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TENSION FREE VAGINAL TAPE OPERATION. RESULTS AND POSSIBLE PROBLEMS.

AIMS OF STUDY

This study was undertaken in order to evaluate our results of tension free vaginal tape operation (TVT) for genuine stress incontinence

PATIENTS AND METHODS

From March 1996 to September 1998 39 patients with genuine stress incontinence and 32 patients with mixed incontinence underwent a TVT operation in our department. Two patients had experienced 2 and 16 one incontinence operations earlier. Median age was 58 range (36-87) years. In 8 of the patients the following operations were performed together with the TVT procedures: vaginal hysterectomy, anterior and/or vaginal repair, cervical amputation, laparoscopic ovarian removal and sterilization. Before the operation, history was obtained and 24 hours pad test, 3 urethral pressure profiles, stress test and flow test were performed. During the stress test the patients had to cough vigorously 3 times and jump 20 times on the spot with 300-ml. bladder filling. Twenty patients arrived fasting at the hospital the operating day and 51patients arrived at the hospital one-day prior to the operation. Forty-eight patients left the hospital the day after the operation and 23 patients left the hospital 2 to 7 days after the operation. Midazolam 5 mg. i.m. was given preoperatively. The operations were performed by 2 surgeons in local anesthesia using 0,25% Lidocain and 1-2 mg. Alfentanyl i.v. The vaginal procedures were performed in spinal anesthesia, laparoscopy in general anesthesia after the TVT procedure that was performed in local anesthesia. Cystoscopy was performed after the Prolene tape installation to unveil possible bladder perforation. With 300 ml. saline in the bladder, the tape was tightened till the patient was leaking only drops during vigorous coughing. Especially in patients with maximum urethral closure pressure of 20 cm. water or lower (LCP) it was difficult to find the right position for the tape. Antibiotics were not routinely given. The next morning, a catheter or vaginal ultrasound was used to detect residual urine. If exceeding 100 ml. the residual urine was controlled later in the day. In case of no improvement, tape correction was attempted. An 8 mm. Hegar probe placed in the urethra pulled the tape in dorsal direction. Median hospital stay was 2 (1-10). When residual urine was detected after the hospital departure, the patients were taught to use a catheter. Postoperative control in the outpatient clinic was performed after median 190 days range (155-708) except in one patient. History was obtained and the following recordings were performed: stress test, residual urine -and maximum flow recording. Cure was defined as: no leakage during stress test and/or no subjective leakage more than drops of urine more than 3 times a month. Statistics: Chi-square test

RESULTS

Median and range of leakage during 24 hours pad test and stress test and maximum urethral closure pressure before the operation were respectively 60 gr. (3-668), 29 gr. (0-227) and 29 cm. water (5-80). Sixty-five of 71 patients (92%) did not leak during stress test post operatively and none of these reported they were leaking more than drops of urine more than 3 times a month. Post-operatively 63 patients (89%) were not leaking during stress test. Two patients refused to do the stress test postoperatively, but reported that they were stress continent. Six patients were leaking respectively 2, 3, 5, 8, 22 and 40 ml. during the postoperative stress test. Five patients who did not leak during the post operative stress test, reported that they had been leaking drops of urine, from one to three times per month. They claimed this to be no problem. Twenty-one patients (30%) had LCP. Three of the six patients leaking during postoperative stress test had closure pressures of 7, 12 and 20 cm water respectively. Cure rate among patients with LCP was 86%, while cure rate for patients with a closure pressure higher than 20 cm water was 94%. This difference is significant $p<0,001$. Among the 32 patients with preoperative mixed incontinence 14 were cured for urgency and urge incontinence after 6 months. One patient had urgency and 17 patients had urgency and urge incontinence as before. Among the 39 patients with preoperative genuine stress incontinence, 3 patients reported urgency and 7 patients urge incontinence postoperatively. One bladder perforation was experienced, but healing was obtained after catheter drainage. One patient got a hematoma in the groin of 4cm. diameter. It resolved without intervention. Five patients used a catheter during median 14 days range (3-48) after the operation due to residual urine more than 100 ml. Eleven patients had median 1 episode range (1-4) of

cystitis postoperatively. The frequency of cystitis in these patients preoperatively is not known. Eight patients reported that the micturition was slower after the operation. Three of these had residual volume (median 30 ml. range 27-72) and reduced flow (median 10 ml/sec. range 8-13). Among the 13 patients who had residual urine, exceeding 25 ml. at the control, 5 patients had experienced cystitis postoperatively, 4 patients found the micturtion slower and 2 patients experienced postoperatively urge incontinence that they did not have before. Among the 8 patients who had an additional operation, one was leaking during the postoperative stress test.

CONCLUSIONS

We find a cure rate of 92% promising. Patients with LCP had a significantly lower cure rate than patients with closure pressure higher than 20 cm. water. In these patients it was often difficult to adjust the optimal tape position. Forty-three percent of the patients with mixed incontinence were cured for both urge and stress incontinence after the operation. The TVT procedure was successfully combined with other gynecological interventions. The operation may cause obstruction. Perhaps was this the case in 18 % of our genuine stress incontinent patients with experienced urge incontinence after the operation. Fifteen percent of the patients experienced cystitis after the operation, 18 % had residual urine and 8 % found that they were micturating slower after the operation. The TVT operation is attractive; it requires short operating time, can be performed as an outpatient clinic procedure and the results are promising. However, the operation may cause obstruction and the possible harmful consequences of this are not known.

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A MULTI-CENTRE, PROSPECTIVE, RANDOMISED, CONTROLLED, GROUP COMPARATIVE STUDY OF THE EFFICACY OF VAGINAL CONES AND PFX

Aims of study

Several studies have successfully reported separately on the value of weighted vaginal cones, pelvic floor exercises (PFE) and biofeedback in the treatment of urinary incontinence.

This study aims to compare the response of women with stress urinary incontinence to 12 weeks treatment with these techniques.

Methods and Materials

Some 101 women (age 20 to 64) with stress urinary incontinence were enrolled in the study. They were randomly assigned to one of three groups: Group A (N=41) received Aquaflex Cones (Seton, UK), Group B (N=40) received a PFX (pressure biofeedback device: Cardio Design, Australia) and Group C (N=20) received PFE. All women were seen 5 times during the 3 month study period. Group A patients were instructed to use an appropriate Aquaflex cone for 10 minutes each day. (Aquaflex cones are available in 2 sizes of empty shell and weights are introduced into the shell, according to the woman's ability to retain the cone). Patients in Group B were instructed to use the PFX for 10 minutes each day, in lying and standing, using a patient specific exercise regimen. Group C were instructed to perform patient specific exercises for 10 minutes each day. All groups completed an exercise diary and discontinued treatment during menstruation.

The primary end points were a measure of the reduction in the frequency of incontinence (from a bladder diary) and subjective assessment using a visual analogue scale (VAS). Secondary end points included muscle testing, QOL (Kings College) and pad usage. Adverse events and completion rates were recorded and will be reported in detail in a future paper.

Ethical committee approval was obtained and all patients signed a consent form.

Results

There were no significant differences between groups in any pre-trial variables.

68 women completed the trial and the results are shown in the table.

There was a significant difference in completion rates between the centres but no significant difference between groups.