

Paper

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

Geoff R McCracken¹, Nicola A Henderson², Robin G Ashe³

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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

1. 15014 Cardinal Carter South, St Michael's Hospital, 30 Bond Street, Toronto Ontario, Canada, M5B1W8.

2. Altnagelvin Area Hospital, Glenshane Road, Londonderry, United Kingdom

3. Antrim Area Hospital, 45 Bush Road, Antrim BT41, 2RL, United Kingdom

Correspondence to Dr McCracken

E: mcrackengeoff@hotmail.com

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	-

the disease specific Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire and the generic quality of life questionnaire Short-Form 12 (SF-12). The questionnaires were posted in January 2005, along with a covering letter and self addressed envelope. This was repeated at two and six weeks. In total 60 questionnaires were returned, a 63% response rate, with 30 questionnaires for each procedure.

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

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)¹² 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% &

TABLE III.

Pre-operative clinical diagnosis and urodynamic findings.

	TVT (n=32)	Colposuspension (n=31)
Clinical Findings		
Stress urinary incontinence	10	7
Urge urinary incontinence	1	-
Mixed urinary incontinence	19	24
Voiding disorder	1	-
MUI & voiding disorder	1	-
Urodynamic Findings		
Detrusor Overactivity	2	-
Urodynamic stress incontinence	15	21
Both	10	10
Other	5	-

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 surgical 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 IV.

Operative complications (more than 1 complication may occur per patient).

	TVT n=32 (%)	Colposuspension n=31 (%)
Bleeding		
-significant vaginal loss	6 (19%)	1 (3%)
-blood transfusion	-	1 (3%)
Re-catheterisation	8 (22%)	3 (9%)
ISC	2 (6%)	1 (3%)
UTI	5 (16%)	4 (13%)
Pyrexia >38°C	1 (3%)	6 (19%)
Discharged with SPC or voiding problem	-	6 (19%)
Wound dehiscence	-	1(3%)
Total	22 (69%)	23 (72%)

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 the time of discharge from the outpatient clinic. Whereas 72% (23/32) of TVT patients at discharge from the outpatient clinic were symptom free or had minimal voiding problems, One patient developed voiding problems two years later that required splitting of tape. 68% (21/31) of colposuspension patients at discharge were symptom free or had minimal voiding problems.

The BFLUTS results are summarized in Table V. Fisher's exact test was used for contingency tables. No significant difference in subjective outcome at the 5% level was noted at >5 year after initial surgery between the two procedures.

The results from the SF-12 are summarized in table VI. Statistical analysis using the non-parametric Mann-Whitney test was performed. No significant difference at the 5% level was noted.

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 literature⁵ 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

TABLE V.

Results of Bristol Female Lower Urinary Tract Symptoms.

	TVT n=30 (%)	Colposuspension n=30 (%)
Urinary Questions		
Nocturia	18 (60)	16 (54)
Urgency*	10 (33)	11 (36)
Frequency >2 hourly	8 (27)	15 (50)
Urge urinary incontinence*	5 (17)	9 (30)
Stress urinary incontinence*	5 (17)	3 (10)
Hesitancy*	1 (3)	3 (10)
Intermittency*	1 (3)	2 (6)
Sexual questions		
Sex life spoilt [#]	11 (37)	14 (47)
Incontinence during sex [#]	1 (3)	3 (10)
Lifestyle questions		
Change clothes*	2 (6)	3 (10)
Fluid restriction*	2 (6)	3 (10)
Ability to perform daily activities [#]	5 (17)	4 (13)
Avoiding places*	7 (23)	7 (23)
Interfering with life overall*	8 (27)	9 (30)

* most of the time or all of the time, [#] somewhat or a lot

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.

TABLE VI.

Summary of Short Form-12 survey.

Dimension score	TVT (mean)	Colposuspension (mean)	P value
Change in health	41.7	42.5	.74
Energy/vitality	41.9	40.5	.754
General health perception	52.3	44.2	.248
Mental health	60.6	66.1	.472
Pain	51	49	.879
Physical function	60.1	54.8	.632
Role limitation-emotional	50.6	70.7	.159
Role limitation physical	43.8	46.2	.946
Social functioning	60.5	33.7	.4

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 TVT¹³.

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 years² 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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