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Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up

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Objective To compare the long-term outcomes of tension-free vaginal tape (TVT) and colposuspension as primary treatment for stress incontinence.

Study design Multicentre randomised controlled trial.

Setting Secondary and tertiary care gynaecology, urology and urogynaecology departments in 14 centres in the UK and Eire.

Population Women with urodynamically confirmed stress incontinence and who had previously failed to respond to conservative treatment were invited to participate.

Methods Three hundred and forty-four women were randomised; 175 to TVT and 169 to colposuspension. This paper reports the 5-year outcomes.

Main outcome measures The primary outcome at 5 years was a 1-hour perineal pad test; other outcomes included clinical examination, Short Form-36 (SF-36) health status and Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaires.

Results A negative 1-hour pad test was recorded in 58/72 (81%) women in the TVT group and 44/49 (90%) in the colposuspension group ($P = 0.21$, Fisher's exact test) at 5 years. There was an increase in enterocoele and rectocele in the colposuspension group; three late tape complications were seen in the TVT group.

Conclusion This study did not detect a significant difference between TVT and colposuspension for the cure of stress incontinence at 5 years. The effect of both procedures on cure of incontinence and improvement in quality of life is maintained in the long term. Vault and posterior vaginal wall prolapse are seen more commonly after colposuspension. Tape erosion may occur several years after surgery.

Keywords Colposuspension, follow-up studies, randomised controlled trial, stress, suburethral slings, tension-free vaginal tape, urinary incontinence.

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Introduction

Of the large number of surgical procedures that exist for the treatment of urodynamic stress incontinence, there has been no consensus as to which procedures are the most effective largely due to the lack of high-quality research in this area.[1,2] Many procedures have been introduced and adopted with great enthusiasm following publication of short-term data from retrospective case series, later to disappear from use when disappointing long-term results become apparent.[3]

The tension-free vaginal tape (TVT) was first described as a treatment for stress incontinence in 1996 and by 2001 had become the most frequently performed operation for stress incontinence in the UK.[4] Prior to the introduction of the TVT, colposuspension was the most common procedure for primary surgery. Long-term follow-up studies have reported cure rates for colposuspension ranging from 63 to 81% with 5- to 20-year follow up.[5–10] Although 3–29% women subsequently require surgery for vaginal prolapse, it has not been established that colposuspension is causative.[2,11]

The TVT procedure has been extensively investigated, but there have been relatively few randomised trials or long-term studies. This study, which started in 1998, aimed to compare TVT with colposuspension. We have previously reported

* Information on other investigators is given at the end of the paper.

6-month and 2-year results from this study, finding no differences in effectiveness between TVT and colposuspension for the treatment of primary urodynamic stress incontinence.[12,13]

This 5-year extension of the original study aimed to assess the comparative long-term successes of the two procedures and to provide further data on the incidence of postoperative complications.

Methods

As described in the original report of this study, women with urodynamic stress incontinence, whose family was complete, and who had failed to respond to pelvic floor muscle exercise were invited to participate.[12,13]

Fourteen centres in the UK and Ireland recruited women to the study, and 11 of these participated in the 5-year extension. All women were re-contacted and consented for the long-term follow-up study. A detailed description of study methods including inclusion and exclusion criteria, randomisation, blinding, surgical procedures, ethical approval and baseline evaluation has been reported previously.[12,13]

In this extension to the protocol, symptom review, clinical examination, 1-hour perineal pad test, Short Form-36 (SF-36) and Bristol Female Lower Urinary Tract Symptoms (BFLUTS) were undertaken annually up to 5 years. Questionnaires were completed by the woman in the clinic when they attended for review. Women who failed to attend for review were sent the questionnaires by post.

Outcome measures

The primary outcome measure at 5 years was cure of stress incontinence based on a negative 1-hour pad test (<1 g change in weight). Secondary outcome measures included subjective cure and the development of urgency (measured with the BFLUTS questionnaire) and vaginal prolapse. Prolapse was assessed by interview with women and by clinical examination. The finding of prolapse on clinical examination was divided into cystocele and/or cystourethrocele, rectocele and enterocoele and/or cervical or vault descent. Prolapse was said to be present if one or more of these was recorded as 'slight' or 'marked'. Prolapse was classified as asymptomatic or symptomatic by patient response at interview. Symptoms of prolapse were of either dragging/discomfort or a lump at the vulva.

Statistical analysis

The sample size calculation given in our original report suggested that 197 women would be required in each arm to detect a 10% difference in cure rate between procedures with 80% power, assuming a 90% cure following colposuspension.[2,12]

Analysis was by intention to treat. Objective and subjective cure rates and treatment differences in the incidence of adverse events and complications were tested using Fisher's exact test. Unpaired data were analysed using the Wilcoxon rank sum test and paired data using the Wilcoxon matched pairs test. Further analysis was carried out testing different assumptions about withdrawals and losses to follow up using Fisher's exact test. Odds ratios with 95% CIs are given.

Methods, definitions and units conform to the standards proposed by the International Continence Society, except where specifically noted.[14]

Ethics

The protocol modification, enabling trial extension to 5 years was approved by the Multicentre Research Ethics Committee.

Results

Three hundred and forty-four women were randomised; their progress through the trial is shown in Figure 1. There was no differences in the baseline characteristics between the two groups.[12] Twenty-eight women withdrew from the trial after randomisation but before surgery; 23 withdrew having been randomised to colposuspension and 5 after randomisation to TVT. Ninety-eight of those who had TVT and 79 of those having colposuspension returned for 5-year follow up; 72 in the TVT group and 49 in the colposuspension group with full subjective and objective data. The reasons for missing data at 5 years were: loss due to investigator withdrawal—that is investigators elected not to take part in the 5-year extension to the study (21 TVT and 17 colposuspension), loss to follow up (40 and 39) and patient withdrawal (11 and 11). There was no differences in baseline characteristics between the two groups who attended. The baseline characteristics of women who underwent surgery but failed to attend for 5-year follow up did not differ from those continuing in the trial, in either group.

Primary outcome measure

A negative 1-hour pad test was recorded in 58 (81%) women in the vaginal tape group and in 44 (90%) women in the colposuspension group at 5 years, and the change in pad weight decreased significantly to a median of 0 g in both groups (Table 1) A sensitivity analysis was performed to explore the effect of different assumptions about withdrawals and missing data (Table 2). No differences was seen between the procedures for any of these assumptions. A last observed result carried forward (LOCF) analysis was carried out, in which pad test data from the last available follow-up visit were imputed to substitute missing data. On this basis, the cure rates were 75% for TVT and 69% for colposuspension (OR 1.32 [95% CI 0.82–2.12]).

Secondary outcome measures

Results from the BFLUTS questionnaire are shown in Table 3. Significant reduction in the reporting of symptoms

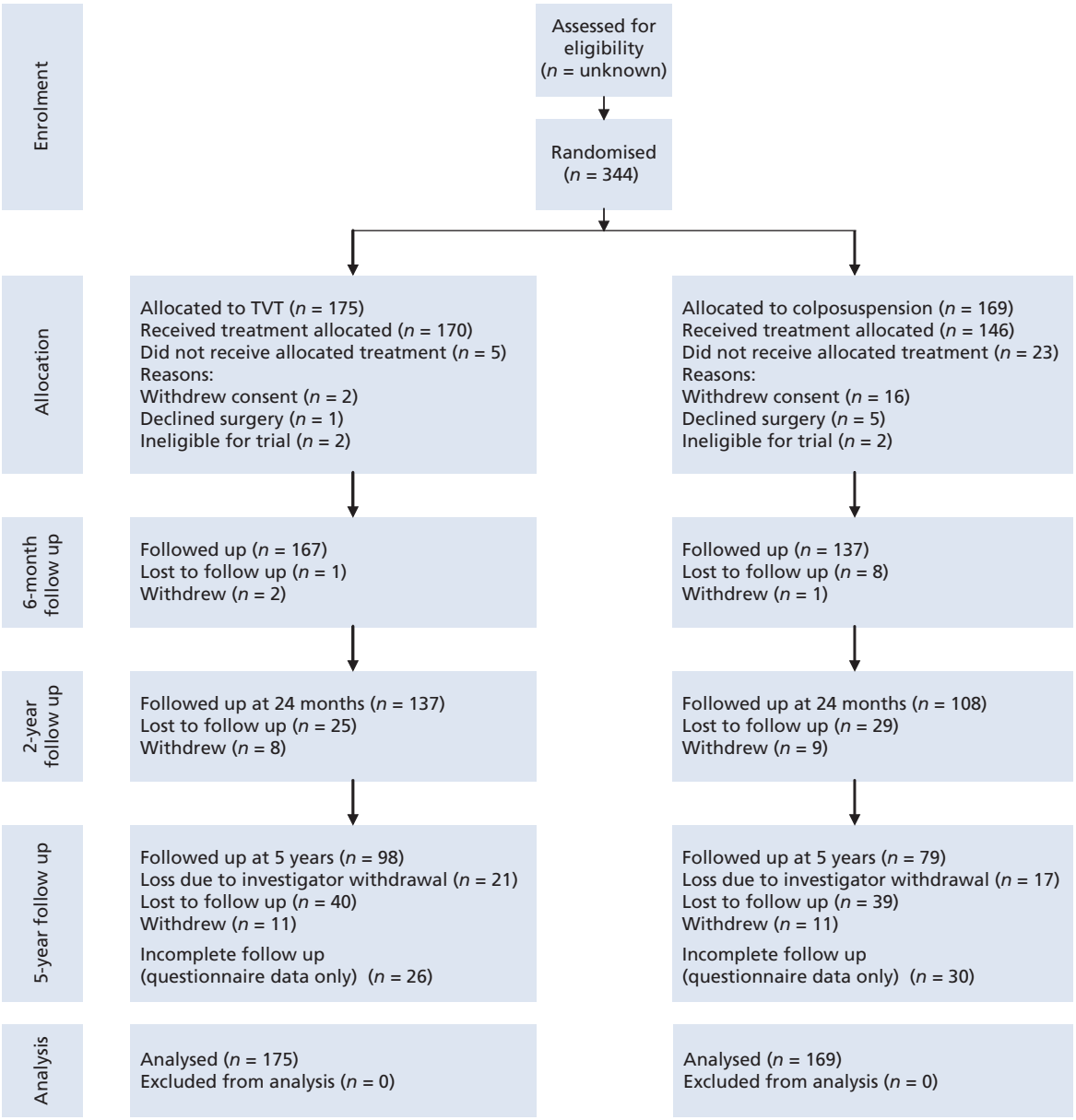

Figure 1. Progress of women through trial.

of frequency, urgency, urge incontinence, stress incontinence and unexplained incontinence was seen in both groups 5 years after surgery. *De novo* urgency and urge incontinence occurred in 2 (2%) and 1 (1%) of the TVT group and 4 (5%) and 3 (4%) of the colposuspension group, respectively. 38/98 (39%) women in the TVT group and 36/79 (46%) in the colposuspension group reported no leakage under any circumstances 5 years after surgery (BFLUTS questionnaire items 4, 6–9). The number of women reporting cure of stress leakage was 62/98 (63%) and 55/79 (70%), respectively (item 7).

Incontinence during intercourse and disruption of sex life by urinary symptoms in general were less commonly reported following both procedures. Overall, 91% of the women who had undergone TVT and 90% who had undergone colposuspension regarded themselves as satisfied or very satisfied with the results of their surgery at 5 years.

Results of the SF-36 health status questionnaire are shown in Table 4. The responses were combined and transformed to generate eight health dimensions, with a potential score of 0–100.[15] Higher scores indicate better perceived health. At 5 years, no differences were seen between the groups in any of the health dimensions measured by the SF-36.

There was no differences between the groups in the preoperative findings of prolapse. A significant reduction in the

Table 1. One-hour perineal pad test data before and 5 years after surgery in both groups. Results are given as median [interquartile range] unless otherwise indicated

	TVT		Colposuspension		*P*
	Before surgery (*n* = 170)	5 years (*n* = 72)	Before surgery (*n* = 157)	5 years (*n* = 49)	
1-hour perineal pad test					
Pad weight change (g)	18 [6–36]	0 [0–0.6]	16 [6–38]	0 [0–0]	0.93*
Weight change of <1 g	4 (2%)	58 (81%)	5 (3%)	44 (90%)	0.21**

*Wilcoxon rank sum test, [95% CIs for difference −7.0 to 6.8].
**Fisher's exact test, comparing proportion of negative pad tests at 5 years in each group.

number of women with cystocele was found in both groups 5 years after surgery. Enterocoele or vault/cervical prolapse and rectocele were found more commonly in the colposuspension group at 5 years (Table 5).

Operative complications and adverse effects up to 2 years have been reported previously.[12,13] A cumulative summary of procedure-related complications occurring from surgery to 5 years is shown in Table 6. The rates of re-operation for urodynamic stress incontinence did not differ significantly between the two groups. Significantly, more women in the colposuspension group (11 [7.5%]) underwent surgery for prolapse during the follow-up period than those in the TVT group (3 [1.8%]).

Tape-related complications were seen in six women. In the first year, one tape was divided for obstructed voiding; there was one suprapubic extrusion and one vaginal erosion (previously reported).[13] Two further vaginal erosions were detected at 5-year follow up, and in addition, one woman was found to have tape within the bladder at cystoscopy after complaining of overactive bladder symptoms. This was removed by cystotomy. At the time of TVT that woman was noted to have a bladder 'abrasion' on cystoscopy, however, intravesical tape was not identified, and she was treated with antibiotics and indwelling catheterisation. There was no reported suture-related complications in the colposuspension group.

Discussion

To date, there have been few randomised trials of surgery for stress incontinence with long-term follow up; although this is one of the largest trials reported to date on this subject, its impact is somewhat limited by the high number of postrandomisation drop outs, both before and after surgery.

Surgical treatment for stress incontinence is an area that has changed rapidly in the 10 years following the introduction of TVT. A number of other mid-urethral polypropylene tape devices, using alternative operative techniques, have since been widely adopted into practice. The impact of this changing field on recruitment to, and retention within this study is difficult to quantify. The problems with assessing new and fast changing technologies have been well documented.[16] At the start of this study, investigators participated with genuine equipoise over the choice of treatment. During the course

Table 2. Analysis of pad test results at 5 years, using different assumptions about outcome for patients with missing data

	TVT *n/N*	%	Colposuspension *n/N*	%	OR	95% CI	*P* value*
Assumption							
Woman with data available at 5 years	58/72	81	44/49	90	0.47	0.16–1.4	0.21
Assuming at withdrawals are failures	58/175	33	44/169	26	1.41	0.88–2.24	0.16
Assuming all withdrawals are cured	138/175	79	140/169	83	0.77	0.45–1.33	0.41
LOCF	131/175	75	117/169	69	1.32	0.82–2.12	0.28
Assuming presurgery withdrawals are cured and last postoperative result carried forward	143/175	82	134/169	79	1.17	0.68–1.99	0.59

*Fisher's exact test.

Table 3. Responses to BFLUTS questions before and 5 years after surgery. Results are given as % reporting symptom (% reporting symptom as a bit of a problem, quite a problem or a serious problem)

Symptom	TVT		Colposuspension		*P**
	Before surgery (*n* =168)	5 years (*n* =98)	Before surgery (*n* =155)	5 years (*n* =79)	
Urinary questions					
Daytime frequency (>7)**	80 (74)	47 (22)	79 (66)	44 (16)	0.63 (0.13)
Nocturnal frequency (>0)	80 (54)	65 (29)	83 (53)	81 (19)	0.47 (0.40)
Urgency**	95 (82)	86 (40)	93 (80)	77 (37)	0.40 (0.60)
Urge incontinence**	95 (93)	71 (44)	95 (91)	68 (35)	0.72 (0.95)
Bladder pain	50 (40)	30 (15)	41 (32)	19 (10)	0.65 (0.71)
Stress incontinence**	100 (100)	51 (29)	100 (99)	46 (24)	0.54 (0.74)
Unexplained incontinence**	85 (80)	24 (201)	83 (81)	20 (16)	0.73 (0.94)
Enuresis**	45 (40)	11 (10)	46 (41)	11 (8)	0.92 (0.53)
Frequency incontinent episodes (>never)**	99 (98)	68 (40)	100 (99)	58 (30)	0.05 (0.23)
Quantity of urine loss (>none)**	98 (not applicable)	59 (not applicable)	100 (not applicable)	53 (not applicable)	0.61 (not applicable)
Wearing protection**	96 (not applicable)	26 (not applicable)	95 (not applicable)	32 (not applicable)	0.35 (not applicable)
Changing outer clothing	83 (not applicable)	13 (not applicable)	77 (not applicable)	18 (not applicable)	0.97 (not applicable)
Hesitancy	34 (24)	36 (10)	36 (24)	43 (8)	0.81 (0.78)
Straining	11 (9)	12 (6)	14 (13)	14 (4)	0.64 (0.19)
Intermittent stream	40 (22)	46 (10)	40 (22)	48 (10)	0.18 (0.35)
Abnormal urinary stream	39 (24)	50 (13)	36 (22)	49 (11)	0.71 (0.49)
History of retention	3 (not applicable)	7 (not applicable)	3 (not applicable)	3 (not applicable)	0.38 (not applicable)
Dysuria	36 (26)	18 (14)	34 (22)	18 (6)	0.84 (0.83)
Incomplete emptying**	79 (60)	51 (23)	74 (59)	59 (18)	0.88 (0.49)
Inability to stop midstream**	78 (not applicable)	55 (not applicable)	78 (not applicable)	52 (not applicable)	0.90 (not applicable)
Sexual questions					
Pain due to dry vagina	34 (31)	28 (19)	39 (32)	32 (22)	0.25 (0.36)
Sex life spoilt by urinary symptoms**	72 (68)	18 (14)	62 (58)	15 (11)	0.88 (0.20)
Pain with intercourse	35 (34)	15 (13)	32 (25)	22 (19)	0.88 (0.61)
Incontinence with intercourse**	60 (56)	6 (4)	62 (53)	9 (8)	0.51 (0.55)
Lifestyle questions					
Fluid restriction**	72 (57)	39 (16)	71 (49)	32 (18)	0.47 (0.17)
Ability to perform daily tasks**	81 (74)	14 (10)	81 (78)	14 (11)	0.88 (0.94)
Avoiding places/situations**	73 (68)	37 (27)	73 (69)	28 (18)	0.37 (0.36)
Interfering with physical activity**	95 (93)	18 (17)	93 (90)	18 (14)	0.80 (0.53)
Interfering with social relationships**	72 (70)	13 (12)	76 (74)	14 (10)	0.72 (0.40)
Interfering with life overall**	98 (not applicable)	31 (not applicable)	94 (not applicable)	24 (not applicable)	0.30 (not applicable)

*Wilcoxon rank sum test, comparing the change from baseline to review between the two groups.
**Significant reduction in reporting of symptoms in both groups 5 years after surgery ($P < 0.0001$, Wilcoxon matched pairs test).

of the 5-year extension to the study, it is possible that investigators will have developed a preference for the new procedure (TVT) or even for one of the more recently introduced procedures. This may have affected their research priorities with potential loss of motivation to continue to contribute to the study in the long term.

Although attempts were made to maximise data collection by sending postal questionnaires to women who did not attend and to those whose centres were unable to perform follow-up assessments, this led to only a modest increase in follow-up numbers.

There are a number of possible reasons for missing data within a trial, and it is important to examine each to establish whether the available data may be biased.[17] Examples of reasons for missing data in this study are as follows:

1 Women lost to follow up before the end of the study, including those who withdrew either before or after surgery (56 women in TVT group and 73 in colposuspension group).

Table 4. Baseline SF-36 general health status scores and change in score at 5 years after surgery. Values are given as mean

Dimension	Baseline		Change (5 years baseline)		Difference in change
	TVT (n = 166)	Colposuspension (n = 141)	TVT (n = 90)	Colposuspension (n = 69)	P value for difference in change*
Physical function	65.5	66.4	15.6	16.1	1.00
Role physical	68.0	64.2	10.7	10.8	0.70
Role emotional	70.1	72.8	13.6	9.8	0.55
Social functioning	74.5	77.0	11.2	8.0	0.83
Mental health	66.0	67.4	8.7	8.0	0.62
Energy/vitality	51.6	53.0	8.2	8.2	0.60
General health	69.9	69.3	3.6	4.2	0.56

Significant values indicate a difference between treatments.
*Wilcoxon rank sum test.

2 Women with incomplete follow up, where some assessments were omitted (26 in TVT group and 30 in colposuspension group at 5-year follow up).
3 Withdrawal of centres from the trial (three centres, affecting 21 women in TVT group and 17 in colposuspension group).

Within the discussion of the results of this trial at earlier follow up, we highlighted presurgery withdrawal of a higher number of women in the colposuspension group who were shown to have less severe incontinence than those continuing in the trial.[12] Since this implied that data were not missing at

Table 5. Examination findings of prolapse before and after surgery. Values are numbers with examination finding of slight or marked prolapse (those women who also had symptoms of prolapse)

	Before surgery						
	TVT (n = 173)	%	Colposuspension (n = 163)	%	P value*	Difference (%)	95% CI for difference
Cystocele/cystourethrocele**	103 (19)	60	103 (17)	63	0.50	−3.7	−13.9 to 6.7%
Vault or cervical prolapse/enterocoele***	28 (9)	16	34 (6)	21	0.32	−4.7	−13 to 3.6%
Rectocele****	45 (9)	26	53 (9)	33	0.23	−6.5	−16.1 to 3.2%
	5 years postoperatively (including patients who have had surgery for prolapse)						
	TVT (n = 81)	%	Colposuspension (n = 59)	%	P value*	Difference (%)	95% CI for difference
Cystocele/cystourethrocele or anterior colporrhaphy**	33(10)	41	22(3)	37	0.73	3.5	−13.2 to 20.2%
Vault or cervical prolapse/enterocoele or vaginal hysterectomy for prolapse/vault support procedure***	19(9)	23	25(7)	42	0.026	21.4	3.8 to 39%
Rectocele or rectocele repair****	26(4)	32	31(5)*****	49	0.023	20.6	4.0 to 37.3%

*Fisher's exact test comparing the difference between the two groups.
**Significant reduction in cystocele from pre to 5 years postoperatively in both groups (P = 0.0068, TVT group; P = 0.0007 colposuspension group, Fisher's exact test).
***Significant increase in vault prolapse/enterocoele/cervical descent from pre to 5 years postoperatively in colposuspension group (P = 0.0019, Fisher's exact test).
****Significant increase in rectocele from pre to 5 years postoperatively in colposuspension group (P = 0.022, Fisher's exact test).
*****n = 63 as four patients did not return for review following rectocele repair.

Table 6. Postoperative complications and additional surgery up to 5 years. Values are numbers of patients (percentage)

	TVT (n = 170)	Colposuspension (n = 146)	P value
Surgery for urodynamic stress incontinence	4 (2.3)	5 (3.4)	0.74
TVT	0	3	
Colposuspension	2	0	
Fascial sling	1	0	
Unspecified (surgery outside trials centres)	1	2	
Surgery for prolapse	3 (1.8)	11 (7.5)	0.025
Vaginal hysterectomy ± SSF	0	1	
Vaginal hysterectomy and colporrhaphy ± SSF	1	4	
Posterior colporrhaphy ± SSF	0	6	
Anterior and posterior colporrhaphy	2	0	
Incisional hernia repair	NA	5	
Tape-related complications	6	NA	
Erosion into vagina*	3		
Obstructed voiding**	1		
Suprapubic extrusion of mesh	1		
Erosion into bladder***	1		

NA, not applicable; SSF, sacrospinous ligament fixation.
*Occurring at 8 months in one woman and at 5 years in two women.
**Requiring tape division at 11 months.
***Occurring at 5 years and requiring cystotomy and tape removal.

random, this was identified as a potential source of bias. At 5-year follow up, no differences was detected for any preoperative characteristics of women who withdrew or were lost to follow up and those who attended and those for whom data were available. It would be reasonable to assume therefore that those who attended were a representative sample of the randomised group. Despite this, we cannot be certain that data are missing completely at random and there remains the possibility that withdrawal or loss to follow up may be related to outcome. It would seem unlikely that the decision taken by a small number of investigators to discontinue participation in the study extension was related to patient outcomes and therefore this in itself is an unlikely source of bias.

Conclusions regarding the effectiveness of procedures that can be drawn from this trial are heavily dependent on the handling of missing data and the assumptions made about those who withdrew. The LOCF technique is an attractive method of estimating (imputing) missing data; however, it is less useful in long-term studies where it may mask deterioration in cure rate over time. Although the analysis of different assumptions concerning missing data gives a wide range of cure rates (Table 2; 26–90%), no differences was demonstrated between the two procedures. The confidence intervals around the odds ratios are wide, however, we cannot be certain therefore that a difference does not exist.

Of women who attended for follow up, subjective and objective cure rates are maintained at the same level as previously reported at 6 months and 2 years. This is compatible with published evidence from case series on long-term cure rates for colposuspension and 7-year results for TVT.[18] Improvements in other urinary symptoms previously reported have also been maintained at 5 years compared with baseline. Overactive bladder symptoms occurring *de novo* have been reported in up to 27% following colposuspension.[2] This is in contrast to our study where *de novo* urgency and urge incontinence were reported by less than 2% after TVT and less than 5% after colposuspension. This is perhaps unsurprising given the high rates (around 95%) of overactive bladder symptoms reported preoperatively in our women.

Previously reported long-term case series have reported an increase in symptomatic prolapse, as well as a substantial requirement for prolapse surgery following colposuspension which may be as high as 32%.[19] Our data support these findings with a high incidence of posterior vaginal wall and vault prolapse following colposuspension. This is the first study in which comparison with a control group has been made. A similar increase in prolapse was not seen in the TVT group, and it is likely therefore that colposuspension is indeed contributory to the development of vault and posterior wall prolapse, albeit in a group of women with known pelvic floor dysfunction.

Erosion of synthetic sling material into the vagina, bladder and urethra has been described following the TVT and related procedures. It has been suggested that early vaginal erosion is the result of failure of vaginal skin healing rather than true erosion. In this study, there were two true vaginal erosions (only one of which was symptomatic) in the 72 women examined at 5 years. Although these women suffered only minimal morbidity, it is important to be aware that synthetic sling materials have the potential to erode many years after implantation. The woman who was found to have tape within the bladder may have had an unrecognised perforation at the time of operation. It is possible that our figures represent an underestimate of tape complications and suture-related colposuspension complications as less than half the women who underwent surgery were examined at 5 years.

Conclusion

The TVT appears to be as effective as colposuspension for the treatment of stress incontinence at 5 years. The effect of both procedures on cure of incontinence and improvement in quality of life and sexual health is maintained in the long term. Vault and posterior vaginal wall prolapse are seen more

commonly following colposuspension. While many tape-related complications may be missed operative injuries, tape erosion may occur several years after surgery.

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Contribution to authorship

P.H. (principal investigator) and K.L.W. (trial coordinator) conceived the idea for the study, designed the trial protocol, performed the analysis of data and wrote the paper. The following were members of the UK and Ireland TVT trial group participating in the 5-year extension: Paul Abrams (Southmead Hospital, Bristol), Jonathan Bibby (Northampton General Hospital), Linda Cardozo (King's College Hospital, London), Malcolm Frazer and Ezzat Kozman (Warrington Hospital), P.H. and K.L.W. (Royal Victoria Infirmary, Newcastle upon Tyne), David Holmes (St Paul's Hospital, Cheltenham), Mohsen Iskander (Southport General Hospital), Declan Keane (National Maternity Hospital, Dublin), Ash Monga (Princess Anne Hospital, Southampton), David Richmond (Liverpool Women's Hospital) and David Sanderson (Colchester General Hospital).

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