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A CLINICAL ASSESSMENT OF GYNCARE TVT WITH ABDOMINAL GUIDES

Hypothesis / aims of study

Long term data has demonstrated that GYNECARE TVT using the vaginal approach is a safe and effective treatment for stress urinary incontinence (SUI). GYNECARE TVT *with abdominal guides* was introduced as an alternative to the transvaginal procedure for those physicians more familiar with a "top down" approach to pelvic surgery. Tape placement is identical to the vaginal approach; only the method of insertion is changed. The current study was performed to record the incidence of intraoperative and postoperative complications and collect effectiveness data using this new technique.

Study design, materials and methods

17 North American investigators experienced with the vaginal approach participated. Women with SUI were evaluated preoperatively and at 6 weeks, 6 months, and 1 year postoperatively.

Results

115 women were enrolled. The mean age was 59 and the mean duration of SUI was 7 years. 89 (77%) subjects had hypermobility, 28 (24%) had intrinsic sphincter deficiency, and 3 (3%) had both. 43 (37%) had urge incontinence (UI). 26 (23%) had previous anti-incontinence surgery. 44 (38%) had concurrent surgery. Patient reported success rates at 6 months and 1 year are in the tables below.

Evaluable Analysis	SUI Absent	SUI Improved	SUI Unchanged	SUI Worse
6 months (N=97)	80 (82%)	13 (14%)	3 (3%)	1 (1%)
1 year (N=88)	72 (82%)	13 (15%)	3 (3%)	0 (0%)

Intent to Treat Analysis	SUI Absent	SUI Improved	SUI Unchanged	SUI Worse	Not Seen
6 months (N=115)	80 (70%)	13 (11%)	3 (3%)	1 (1%)	18 (15%)
1 year (N=115)	72 (63%)	13 (11%)	3 (3%)	0 (0%)	27 (23%)

Of the 43 subjects with preoperative UI, 35 (81%) reported absent or improved UI postoperatively. 3 subjects reported the onset of *de novo* UI following their procedure. There were 9 (8%) bladder perforations and 1 (1%) urethral perforation, none of which required additional intervention. A total of 9 (8%) subjects had urinary retention and 6 (5%) had voiding dysfunction postoperatively. 3 of these required a midline release procedure while the others resolved with catheterization. Of the 3 subjects who underwent midline release 1 reported SUI symptoms as absent and the other 2 reported SUI symptoms as unchanged from their pre-operative baseline.

Interpretation of results

The subjective cure rate in this study of the abdominal approach is well within the range reported for the vaginal approach. With the exception of the single urethral perforation, which appears to be unique to the abdominal approach, the rate of intraoperative and early postoperative complications is also similar to that reported for the vaginal approach.

Concluding message

Early results with this new abdominal approach demonstrate similar safety and effectiveness when compared to the vaginal approach. Surgeon preference should be the primary factor in deciding which method to use. However, when performing the abdominal approach, extra care should be taken to avoid inadvertent damage to the urethra. This is because the tip of the needle is in close proximity to the urethra at the end of its passage. To avoid inadvertent

damage to the urethra a finger should guide the tip of the needle lateral to the urethra at the end of its passage. Only after palpating the tip vaginally should the needle then be turned medially to exit the vaginal incision.

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