

## LAPAROSCOPIC BURCH COLPOSUSPENSION VERSUS THE TENSION-FREE VAGINAL TAPE PROCEDURE: A RANDOMIZED CLINICAL TRIAL

### Aims of Study

To compare the laparoscopic Burch colposuspension (LBC) with the Tension-Free Vaginal Tape procedure (TVT) for efficacy and safety.

### Methods

Seventy-two women from two institutions were randomized: 36 LBC and 36 TVT. Multichannel urodynamics were performed preoperatively and one year after surgery. Inclusion criteria were primary urodynamic stress incontinence, points Aa and Ba by Pelvic Organ Prolapse Quantification (POPQ) examination at 0 (the hymen) or above, and no concomitant surgeries for anterior vaginal wall prolapse. Exclusion criteria were an abdominal leak point pressure < 60 cmH<sub>2</sub>O and presence of detrusor overactivity on preoperative urodynamic investigation. A research nurse administered the Urinary Distress Inventory (UDI), the Incontinence Impact Questionnaire (IIQ), and pelvic examinations using the POPQ system preoperatively, six months, one year, and two years after surgery. Voiding diaries were collected at one and two years. Patients underwent office cystometry and cough stress test at two years after surgery. Primary outcome was objective cure defined as no evidence of urinary leakage during postoperative urodynamic studies. Secondary outcomes included subjective continence, operative time, complications, length of stay, POPQ and Q-tip examinations, urinary diaries, and quality of life. Continuous variables were compared with two-tailed ttest and categorical variables were compared with Fisher's exact test. Kaplan-Meier survival curves were generated for the development of symptoms of incontinence postoperatively and comparisons were made with the log rank test. Number of incontinence episodes recorded on the bladder diary and UDI and IIQ scores were compared using repeated measures ANOVA.

### Results

Thirty-six patients were allocated to each group. In the LBC group, 1 patient withdrew prior to surgery and 4 subjects were lost to follow-up after surgery. In the TVT group, 1 patient died unrelated to surgery prior to follow-up and 5 subjects were lost to follow-up. Thus, 31 LBC and 30 TVT patients were analysed with a mean follow-up of 18.8 months (range 6-43). Both groups were similar with respect to demographics and concomitant procedures performed except more adhesiolyses were done in the LBC group. Mean operative time was significantly greater in the LBC vs. TVT groups ( $p=.0009$ ). Intraoperative complications included 3 conversions to laparotomy in the LBC group and 2 cystotomies in the TVT group. Postoperative hospital stay, analgesia requirements, and complications were similar between groups. No differences were found in mean voiding times and no patients required suprapubic tube drainage > 19 days. One patient from each group required readmission: 1 for pyelonephritis in the LBC group and 1 for physical rehabilitation in the TVT group. One patient in the TVT group required mesh transection for urinary urgency; another patient required conservative management for vaginal erosion of the TVT mesh. Multi-channel urodynamic studies in 26 LBC and 28 TVT patients showed a significantly higher rate of urodynamic stress incontinence at one year in the LBC group, 23% vs. 3.6% ( $p=.046$ ). Detrusor overactivity was more common in the TVT vs. LBC group: 13.8% vs. 3.9% ( $p=0.35$ ). Voiding dysfunction was similar between groups. There was a significant improvement in the number of incontinent episodes/week and UDI and IIQ scores in both groups at 1 and 2 years after surgery ( $p<.001$ ). However, postoperative subjective symptoms of incontinence (stress, urge and any) were reported significantly more often in the LBC group than the TVT group ( $p<.03$  for each category). There was no significant difference in postop vaginal support as measured by POPQ, however urethral mobility was significantly greater in the TVT group (mean straining angle  $40 \pm 3.8$ ) than the LBC group (mean straining angle  $21 \pm 3.7$ ).

**Conclusions**

The TVT procedure results in significantly greater objective and subjective cure rates for urodynamic stress incontinence than the laparoscopic Burch colposuspension. Although LBC is associated with a longer mean operative time, both groups are similar with respect to length of hospital stay and intraoperative and postoperative complications.