

## Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence

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### Abstract

**Objective** To compare tension-free vaginal tape with colposuspension as primary treatment for stress incontinence.

**Design** Multicentred randomised comparative trial.

**Setting** Gynaecology or urology departments in 14 centres in the United Kingdom and Eire, including university teaching hospitals and district general hospitals.

**Participants** 344 women with urodynamic stress incontinence; 175 randomised to tension-free vaginal tape and 169 to colposuspension

**Main outcome measures** Assessment before treatment and at six months postoperatively with the SF-36, the Bristol female lower urinary tract symptoms questionnaire, the EQ-5D health questionnaire, a one week urinary diary, one hour perineal pad test, cystometry, and, in some centres, urethral profilometry.

**Results** 23 women in the colposuspension group and 5 in the vaginal tape group withdrew before surgery. No significant difference was found between the groups for cure rates: 115 (66%) women in the vaginal tape group and 97 (57%) in the colposuspension group were objectively cured (95% confidence interval for difference in cure –4.7% to 21.3%). Bladder injury was more common during the vaginal tape procedure; postoperative complications, in particular delayed resumption of micturition, were more common after colposuspension. Operation time, duration of hospital stay, and return to normal activity were all longer after colposuspension than after the vaginal tape procedure.

**Conclusion** Surgery with tension-free vaginal tape is associated with more operative complications than colposuspension, but colposuspension is associated with more postoperative complications and longer recovery. Vaginal tape shows promise for the treatment of urodynamic stress incontinence because of minimal access and rapid recovery times; cure rates at six months were comparable with colposuspension.

### Introduction

Urinary incontinence is reported by 14% of women, and about half have urodynamic stress incontinence—

the involuntary leakage of urine during increased abdominal pressure in the absence of detrusor contraction.<sup>1-3</sup> Cure rates of around 50% are reported with physiotherapy,<sup>4</sup> and surgery is recommended for those women who fail to respond. Systematic reviews have shown that colposuspension has cure rates of up to 90%, although there are only limited data from randomised trials.<sup>5-6</sup> Previous studies have been criticised for insufficient numbers of participants and statistical power as well as lack of standardised criteria for entry to the study and outcome measures.<sup>6</sup> Some authors, however, have reported less than half of patients remaining dry and free of complications long term.<sup>7-9</sup> Complications include haemorrhage, haematoma, bladder injury, and urinary tract infection. Up to 20% of women may develop de novo detrusor overactivity<sup>5-9</sup>; voiding dysfunction has been reported in 3% to 32% of women, and surgery for vaginal prolapse may be required in 2.5% to 26.7% after the procedure.<sup>5</sup>

The tension-free vaginal tape procedure is a relatively recent treatment for stress incontinence.<sup>10</sup> A polypropylene tape is inserted suburethrally under local anaesthesia with sedation. The procedure is thought to work by providing a pubourethral “neoligament.” Increased intra-abdominal pressure results in a kink at the point of fixation, which prevents urine loss. Data from three early case series suggest objective cure rates of 84-100%, with few complications.<sup>10-12</sup> We compared the tension-free vaginal tape procedure with colposuspension in a prospective randomised manner.

### Methods

Women with stress incontinence, who had completed their family, were invited to take part. Exclusion criteria were detrusor overactivity, vaginal prolapse requiring treatment, previous surgery for prolapse or incontinence, a major degree of voiding dysfunction, neurological disease, and allergy to local anaesthetic.

The trial was conducted at gynaecology or urology departments in 14 centres in the United Kingdom and Eire. Women were recruited from outpatient clinics once surgery had been selected for their stress incontinence.

The sample size calculation was performed assuming a 90% cure rate with colposuspension, and that a



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10% difference in cure rate between procedures would be clinically important.<sup>5</sup> To detect this level of difference with 80% power would require 197 patients in each arm of the trial. Recruitment was limited to the period May 1998 to August 1999 owing to logistic and financial constraints.

Researchers randomised participants via a telephone system, which allocated trial identification number and treatment group. It was not possible to blind investigators or participants to the treatment allocation. The tension-free vaginal tape procedure was performed as described by Ulmsten, under local anaesthesia and sedation.<sup>10</sup>

At initial assessment, urodynamic evaluation was performed by medium fill dual channel subtracted cystometry with simultaneous pressure and flow voiding studies or videocystourethrography; in some centres urethral pressure profilometry at rest and at

**Table 1** Operative, admission, and postoperative details of women allocated tension-free vaginal tape procedure or colposuspension. Values are numbers (percentages) unless stated otherwise

	Vaginal tape group (n=170)	Colposuspension group (n=146)	P value
Median (interquartile range) theatre times (min):			
Holding bay	5 (5-10)	5 (5-12)	0.48*
Anaesthetic room	15 (10-50)	17 (14-25)	<0.001*
Operating theatre	40 (30-48)	50 (35-60)	<0.001*
Recovery area	41 (31-60)	85 (65-115)	<0.001*
Anaesthesia:			
General	3 (2)†	145 (99)	
Spinal	3 (2)‡	1 (1)	
Local and sedation	164 (96)	Not applicable	
Median (interquartile range) blood loss (ml)	50 (30-100)	128 (74-200)	<0.001*
Opiate analgesia used in first 24 hours postoperatively	35 (21)	133 (91)	<0.001§
Duration of catheterisation (suprapubic, urethral, or intermittent):			
1-7 days	64 (38)	146 (100)	
8-28 days	9 (5)	48 (33)	<0.0001§
29 days to 6 months	5 (3)	19 (13)	<0.001§
>6 months	5 (3)	11 (8)	0.0746§
Complications:			
Bladder injury (perforation or evidence of trauma)	15 (9)	3 (2)	0.013§
Vaginal perforation	5 (3)	0	0.06§
Wound infection	4 (2)	10 (7)	0.06§
Fever**	1 (1)	7 (5)	0.027§
Deep vein thrombosis	0	3 (2)	0.10§
Incisional hernia	Not applicable	3 (2)	
Retropubic haematoma	3 (2)	0	0.25§
Vascular injury¶	1 (1)	0	1.0§
Tape erosion	1 (1)	Not applicable	
Urinary tract infection (in six weeks after surgery)	38 (22)	46 (32)	0.074§
Total complications (excluding fever)**	67 (39)	65 (44.5)	0.36§
Median (interquartile range) postoperative hospital stay (days)	1 (1-2)	5 (5-7)	<0.001*
Median (interquartile range) time to return to normal activities (weeks)	3 (2-4)	6 (4-8)	<0.001*
Median (interquartile range) time to return to work (weeks)	4 (3-7)	10 (8-12)	<0.001*
Response to procedure:			
Satisfied or very satisfied	145 (85)	119 (82)	
Dissatisfied	7 (4)	4 (3)	
Would recommend to relative or friend	143 (84)	119 (82)	

\*Wilcoxon rank sum test.

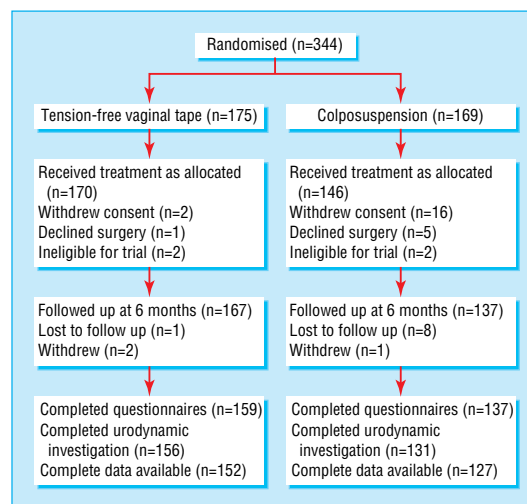
†General anaesthesia induced during procedure because of poor respiratory effort in one case, methaemoglobinaemia after injection of prilocaine in another, and for discomfort in third.

‡Breached protocol.

§Fisher's exact test.

¶Abnormal obturator artery injured requiring laparotomy and blood transfusion (4 units).

\*\*Considerable overlap between postoperative fever and wound infection, hence fever excluded from totals.



Flow of participants through trial

stress was also carried out.<sup>13</sup> Patients were asked to complete a urinary diary for one week, and a one hour perineal pad test was performed.<sup>3</sup>

Patients' perceptions of changes in their symptoms and treatment outcome were measured with the SF-36 and the Bristol female lower urinary tract symptoms questionnaire.<sup>14 15</sup> Six weeks after surgery a postal questionnaire was sent out comprising the SF-36 and questions about recovery. Six months after surgery reassessment was undertaken with symptom review, clinical examination, the one hour pad test, and urodynamic studies. The SF-36 and Bristol female lower urinary tract symptoms questionnaires were completed by the patient in the clinic, and they were given a urinary diary to complete over one week and return by post.

### Outcome measures

The primary outcome measure was objective cure of stress incontinence based on a negative stress test on urodynamic testing, combined with a negative one hour pad test (< 1 g change in weight). Secondary outcome measures included subjective cure of incontinence and the development of voiding problems, urge symptoms, and vaginal prolapse. Analysis of results was by intention to treat.

### Results

Overall, 344 women were randomised over 15 months (figure). The baseline characteristics of the two groups were comparable.

Operative complications were more common after the vaginal tape procedure (table 1), largely injury to the bladder and vagina. Operation times, blood loss, analgesic requirements, postoperative complications, and catheterisation were greater in the colposuspension group than the vaginal tape group.

### Primary outcome measure

A negative one hour pad test was recorded in 128 (73%) patients in the vaginal tape group and 109 (64%) in the colposuspension group. The change in pad weight decreased significantly in both groups, but there was no significant difference between the groups. Stress testing for urodynamic stress incontinence was negative at cystometry in 142 (81%) patients after the

**Table 2** Mean baseline SF-36 scores and change in score at 6 weeks and 6 months after vaginal tape procedure or colposuspension

Dimension	Baseline		Change (6 weeks)		P value for difference in change*	Change (6 months)		P value for difference in change*
	Vaginal tape group (n=166)	Colposuspension group (n=141)	Vaginal tape group (n=144)	Colposuspension group (n=123)		Vaginal tape group (n=159)	Colposuspension group (n=127)	
Physical function	65.5	66.2	11.0	4.8	0.002	17.5	16.7	0.75
Role physical	68.0	64.3	-18.0	-26.9	0.085	9.9	10.2	0.90
Role emotional	70.1	73.1	-0.9	-19.7	<0.001	12.1	5.4	0.05
Social functioning	74.5	77.0	-0.4	-11.9	<0.001	11.7	4.0	0.028
Mental health	66.0	67.4	3.7	1.5	0.36	7.9	2.7	0.023
Energy/vitality	51.6	53.0	-1.7	-7.1	0.013	8.7	3.6	0.035
Pain	75.4	76.6	-8.8	-14.0	0.11	1.1	-1.5	0.49
General health	69.9	69.3	0.8	0.6	0.80	1.5	2.4	0.98

Significant values indicate difference in treatments.

\*Wilcoxon rank sum test.

vaginal tape procedure and 114 (67%) after colposuspension. Objective cure, defined as a negative pad test and negative cystometry, was found in 115 (66%) patients in the vaginal tape group and 97 (57%) in the colposuspension group (P=0.099, 95% confidence interval for difference in cure -4.7% to 21.3%). More detailed results are given on [bmj.com](#)

### Secondary outcome measures

Both groups showed significant changes in most urinary symptoms at six months, although there was no significant difference between the vaginal tape procedure and colposuspension for any of these items. Only 63 (36%) patients in the vaginal tape arm and 48 (28%) in the colposuspension arm reported no leakage under any circumstance after surgery; the number of women reporting cure of stress leakage was 103 (59%) and 90 (53%), respectively.

The responses for the SF-36 were combined and transformed to generate eight health dimensions, with a potential score of 0 to 100 (table 2).<sup>16</sup> Higher scores indicate better perceived health. Significant differences were seen at six weeks in emotional, social, and physical function and vitality, with the colposuspension group having lower scores than the vaginal tape group. By six months, scores in the colposuspension group had shown significantly less improvement in emotional and social functioning, vitality, and mental health than those in the tape group.

## Discussion

Blinding may be possible in a trial of surgery for stress incontinence, as shown in a trial of laparoscopic versus open colposuspension.<sup>17</sup> We believed that patients in our trial would be aware of their allocated treatment owing to differences between the procedures in incision, anaesthesia, and catheterisation. Staff undertaking postoperative assessments were not blinded to the procedure for logistical reasons, and will have been vulnerable to observer bias.

Surgery and anaesthesia for the vaginal tape procedure was standardised and was performed as described by Ulmsten.<sup>10</sup> Although colposuspension was performed according to that used by the units it was standardised for numbers of suspensory sutures, suture material, and postoperative catheterisation. The investigators all had expertise in continence surgery, but were from a mixed background including gynaecologists, urogynaecologists, and urologists and represented both general hospitals and university teaching hospitals. All surgeons had undergone similar

### What is already known on this topic

Few randomised trials exist on surgery for stress incontinence

Systematic reviews suggest that colposuspension is associated with cure rates of up to 90%

Case series of tension-free vaginal tape suggest cure rates of about 85%, with rapid return to normal activity

### What this study adds

At six months the tension-free vaginal tape procedure is as effective as colposuspension for the primary treatment of stress incontinence

Operative complications were more common with vaginal tape, but duration of hospital stay and return to normal activity were shorter than with colposuspension

Postoperative complications were more common after colposuspension

training in the vaginal tape procedure, although they had variable experience before recruitment. The group therefore reflects the current practice in the United Kingdom and Eire and as such increases the external validity of the study.

The number of patients recruited fell short of the target determined by a sample size calculation owing to limitations of resources and time. Although differences between the procedures for cure of stress incontinence were not shown, the numbers were not sufficient to achieve the power required to assume equivalence. Given that the objective cure for colposuspension was lower than expected from previous literature, the numbers recruited would give only 50% power to detect a 10% difference or 80% power to detect a 15% difference in cure rates.

No differences were shown between the vaginal tape procedure and colposuspension for objective cure of urodynamic stress incontinence, as measured by the pad test and urodynamic testing. Objective cure rates are lower than those previously reported. This may be due to the stricter definition of cure in this study. There has been little consistency in the objective outcome measures used in previous studies, and cure rates are often quoted for single tests. The cure rates for both procedures as measured by single urodynamic tests

range from 74% to 84% and are comparable to those reported in previous series. Most reports of incontinence surgery give no information on non-attenders or the handling of missing data. They have by default assumed that non-attenders are equivalent to attenders. We have considered non-attenders or patients with missing data as treatment failures.

Long term follow up is needed to assess the continuing success of the two procedures and to provide further data on the development of prolapse and tape erosion; follow up to five years is planned.

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## Adult height after long term treatment with recombinant growth hormone for idiopathic isolated growth hormone deficiency: observational follow up study of the French population based registry

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### Abstract

**Objective** To evaluate the efficacy of recombinant growth hormone for increasing adult height in children treated for idiopathic isolated growth hormone deficiency.

**Design** Observational follow up study.

**Setting** Population based registry.

**Participants** All 2852 French children diagnosed as having isolated idiopathic growth hormone deficiency whose treatment started between 1987 and 1992 and ended before 1996.

**Main outcome measures** Change in height between the start of treatment and adulthood; classification of patients according to whether treatment was completed as scheduled or stopped early.

**Results** Adult height was obtained for 2165 (76%) patients. The mean dose of growth hormone at start of treatment was 0.42 IU/kg/week. Height gain was 1.1 (SD 0.9) standard deviation (SD) scores, resulting in an adult height of -1.6 (0.9) SD score (girls, 154 (5)

cm; boys, 167 (6) cm). Patients who completed the treatment gained 1.0 (0.7) SD score of height in 3.6 (1.4) years. Patients with treatments stopped early gained 0.6 (0.6) SD score in 2.7 (1.4) years while receiving treatment and a further 0.4 (0.9) SD score after the end of treatment. Most of the variation in height gain was explained by regression towards the mean, patients' characteristics, and delay in starting puberty. Severe growth hormone deficiency was associated with better outcome. Each year of treatment was associated with a gain of 0.2 SD score (1.3 cm).

**Conclusion** The effect of growth hormone is unclear in many patients treated for so called idiopathic isolated growth hormone deficiency. Most of the patients have pubertal delay and a spontaneous growth potential, which must be taken into account when measuring the effect and cost effectiveness of treatments. Growth hormone deficiency should be clearly distinguished from pubertal delay, and criteria