

## 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,  $3.7 \pm 2.5$  vs  $5.0 \pm 2.6$ ,  $p < 0.05$ ) 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  $4.5 \pm 0.6$  in TVT-O group and  $4.4 \pm 1.0$  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 ( $4.1 \pm 1.2$  vs  $2.9 \pm 1.5$ ,  $p < 0.05$ ).

### 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.

<b>Specify source of funding or grant</b>	<b>NONE</b>
<b>Is this a clinical trial?</b>	<b>Yes</b>
<b>Is this study registered in a public clinical trials registry?</b>	<b>No</b>
<b>Is this a Randomised Controlled Trial (RCT)?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>The ethical Review Board of CHA medical university Gumi CHA Hospital</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>