes applied use the same surgical technique; the classic TVT tape by Gynecare compared with LIFT by Cousin Biotech, with the distinctive feature of a suburethral pad. The objective of the study was to assess differences in surgical outcome, perioperative complications and long-term results.

Study design, materials and methods

The study was conducted as an open, prospective, randomized, multicentric study. 254 patients participated in the period between April 2003 and May 2005 (TVT group n=123 and LIFT group n=125).

Follow-up examinations were scheduled at six months (clinical examination alone), and 12 months (clinical examination and urodynamic studies), followed by an additional clinical follow-up examination at 24 months. Patients were also questioned in a standardised way on their subjective perception of cure in the form of a Visual Analogue Scale (VAS). A subjective evaluation of quality of life was also included. Objective evaluation was conducted by analysing preoperative and postoperative urodynamic measurements, or results of a PAD or clinical stress test.

Results

The overall subjective response rate was 96.1% (73.3% cured, 22.8% improved) in the TVT group and 95.4% (73.4% cured, 22.0% improved) in the LIFT group after 6 months. After 12 months a subjective cure rate of 87.1% and improvement of 8.1% for TVT, 87.5% and 10.4% for LIFT respectively was measured. Statistical analyses failed to detect significant differences between the both tapes for patient specifications. Overall, both tapes used in the study showed very low perioperative complication rates. There were 3 intraoperative bladder perforation (n=2 TVT and n=1 LIFT respectively), one case of haemorrhage, and only one patient with haemorrhage more than 300 ml blood loss, both with the use of a TVT. Tape transection was required in 3.3% (TVT) and 7% (LIFT) of cases. There was no erosion of tapes into the urethra, but n=3 of TVT cases and n=7 of LIFT cases exhibited vaginal erosion, and bladder penetration occurred in 1 case from each group.

Interpretation of results

TVT and LIFT are comparable in terms of surgical effort, perioperative complication rate, and postoperative continence rate. No advantages or disadvantages could be identified for the use of the suburethral LIFT pad for the treatment of urethral incontinence. In case of an urethral pad there is a little increasing of vaginal erosion and initial obstruction.

Concluding message

TVT and LIFT slings are safe procedures in the management of SUI with similar success rates up to 1 year follow-up and a very low complication rate.

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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 did not need ethical approval because not necessary but followed the Declaration of Helsinki Informed consent was obtained from the patients.