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A COMPARATIVE STUDY OF TENSION FREE VAGINAL TAPE (TVT) VERSUS PERCUTANEOUS VAGINAL TAPE (PVT) FOR FEMALE STRESS URINARY INCONTINENCE: IS THE GOLD STILL NEEDED IN THE STANDARD?

Hypothesis / aims of study

Both TVT and PVT have comparable clinical reported results. We hypothesize that the self-fashioned polypropylene mesh sling technique is an alternative to the fascial sling or tension-free vaginal tape, and achieves a high success rate with few complications but with a lower cost.The aim of the study is to compare the effectiveness and safety of TVT versus PVT.

Study design, materials and methods

This is a prospective non-randomized study. All women who attended the outpatient clinic complaining of stress urinary incontinence, that can be objectively or urodynamically demonstrated, were our study subjects. Included in our study patients who had a previously failed anti-incontinence procedure, women with mixed incontinence, and SUI associated with pelvic organ prolapse. Exclusion criteria were intrinsic sphincter deficiency defined urodynamically as Abdominal Leak Point Pressure less than 60 cm H_20, Valsalva-induced detrusor instability, and neuropathic lower urinary tract dysfunction. Patients perception of their symptoms and quality of life were assessed by asking the patient to complete 3 validated questionnaires before the operation: the Patient global subjective score (visual analog scale), Incontinence Impact Questionnaire- Short form (IIQ-7), Urogenital Distress Inventory - Short-form (UDI-6). One year after the operation, changes in the patients symptoms, their quality of life and treatment outcome were reassessed. Anti-incontinence surgery response score (AISRS) (this is only a postoperative scoring system and was the primary outcome measure), Patient Global Subjective Score, IIQ-7, and UDI-6. Evaluation of the Safety was assessed by recording any intra- or post-operative complications as bleeding necessitating blood transfusion, bladder perforation, voiding difficulty defined as residual urine of 150 ml or more after spontaneous micturation, erosion into the urethra or vagina, infection whether at the surgical wound or in the sling. Patient was considered cured when scored a 0 on the AISRS (primary outcome measure). Non-inferiority of PVT to TVT was assessed with 1-tailed tests at 0.05 significance level testing the difference between means or proportions and using a delta value of 0.05 for proportion cured, and 20% of the scale for IIQ-7 (delta=3), UDI (delta=2) and global (delta=1).

Results

189 patients are included in our study. 97 TVT cases and 92 PVT cases. PVT is non-inferior to TVT using IIQ-7 (P=0.05). When AISRS is used as primary outcome, cure rate for TVT is 58% and 64% for PVT. PVT is an estimated 6% better than TVT, with 95% CI (19.5 better, 7.2 worse). Confidence interval is narrow; we are 95% confidant that true difference between PVT and TVT success by AISRS is between –19.5 (PVT better by 19.5%) and 7.2 (TVT better by 7.2%). There is no statistical evidence to support an association between prolapse and outcome (95% CI: -10.67, 38.75), P=0.27), to support an association between previous surgery and outcome (95% CI: -32.10, 20.99), P=0.68), or to support an association between urgency and outcome (55% of patients with pure SUI and 52% patients with Mixed Incontinence are cured (P=0.81).

Cure by AISRS(Primary outcome measure)	**TVT**	**PVT**	**P value**
Cured [No (%)]	57 (58%)	59 (64%)	1 -tailed test on non-inferiority = 0.08
Not-cured [No (%)]	40 (42%)	33 (36%)	
Total	**97**	**92**	

Table 1: proportions cured by PVT and TVT according to AISRS (Primary outcome measure)
Cure is defined as score = 0. not cured includes: good response (scores: 1-2), fair response (scores: 3-4), poor response (scores: 5), failure (scores: 6)

Interpretation of results

Based on current sample size, PVT is not inferior to TVT in regard to efficacy using IIQ-7 outcome or in comparison to TVT outcomes achieved with associated conditions. Furthermore, primary outcome is approaching significance as we near the number of cases required to power the study at this interval date.

Concluding message

Our results challenge the validity of any additional measures used other than the placement of a simple piece of prolene mesh at the midurethral level using the PVT method.