

OBSERVATIONAL STUDY ON THE IMPLANTATION OF THE TVT-SECUR UNDER LOCAL ANESTHESIA

Hypothesis / aims of study

Stress urinary incontinence (SUI) is a common problem, affecting women of all ages. Treatment options for SUI include physiotherapy and surgical interventions, such as retropubic operations and midurethral slings. Conventional retropubic and transobturator tapes are the preferred choice for most surgeons, because of their wide applicability, technical simplicity and clinical efficacy. However, even if their implantation under local anesthesia has been studied and proven relatively safe, this practice has not gained popularity. The new TVT-SECUR shows a potential for implantation under local anesthesia, because of a less-invasive technique using minimal vaginal dissection as well as avoidance of retropubic space and obturator fossa.

This is a prospective, clinical, non-comparative study with primary objective to observe the satisfaction and short-term efficacy of the implantation of the TVT-SECUR under local anesthesia, with the use of questionnaires completed by the patients.

Study design, materials and methods

The population consists of 35 women operated from January 23rd 2007 to February 26th 2008. The implantation of the TVT-SECUR under local anesthesia was done by one surgeon, using the 'Hammock' technique in the first 23 cases and the 'U-method' in the last 12 cases. Local anesthesia consisted of a mixture of 35 ml of lidocaine 2%, with or without epinephrine, and 5 ml of bicarbonate 3%. Sedation was used in association with local anesthesia, comprising 1 mg of lorazepam sublingual as well as a combination of 0,5 to 2 mg intravenous (IV) of midazolam and 50 to 200 ug IV of fentanyl. Postoperative analgesia consisted of a prescription of 30 tablets of morphine 5 mg.

Data was collected through five questionnaires completed by the patients at baseline, immediately, 1 week, 2 months and 6 months after surgery. Questions were related to local anesthesia satisfaction, improvement in SUI symptoms and overall satisfaction. Perioperative and postoperative complications were recorded.

Results

The following are preliminary results on 35 patients with a mean follow-up of 9 months. Mean age of the population was 60 y.o. (38-85), 51% (18/35) had genuine SUI and 9% (3/35) had undergone a previous anti-incontinence surgery. Regarding local anesthesia satisfaction, 97% (34/35) required 1 mg IV of midazolam or less and 74% (26/35) required only 50 ug of fentanyl. 'Visual Analogue Scale' for pain immediately and 1 week after surgery showed a mean score of 17/100 and 28/100 respectively. After 1 week, 67% (22/33) had used 5 tablets of morphine or less. At 1 week, 2 months and 6 months after surgery, the improvement in SUI symptoms rate was 79% (26/33), 81% (21/26) and 69% (9/13) respectively and the satisfaction rate was 70% (23/33), 73% (19/26) and 77% (10/13). Perioperative complications included 1 urethral laceration that was repaired during the initial procedure and needed a Foley catheter for 14 days. Postoperative complications included 2 transient urinary retentions as well as 6 partial tape exposures that needed revision in all cases.

Interpretation of results

Local anesthesia and light sedation appeared to provide satisfactory analgesia during implantation of the TVT-SECUR. However, the improvement in SUI symptoms was low compared to other midurethral slings and the complication rate was high regarding partial tape exposure.

The lack efficacy may be explained by the technique used, as the 'U-Method', used in the last 12 cases, appears to offer a better support to the urethra. Also, tightness applied to the tape should probably be more than for other midurethral slings, as less retraction is experienced with the TVT-SECUR. The high rate of partial tape exposure could involve multiple factors, from the technique used, 'Hammock' versus 'U-Method', to the type of local anesthesia, with or without epinephrine, and the type of sutures done, continuous versus interrupted.

Concluding message

The TVT-SECUR shows a potential for implantation under local anesthesia. However, this new midurethral sling has shown concern regarding improvement in SUI symptoms and complication rate. Refinement of the technique may improve cure rate and help lower the number of complications. Long-term follow-up is needed in order to evaluate the safety and efficacy of the TVT-SECUR.

Specify source of funding or grant	Department of Surgery of the Faculty of Medicine of the Sherbrooke University
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Ethics committee on human research of the Sherbrooke University Hospital Center and the Faculty of Medicine of the Sherbrooke University
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes