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Title: PROSPECTIVE MULTI-CENTER STUDY OF GYNECARE TVT TENSION-FREE SUPPORT FOR INCONTINENCE

Aims of Study:

To investigate the incidence of stress urinary incontinence in women who underwent a pubovaginal sling procedure using GYNECARE TVT Tension-free Support for Incontinence

Methods:

A pubovaginal sling procedure using GYNECARE TVT Tension-free Support was performed on subjects with genuine stress urinary incontinence (GSUI) at four US centers. Evaluations included urodynamic assessment (pre, 6 mo.), and patient-completed questionnaires (pre, 2, 6, 12 mo.).

Results:

Results were based on 55 evaluable subjects. Patient self-assessment of symptoms at 12 months indicated 37 (76%) cured, 11 (22%) improved, 1 (2%) no change, and 0 (0%) worsening (n=49). Forty-two of 48 subjects (88%) had no objective evidence of GSUI at the 6 month urodynamic visit. Forty-two of 55 subjects (76%) voided spontaneously on the day of surgery, 10 (18%) required an indwelling catheter for less than 2 days, and 3 (6%) required an indwelling catheter for 3-5 days. The postoperative post-void residuals (PVRs) were no different from the preoperative PVRs ($p=0.2$, $n=47$). One uncomplicated retro-pubic hematoma and 10 bladder perforations were reported. None of the complications required surgical intervention. A subset of 13 subjects had a preoperative urodynamic diagnosis of intrinsic sphincter deficiency (ISD) with hypermobility of the urethra. There was no objective evidence of GSUI at 6 months for these subjects. Patient self-assessment of symptoms in this subset at 12 months indicated 10 (77%) cured, 3 (23%) improved, and 0 (0%) no change or worsening.

Conclusions:

Pubovaginal sling using GYNECARE TVT Tension-free Support is an effective treatment for genuine stress urinary incontinence with or without ISD (88% objectively cured at 6 months, 98% subjectively cured or improved at 12 months). (Supported by ETHICON, INC. research grant.)