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# THE TENSION-FREE VAGINAL TAPE OPERATION: RESULTS OF A REGISTRY

# Aims of Study

The tension-free vaginal tape (TVT, Ethicon) operation was introduced in our area in 1998 and quickly became popular. In 1999, in the absence of completed randomized trials, we initiated a central registry to assess the use of and perioperative complications with the new operation. The registry was later expanded to include other vaginal tape systems.

### **Methods**

65 gynecology units agreed to participate and entered patients. Per operation a single-page questionnaire was completed containing items on the patient (age, parity, previous gynecologic surgery), the operation (operating time, concomitant procedures, anesthesia, intraoperative problems, bladder drainage), and the postoperative period (days until residual urine <100 mL, postoperative stay, reoperation).

## **Results**

As of 1 March 2003 a total of 5157 patients undergoing the TVT operation were entered. The number of reports of other vaginal tape systems than the TVT was too small for meaningful analysis. 1453 women (28%) had undergone previous surgery for prolapse or incontinence, including 206 Burch colposuspensions. 59% of TVTs were performed in isolation, 41% with other procedures. Most concomitant operations were for pelvic organ prolapse. The results in patients undergoing a TVT procedure with or without a concomitant operation are shown in Table 1. The bladder perforation rate was 2.9% overall and higher in women with than in those without previous surgery (4.7% vs. 2.2%, P<.05). The bladder perforation rate among 206 women after colposusension was 5.3%. There appeared to be no lasting sequelae of bladder perforation.

Table 1. Perioperative Data	TVT in combination (N = 2128)	TVT only (N = 3029)
Operating time (min., median, range)	81 (15-390)	30 (9 -172)
Anesthesia		
Local	5%	45%
Regional	48%	42%
General	47%	13%
Bladder drainage		
Intermittent catheterization	6%	26%
Urethral Foley	65%	61%
Suprapubic	27%	6%
Intraoperative complications		
Bleeding	2.0%	1.9%
Bladder perforation	53 (2.5%)	95 (3.1%)
Postoperative stay (days)	7 (0-65)	3 (0-37)
Days until residual urine <100 mL	3 (0-95)	1 (0-64)

There were 138 reoperations (2.7%) for reasons related to the TVT. The most common cause of reoperation was urinary retention: 88 patients (1.7%) underwent division, loosening or removal of the TVT or secondary placement of a suprapubic catheter. 38 patients (0.7%) underwent reoperation for hematoma or bleeding.

There was one small bowel injury treated successfully with bowel resection 2 days after TVT. One patient undergoing radical resection of recurrent vulvar cancer and TVT placement died of multiorgan failure due to sepsis 46 days after surgery. One patient developed necrotizing fasciitis of the lower abdominal wall.

#### **Conclusions**

The TVT quickly became a frequently performed operation in our area for patients with primary or recurrent stress incontinence. The bladder perforation rate is increased in women with previous urogynecologic surgery, particularly colposuspension, but there were no sequelae of perforation. The TVT operation is frequently performed with other surgery, most commonly for pelvic organ prolapse. There are considerable variations in clinical practice. For example, only 45% of isolated TVTs were performed with local anesthesia and 61% of patients undergoing a TVT only had an indwelling urethral catheter. The high rate of indwelling bladder drainage probably reflects the frequent use of regional anesthesia. Major complications were rare. Urinary retention [1] and hematomas account for the large majority of reoperations after TVT.

#### References

1. Rardin CR, Rosenblatt PL, Kohli N, Miklos JR, Heit M, Lucente VR. Relaease of tension-free vaginal tape for the treatment of refractory postoperative voiding dysfunction. Obstet Gynecol 2002;100:898-902.