

I-Stop (CL Medical)

Slings for ISD-associated stress incontinence: Does elasticity or urethral positioning matter?



R Lefevre, T Peterson, G.W Davila. Section of Urogynecology & Pelvic Reconstructive Surgery Cleveland Clinic Florida Weston, Florida



TVT (Gynecare)

Objective

To compare the efficacy of a non-elastic bladder-neck sling to a mid-urethral elastic one in the treatment of (ISD) Intrinsic Sphincter Deficiency:

• I-STOP (CL Medical) vs. TVT (Gynecare)

Background

Urethral positioning during sling placement and inherent mesh characteristics such elasticity are factors that influence surgeons' choice of slings when managing urinary stress incontinence. Retropubic bladder-neck slings have been traditionally recommended for patients with urethral hypermobility and ISD. The use of a suburethral tape with minimal elasticity allows for a more precise individualized tensioning in order to improve sphincteric function[1]. Case series on the success rate of TVT for ISD patients have been published but comparative data is lacking[2]. We investigated the efficacy of 2 commonly used retropubic slings for the treatment of ISD: I-STOP (CL Medical) and TVT (Gynecare)

Methods

Our clinical database was queried for all patients with:

- Stress incontinence with urethral hypermobility
- Valsalva leak point pressures ≤ 60 cm H2O who had a TVT or I-STOP slings performed. They were then matched by age, parity, menopausal status and BMI. Daily incontinence episodes, patient selfassessments, daily pads use, results of standardized stress test (ST), urgency symptoms and de novo urge incontinence were tabulated.

Success was defined as:

- Cured or greatly improved on patient self-assessment
- 0 to1-2 incontinence episodes/day
- 0 to 1-2 daily pads use
- Negative ST

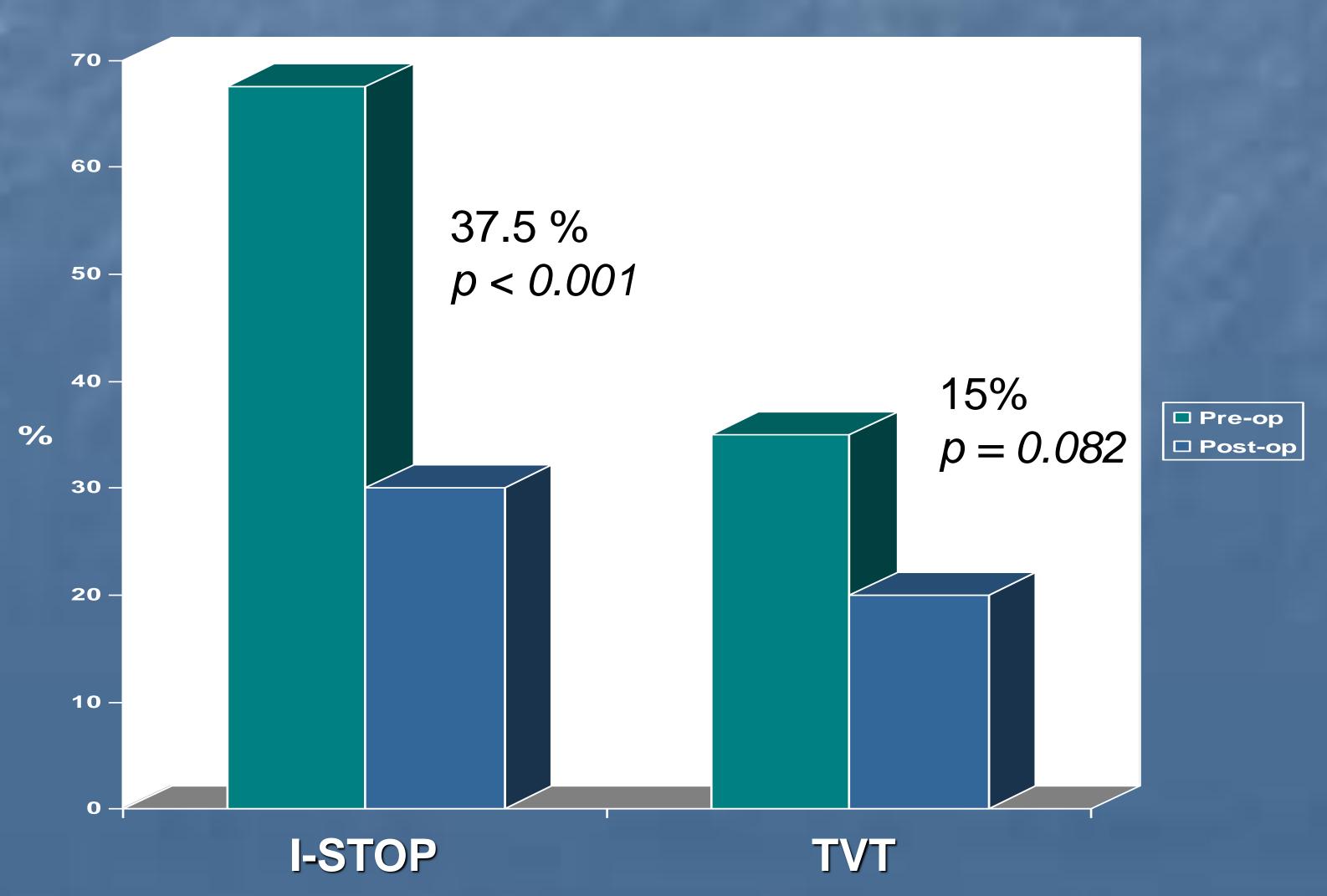
A paired *t*-test was used to compare continuous measures. A Mc Nemar Chi-square test was used for comparing success rates within each category and for comparing pre and post-operative urge incontinence rates. All analyses were performed at a significance level of 0.05 with SPSS software

Results

- 40 cases of TVT were matched to patients who had undergone an I-STOP sling.
- Mean post-operative follow-up period was 41.0 weeks and 37.15 weeks respectively.
- No difference in success rates in any of the outcomes measured (Table 1).
- De novo urge incontinence rates were similar in I-STOP and TVT group (13.3% vs. 11.6%, respectively, p = 1.00).
- Resolution of urgency symptoms post-operatively was statistically significant in the I-STOP group (67.5% preoperatively to 30 %, p < 0.001) vs. the TVT patients (35 % to 20 %, p=0.082) (Table 2).
- 2 patients from each group who required subsequent urethral bulking injections

Table 1: Outcome Measures I-STOP <u>TVT</u> Success (%) Success (%) p 34 (85) 36 (90) 0.687 Self Assessment 36 (90) 36 (90) Incont/day 1.00 Pads/day 35 (87.5) 37 (92.5) 0.687 **Stress Test** 40 (100) 40 (100) 1.00

Table 2: Urgency Reduction



Conclusion

I-STOP and TVT retropubic slings demonstrated comparable subjective and objective success rates for the treatment of ISD.

The reduction of urgency symptoms postoperatively was statistically significant in the ISD patients who underwent a non-elastic bladder neck sling (I-STOP). This clinical finding should be considered when choosing a sling for ISD.

Rechberger, T et al. A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery. Int Urogynecol J (2003) 14 432-436

Paick JS, Ku JH, Shin JW, Son H, Oh SJ, Kim SW. Tension–free vaginal tape procedure for urinary incontinence with low Valsalva leak point pressure. J Urol 2004 172:1370-1373