COMPARISON BETWEEN TRANSOBTURATOR VAGINAL TAPE INSIDE OUT AND SINGLE INCISION SLING SYSTEM IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: PROSPECTIVE RANDOMIZED STUDY

Hypothesis / aims of study
To compare between transobturator vaginal tape inside out (TVT-O) and single incision sling system (TVT-Secur) in the treatment of female stress urinary incontinence (SUI).

Study design, materials and methods
From January 2009 to September 2009, 80 women with SUI underwent TVT-O (n=39) or hammock approach of TVT-Secur (n=41) under local anesthesia by a single surgeon. Patients were randomly assigned to either TVT-O or the hammock approach of TVT-Secur procedure. Following measures were recorded; detailed history, physical examination, voiding diary, urodynamic study with abdominal leak point pressure (ALPP) and the Stamey symptom severity scale of mild, moderate or severe. At 6 hours after surgery, all patients completed 10cm linear visual analogue scale (VAS) for evaluation of pain. After 3 months and 12 months, surgical outcomes by the Sandvik questionnaire, incontinence quality of life questionnaire (I-QoL), and 5-point likert scale for evaluation of patient satisfaction were evaluated. We analyzed these parameters especially focusing on success rate and quality of life after operation.

Results
There were no statistical differences of preoperative parameter in two groups. Immediately after surgery, TVT-Secur group showed lower pain scale (TVT-Secur vs TVT-O, 3.7±2.5 vs 5.0±2.6, p<0.05) in 10cm linear VAS and less needs of postoperative medication for pain symptoms (24.4% vs 56.4%, p<0.05) than TVT-O group. After 3 months, overall success rates were 97.4% (cured 82.0%, improved 15.4%) in TVT-O group and 95.1% (cured 70.7%, improved 24.4%) in TVT-Secur group. The 5-point likert scales for evaluation of patient satisfaction were 4.5±0.6 in TVT-O group and 4.4±1.0 in TVT-Secur group. There were no significant differences statistically. After 12 months, overall success rate were 94.9% in TVT-O group and 82.9% in TVT-Secur group (p=0.09), but cure rate is higher in TVT-O group compared to TVT-Secur group (76.9% vs 51.2%, p=0.01). A 10cm linear VAS for evaluation of patient’s satisfaction was higher in TVT-O group compared with TVT-Secur group (4.1±1.2 vs 2.9±1.5, p<0.05).

Interpretation of results
TVT-Secur operation was less painful than TVT-O operation, but overall success rate and patient’s satisfaction were higher in TVT-O operation compared with TVT-Secur.

Concluding message
Our results show that TVT-O operation is more effective than TVT-Secur in the treatment of female stress urinary incontinence even though TVT-Secur is less painful compared with TVT-O.

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Is this a clinical trial?  Yes
Is this study registered in a public clinical trials registry?  No
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  The ethical Review Board of CHA medical university Gumi CHA Hospital
Was the Declaration of Helsinki followed?  Yes
Was informed consent obtained from the patients?  Yes