Ulster Med J 2007; 76 (3) 146-149

Paper

Five Year Follow-Up Comparing Tension-Free Vaginal Tape and Colposuspension

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Accepted 5 April 2007

ABSTRACT

Burch colposuspension has been the procedure of choice for stress urinary incontinence, more recently the tension-free vaginal tape (TVT) has been used. A retrospective study on all TVT’s and colposuspensions was performed. The present clinical condition was assessed using the Bristol Female Lower Urinary Tract Symptoms and Short-Form 12 questionnaires. The median operating time was 50-59 minutes for TVT and 70-79 minutes for colposuspension. The median number of day’s hospitalization was 3 and 10 respectively. The overall success rate was 88.5% and 92% respectively. No significant difference in subjective outcome was noted at more than 5 years after surgery between the two procedures for either the BFLUTS or SF-12.

The initial surgical success for TVT surgery is maintained over a period greater than five years.

INTRODUCTION

Stress urinary incontinence (SUI) is a common pathological condition affecting women, and is associated with considerable distress and social inconvenience. A combination of stress and urge urinary incontinence has been estimated to account for up to a third of cases of female incontinence1-2.

Many different surgical procedures are described for the treatment of SUI. One of the more recent surgical options has been the tension-free vaginal tape (TVT) described by Ulmsten3 in 1996 as an ambulatory procedure under local anaesthesia and sedation for the treatment of female urinary incontinence. This involves insertion of a suburethral polypropylene tape. Before the introduction of the TVT for the treatment of urodynamic stress incontinence, Burch colposuspension had been the procedure of choice with a mean cure rate of 89.8% (95% CI 87.5 – 92.05)4.

Outcomes from one prospective multicentre randomised trial at 6 month and 2 year follow-up have shown TVT to be as effective as colposuspension5, with similar cure rates and less postoperative complications. However intraoperative complications are reported in relation to bowel, major blood vessel, bladder and urethral trauma6-8. There are relatively few published articles on long term follow-up greater than 3 years of patients undergoing TVT.

Almost all reported data comparing TVT with colposuspension excludes patients with mixed urinary incontinence. In day to day clinical practice many women with stress urinary incontinence also complain of urge urinary incontinence. Holmgren et al demonstrated initial cure rates of approximately 60% following TVT for the treatment of mixed urinary incontinence. The benefit persisted for up to 4 years but then gradually decreased to only 30% by 8 years9. This retrospective study includes patients with mixed urinary incontinence where stress urinary incontinence is the major symptom.

The objective is to assess if the initial findings reported in the literature at 6 months and 2 years regarding the efficacy and safety of TVT and Burch colposuspension are true at 5 – 10 years after surgery.

SUBJECTS AND METHODS

A retrospective observational study of all TVT’s and colposuspensions performed by a single surgeon from 1994-99, in a Northern Ireland tertiary referral hospital for urogynaecology. TVT was substituted for colposuspension in May 1998 as the procedure of choice. Patients undergoing TVT or colposuspension were identified from theatre diaries and the hospital based computerised coding system. Eighty five patients were identified, 40 patients in the TVT group, two of which were deceased, and 45 in the colposuspension group. The review was undertaken in 2005. Medical records of the patients identified were reviewed; factors examined included demographic details, pre-operative diagnosis, past gynaecological surgery, type of anaesthetic, length of operation, intra-operative and post-operative complications, length of stay in hospital and findings at post-operative review (at 6-12 weeks after surgery). Sixty two hospital charts were reviewed, 32 TVT and 31 colposuspension. 21 charts had been microfilmed and the cost and time implications of retrieval was prohibitive, and these were excluded from analysis.

The patient’s present clinical condition was assessed using

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The BFLUTS questionnaire was analysed using Fisher’s exact test for contingency tables and the SF-12 questionnaire was analyzed using the non-parametric Mann-Whitney test. Table I demonstrates the distribution of patients for the chart review and postal questionnaires.

RESULTS

Demographic characteristics and elapsed time from surgery are given in table II. There was a trend towards older and heavier patients undergoing colposuspension. All the patients identified in the chart review had undergone urodynamic investigation and the findings are documented in table III. The lower urinary tract symptoms as defined by the International Continence Society (ICS)\(^2\) are included. Approximately two thirds in each group, 19/32 and 24/31 (59% & 58% respectively) complained of mixed urinary incontinence whereas approximately a third, 10/32 and 10/31 (31% & 32%) respectively, were found to have combined detrusor overactivity and urodynamic stress incontinence at filling cystometry. Conservative treatment before surgery was undertaken in 88% (28/32) and 90% (28/31) in the TVT and colposuspension groups respectively.

TVT patients had regional anaesthesia and the colposuspension patients received a general anaesthetic. The median operating time, to include anaesthesia, was 50-59 minutes for TVT and 70-79 minutes for colposuspension.

The number of patients who had previously undergone past pelvic surgery were 59% (19/32) for TVT and 71% (22/31) for colposuspension, the commonest reported previous pelvic surgery was hysterectomy with 44% (14/32) and 58% (18/31) respectively.

Intra-operative and post-operative complications before discharge are documented in table IV; the main intra-operative complication was bleeding with 19% (6/32) noted to have moderate or more vaginal loss in the TVT group and only 3% (1/31) in the colposuspension group. One patient in the colposuspension group did require a subsequent blood transfusion. No bladder or urethral perforations were

| Table I. | Distribution of patients for data collection. |
|----------|-----------------------------------------------|
|          | TVT (n=40)                               | Colposuspension (n=45) |
| Medical charts reviewed | 32 | 31 |
| Questionnaires returned | 30 | 30 |
| Chart and questionnaire completed | 25 | 21 |
| Chart only completed | 7 | 10 |
| Questionnaire only completed | 5 | 9 |
| Microfilmed charts | 8 | 13 |
| Medical charts unobtainable | - | 1 |
| Patient deceased | 2 | - |

| Table II. | Demographic characteristics and elapsed time from surgery. |
|----------|-------------------------------------------------------------|
|          | TVT (n=32)                               | Colposuspension (n=31) |
| Parity (mean) | 2.4 | 3.3 |
| Age        |                                             |                            |
| 20-29      | 2 | 0 |
| 30-39      | 3 | 4 |
| 40-49      | 2 | 9 |
| 50-59      | 10 | 12 |
| 60-69      | 11 | 6 |
| 70-79      | 4 | 0 |
| Weight (kg) |                                             |                            |
| <50        | 0 | 1 |
| 50-69      | 8 | 7 |
| 70-89      | 16 | 11 |
| 90-109     | 5 | 10 |
| >110       | 1 | 2 |
| Not recorded | 2 | - |
| Time elapsed from Sx (mths) |                                             |                            |
| 60-72      | 20 | 2 |
| 73-84      | 11 | 2 |
| 85-96      | 1 | 17 |
| 97-108     | 0 | 1 |
| 109-120    | 0 | 6 |
| >120       | 0 | 3 |
noted. Post-operatively 25% (8/32) and 9% (3/31) required re-catheterisation in the short term of one week following surgery. However only 6% (2/32) and 3% (1/31) required intermittent self catheterisation (at one week following surgery) for TVT and colposuspension respectively.

The median number of day’s hospitalization was three for TVT and 10 for colposuspension. The overall success rate, defined as subjective absence of stress urinary incontinence was 88.5% (28/32) and 92% (28/31) respectively for TVT and colposuspension. At 5-10 years postoperatively the cure rate for stress urinary incontinence was 77% (23/30) and 70% (21/30), respectively, where cure was accepted as occasional or absent leakage of urine during exercise, coughing or sneezing on the BFLUT. Although TVT appears to better than colposuspension, the length of follow up for colposuspension exceeded that for TVT. If the patients which did not complete the questionnaire are considered as failures the percentages then drop to 60.5% (23/38) and 46.67% (21/45) respectively.

### DISCUSSION

Initial subjective cure rate at discharge from hospital care from case note review was 88.5% and 92% for TVT and colposuspension respectively, for patients with either stress urinary incontinence or mixed urinary incontinence. This is comparable with reported literature for patients with urodynamic stress incontinence only. At 5-10 years postoperatively the cure rate for stress urinary incontinence was 77% (23/30) and 70% (21/30), respectively, where cure was accepted as occasional or absent leakage of urine during exercise, coughing or sneezing on the BFLUT. Although TVT appears to better than colposuspension, the length of follow
The authors recognise that numbers are small and outcomes are not strictly comparable to other literature due to the inclusion of patients with mixed urinary incontinence. The value of this retrospective study is to provide a subjective outcome at 5-10 years after either TVT or colposuspension in patients with mixed symptoms, where stress urinary incontinence is the major complaint. This is the commonest clinical scenario in everyday practice.

For all women the type of incontinence was confirmed by urodynamic investigation. In the great majority of each group, 88 and 90% for TVT and colposuspension respectively, conservative management was tried and had failed before surgery was considered, which represents compliance with the National Institute of Clinical Excellence (NICE) guidelines regarding the use of TVT.13

There was no significant difference between the two groups regarding the complication rate during or after surgery. All the complications in the study were minor and were resolved easily with standard care. No cases of bladder perforation or vaginal wall erosion in the TVT group were reported. There appeared to be more patients with significant blood loss at TVT, 19% (6/32), when compared with colposuspension 3% (1/31). Subjective assessment of blood loss is a deficiency of this retrospective study. Ideally pre and postoperative haemoglobin measurements would be of more value but it was not routine practice to assess haemoglobin results in TVT patients.

Re-catheterisation was required in 22% (8/32) for TVT and 9% (3/31) for colposuspension. This may be misleading. TVT patients had their catheter removed within 24 hours whereas colposuspension patients often had indwelling catheters for 7 days or more. The need for long term intermittent self catheterisation (ISC) is more relevant. This was two and one patients for TVT and colposuspension respectively.

Following anti-incontinence procedures patients may complain of symptoms associated with detrusor overactivity or outlet obstruction. Although numbers were not large enough for statistical analysis the overall trend was that urge urinary incontinence, frequency and voiding problems were more common in the colposuspension group. However the overall quality of life was similar in both groups. Three patients complained of hesitancy and two had intermittent urinary flow following colposuspension compared with one patient for each symptom after TVT. Similarly more patients complained of frequency and urge urinary incontinence symptoms in the colposuspension group. This compares with the findings at two years and so further adds to the long term advantage of TVT over colposuspension.

The median operating time was approximately 20 minutes longer for colposuspension. Hospital stay was significantly different between the two groups with a seven day median difference in favour of TVT’s. This has major cost implications for NHS hospitals as well as for the patients with less exposure to hospital acquired infections and probable earlier return to normal activities.

CONCLUSION

A mammoth shift in practice has occurred in the mid to late 1990s whereby Burch Colposuspension has been superseded as the surgery of choice by the Tension Free Vaginal Tape. This study tracks this change in a single handed urogynaecology practice. The authors accept that small numbers and differences in age, weight and follow up between the two groups dilutes firm conclusions.

This study has shown that the initial surgical success for TVT surgery is maintained over a period greater than five years in patients with Urodynamic Stress Incontinence and Mixed Urinary Incontinence. Operating time and duration of hospital stay is less for TVT than colposuspension.

The authors have no conflict of interest

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