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A PROSPECTIVE MULTICENTER RANDOMIZED STUDY OF 'U' AND 'H' APPROACH OF TVT-SECUR PROCEDURE FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: ONE-YEAR FOLLOW-UP

Hypothesis / aims of study
The TVT-SECUR (TVT-S) system was developed with an aim to further reduce the invasiveness of the surgical procedures avoiding the passage of the needle through the retropubic or obturator regions. So, the advantages of this technique are related to the short way of the needles that minimize the risk of vascular, nerve or visceral injury. The prosthetic implant is placed under the mid-urethra and can be fixed in the 'hammock (H)' position into the obturator internus muscle or in the 'U'-shaped position into the connective tissue of the urogenital diaphragm behind the pubic bone. But some concerns may arise regarding the strength at the fixation point and the tensioning maneuver. Also, there's lack of comparative study on the surgical outcomes between two types of approach. So, the objectives of this study were to compare the objective and patient-reported outcomes between 'U' and 'H' types of TVT-S procedure in women with stress urinary incontinence (SUI).

Study design, materials and methods
From July 2007 to January 2008, women with urodynamic SUI were enrolled in this prospective, multi-centre, randomized, parallel group study. Patients were randomly assigned to either 'U' or 'H' type of approach. Preoperative evaluation included detailed history, physical examination, standing stress test and a multi-channel urodynamic evaluation. At postoperative 12 months, standing stress test was performed and treatment benefit, satisfaction, and willingness to retreatment/recommend (BSW) were assessed. Additional pre- and post-operative evaluation included incontinence quality of life questionnaire (I-QOL), Bristol female lower urinary tract symptoms scored form ($BFLUTS_{SF}$) questionnaire, incontinence visual analogue scale (VAS), voiding diary, and Sandvik questionnaire. Objective cure was defined as no leakage on the standing stress test and subjective cure was defined as 'no' leakage on the Sandvik questionnaire. Besides the traditional outcome measures, patient-reported goal achievement (PGA) was evaluated. Before surgery, patients completed an open-ended questionnaire on personal goals for the surgery and the goals were categorized into 5 groups; 1) symptom, 2) quality of life, 3) activity/exercise, 4) coping behaviour, 5) sex. At postoperative 12 months, patients reviewed their original goal and assess the degree of goal achievement using a 6-point Likert scale (from '0=not at all achieved' to '5=completely achieved'). 'Successful achievement' was defined as 4 or 5. Intra- and post-operative adverse events were also evaluated.

Results
Of a total of 283 women, 144 had 'U' and 139 had 'H' type of surgery. Mean age was 54.2±9.0 years (U: 55.4± 9.2 vs. H: 53.0±8.9, p=0.014). There was no statistical difference in symptom severity, abdominal leak point pressure, and urethral hypermobility between 'U' and 'H' approach. The objective cure rate was 83.9% (U: 87.5% vs. H: 80.1%, p=0.183) and the subjective cure rate was 76.4% (U: 77.9% vs. H: 75.7%, p=0.786) at 12 months after the operation. Other measures such as I-QOL, $BFLUTS_{SF,}$ incontinence VAS and voiding diary were significantly improved. (Table) Mean duration of the operation was 17±10 min and mean duration of hospital stay was 1.0±1.2 day with no difference between two approaches. Estimated blood loss was 44±80 ml (U: 42±39 vs. H: 46±108, p=0.019). Immediate postoperative pain VAS was 2.4 (U: 2.5 vs. H: 2.3, p=0.530). About 82% (U: 87% vs. H: 77%, p=0.037) were satisfied with the surgical outcome, 82% (U: 87% vs. H: 78%, p=0.053) had a benefit from the surgery. And 85% (U: 92% vs. H: 79%, p=0.002) were willing to have the same surgery if she'd have been in same condition and 88% (U: 93% vs. H: 84%, p=0.026) were willing to recommend the same treatment to other women with SUI. Patient-reported goals for the surgery were mainly related to the symptom relief (69%) and activity/exercise (22%). Successful achievement was 81% (U: 84% vs. H: 78%, p=0.273). Intra-operative complications were 3 cases of vaginal wall perforation which were repaired without problem and 1 case of massive bleeding which needed transfusion. There were 2 cases of acute retention which were resolved after few days of temporary drainage without voiding problem. Ten women had tape tightening procedure for persistent or recurrent SUI and 4 of those women had additional mid urethral sling procedures for persistent leakage.

Interpretation of results
After 1 year of the operation, objective cure rate was about 84% and subjective cure rate was 76% with no difference between 'U' and 'H' type. And PGA was also high as being 81% of successful achievement without significant difference in both types. But the postoperative changes in I-QoL and sub-domain scores of BFLUTS (filling and incontinence sum, QoL score) were more favorable in 'U' type than 'H' type. And satisfaction, willing to have same operation and recommend were also higher in 'U' type.

Concluding message
Both of 'U' and 'H' approach of TVT-SECUR system are effective procedure in terms of cure rate and patient reported outcomes including PGA for the treatment of female stress urinary incontinence. Further study is needed to identify factors that give the inferior outcomes to 'H' type in QoL and satisfaction.

Table. Comparison of the patient reported outcomes, voiding diary and uroflowmetry parameters between preoperative and postoperative 12 months of follow up

Variables	Total		'U' type		'H' type		*p* value
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	U vs H[§]
I-QoL							
Total	37.1	65.4*	37.0	69.2*	37.2	61.5*	0.016
Avo/Lim	41.8	71.3*	41.8	75.3*	41.8	67.2*	0.022
Psychosocial imp	43.3	71.9*	43.4	76.0*	43.2	67.7*	0.021
Social emb	34.7	74.9*	33.9	79.6*	35.5	70.0*	0.015
BFLUTS							
FS	6.18	3.60*	6.20	3.18*	6.15	4.04*	0.022
VS	2.58	1.74*	2.91	1.86*	2.23	1.61*	0.276
IS	8.55	3.46*	8.76	2.82*	8.33	4.12*	0.006
sex	1.74	0.87*	1.81	0.81*	1.66	0.94*	0.421
QoL	7.77	3.46*	7.90	2.80*	7.64	4.15*	0.007
Incontinence VAS	6.82	1.36*	6.90	1.03*	6.75	1.69*	0.056
Voiding diary							
Micturition/24hrs	9.03	7.97*	8.99	8.02*	9.07	7.92*	0.218
Nocturia	1.25	0.68*	1.28	0.68*	1.23	0.69*	0.615
Urgency episode/24hrs	2.37	1.22*	2.88	1.40*	1.86[†]	1.04*	0.329
Urodynamic study							
Qmax	25.7	24.3*	24.8	23.7	26.6	25.0	0.576
PVR	18.0	20.1	18.2	20.6	17.8	19.6	0.306

I-QoL; Incontinence quality of life questionnaire, Avo/Lim; Avoidance and Limiting Behavior, Psychosocial imp; Psychosocial Impacts, Social emb; Social Embarrassment, FS; filling sum, VS; voiding sum, IS; incontinence sum, VAS; Visual analogue scale. Qmax; maximal flow rate, PVR; post-voided residual

* $p<0.05$; comparison between pre- and post-op, Wilcoxon signed rank test or Paired T-test

† $p=0.021$; comparison of pre-op urgency episode/24hrs between 'U' and 'H' type, Wilcoxon two-sample test

§ Wilcoxon two-sample test or T-test

Specify source of funding or grant	**No.**
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	**Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**