Prospective Randomised Controlled Trial Comparing Laparoscopic and Open Colposuspension: a Three-year Follow-up

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Objectives:
To compare the efficacy, safety, complications, and intermediate-term outcomes of the open and laparoscopic colposuspension in women with urodynamic stress incontinence.

Methods:
This randomised controlled trial was conducted from July 1999 to October 2003. 168 women with urodynamic stress incontinence requiring anti-incontinence surgery were recruited. They were randomly allocated to receive open or laparoscopic colposuspension. All patients were assessed at first year and third year after the operation.

Results:
84 women were allocated to receive open colposuspension, while the remaining 84 women received laparoscopic colposuspension. The laparoscopic group experienced significantly less blood loss, faster recovery, and earlier return to normal work, although a longer operating time was required. Subjective and objective success rates at first year and third year were similar for patients in the open and laparoscopic groups—first year: 97.6% vs 95.1% (p=0.389) and 91.7% vs 86.6% (p=0.292) respectively; third year: 95.8% vs 97.1% (p=0.672) and 78.9% vs 71.0% (p=0.283) respectively. There were no significant differences in terms of immediate- and long-term complications at first and third year between groups.

Conclusion:
Laparoscopic colposuspension can be as effective as open colposuspension in treating urodynamic stress incontinence if performed by experienced hands.
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Introduction

Urinary incontinence is a common problem that can significantly affects the quality of life of women. The reported prevalence of urinary incontinence in Hong Kong ranges between 21 and 41%[1,2], of which 40% of women complained of stress incontinence. Surgery for stress incontinence is generally recommended when conservative treatments fail. The open Burch colposuspension has been considered the 'gold standard' in the surgical treatment of urodynamic stress incontinence without intrinsic sphincter deficiency, with a cure rate of 80% at 3 to 5 years[3,4]. The laparoscopic Burch colposuspension was first described in the early 1990s. It was proposed to have the advantages of shorter

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hospital stay, less postoperative pain, and quicker recovery[5].

This prospective randomised controlled trial was performed in a urogynaecology centre in Hong Kong during the year 1999-2003, comparing both objective and subjective cure rates at 1 year and 3 years, as well as the complications rates of open and laparoscopic Burch colposuspension. We also evaluated the outcome of patients 3 years after open or laparoscopic Burch colposuspension and compared it to the findings seen in the first year of follow-up.

Methods

This is a 3-year follow-up of a prospective randomised controlled trial[6]. The research protocol was approved by the Ethics Committee at the Queen Elizabeth Hospital, Hong Kong. The principal outcome measures were the subjective and objective cure rates and operation-related complications. We considered that a difference of 10% in the success rate between the open and laparoscopic colposuspension is of clinical significance. Assuming that the standard deviation is 5%, 79 patients on each arm would be able to achieve an 80% power at 95% confidence interval for correctly detecting such difference[7]. In the original study, 90 patients with urodynamic stress incontinence were recruited between July 1999 and August 2001 with an interim report published in 2003[6]. A further 78 patients were recruited between August 2001 and October 2003. 84 patients were randomly allocated to undergo open colposuspension and the other 84 patients laparoscopic colposuspension. Informed consent was obtained from the patients. All operations were performed by two senior urogynaecologists. They had each performed at least 15 laparoscopic colposuspension procedures prior to commencement of the study. All patients underwent complete preoperative urogynaecological examination — including uroflowmetry, filling / voiding cystometry, 1-hour pad test, a standard questionnaire with visual analogue scale (cure, improved, or unimproved), and a quality-of-life questionnaire. Patients were excluded if they had pathological conditions that might have limited the flexibility of the vaginal wall (such as reduced vaginal capacity or fibrosis) or a history of previous anti-continence surgery or intrinsic sphincter deficiency (resting maximum urethral closure pressure <20 cmH_2O or Valsalva leak point pressure <60 cmH_2O). 10 (11.9%) patients in the laparoscopic group and 42 (50.0%) patients in the open group underwent concomitant hysterectomy (open or laparoscopic) before colposuspension.

Patients were randomised according to a computer-generated random number table. Each patient was assigned by opening the next sequentially numbered sealed, opaque envelope. Outcome measures included operating time, estimated blood loss, duration of bladder training, complications, and change in severity of incontinence. For patients requiring concomitant hysterectomy, the measures of operating time and estimated blood loss were limited to the colposuspension itself. Hysterectomy would be performed before the colposuspension whenever needed, with blood loss estimated after completion. It would then be subtracted from the total blood loss after finishing the whole operation, thus yielding the estimated blood loss for colposuspension alone. Objective outcomes were assessed by urodynamic testing (considered successful if patient was dry during severe cough on urodynamic testing), while subjective outcomes were defined by the women's description of cure or improvement. Student's *t* test and Chi-square test were used for statistical analysis and $p<0.05$ was considered statistically significant.

Operative Techniques

For Burch open colposuspension, it was performed in the usual manner as described by Stanton et al[8]. A transverse skin incision was made two fingers' breadth above the symphysis pubis. With the operator's finger in the vagina elevating the vaginal fornix, the bladder base was dissected medially away from the paravaginal fascia and two 1-0 non-absorbable polybutylate-coated polyester sutures (Ethibond; Ethicon, Brussels, Belgium) were inserted into the fascia at the level of the urethrovesical junctions, and then to the nearest point on the ipsilateral Cooper's ligament. With the surgical assistant's finger in the vagina pushing up towards Cooper's ligament, the suture was tied. The procedure was then repeated on the contralateral side. Following haemostasis, the bladder was drained using a Bonanno suprapubic catheter.

For laparoscopic colposuspension, an 11-mm umbilical or subumbilical cannula site was used for the laparoscope, with three additional working ports: an 11-mm cannula set at approximately three fingers' breadth above the symphysis and two 5-mm lateral trocars

Table 1. Patients' characteristics

Characteristic	Open colposuspension (n=84)	Laparoscopic colposuspension (n=84)	p Value
Mean (SD) age (years)	50.85 (8.30)	52.8 (10.15)	0.174
Mean No. (SD) of parity	2.85 (1.30)	3.02 (1.57)	0.439
Mean No. (SD) of vaginal deliveries	2.64 (1.34)	3.01 (1.56)	0.102
Mean (SD) duration of stress incontinence (years)	4.76 (4.77)	5.59 (4.52)	0.252
Mean (SD) preoperative pad test (g)	31.85 (57.57)	32.88 (42.12)	0.895
Pre-existing detrusor overactivity	19 (22.6%)	11 (13.1%)	0.158

Table 2. Immediate postoperative complications of the procedure

Complication	Open colposuspension No. (%)	Laparoscopic colposuspension No. (%)	p Value
Conversion	-	1 (1.2)	-
Bladder injury	1 (1.2)	2 (2.4)	0.560
Fever	12 (14.3)	5 (6.0)	0.073
Urinary tract infection	5 (6.0)	1 (1.2)	0.096
Wound complication	1 (1.2)	1 (1.2)	1.000
Deep vein thrombosis	0 (0)	1 (1.2)	0.316

set on each side of the lower abdomen approximately 10 cm above the symphysis and 10 cm lateral to the midline. With an indwelling catheter, the bladder was emptied. Both a transperitoneal and an extraperitoneal approach were used. For the transperitoneal approach, the peritoneum cranial to the bladder was cut between the umbilical ligaments, using unipolar scissors. Assess to the space of Retzius was achieved using blunt dissection. Two sutures were inserted on each side in the same manner as the open procedure. The sutures were tied extracorporeally using a sliding knot technique with the Clarke-Reich knot pusher. The space of Retzius was not closed and intra-operative cystoscopy was performed before the operative procedures. Antibiotic prophylaxis was given to patients in both groups (metronidazole 500 mg and cefuroxime 750 mg intravenously for three doses). The patients were encouraged to void after the procedure. The indwelling catheter was removed only if the patients could void satisfactorily (two consecutive residual urine of <100 ml). The time required for bladder training was recorded. All patients preferred to stay in hospital until the indwelling catheters were removed.

All patients were followed up within the first year of operation (ranging from 6 to 12 months). Urodynamic measurements, pad test, and physical examination were performed and patients completed a visual analogue scale and questionnaire. Postoperative complications such as de-novo detrusor overactivity, obstruction (defined as peak flow rate of <15 ml/sec), enterocele and dyspareunia were assessed as well. A similar assessment was carried out 3 years after the operation.

Results

The mean age, parity, and number of vaginal deliveries were similar for patients in each group. No significant difference was found in the duration of stress incontinence, mean preoperative pad test result, or proportion of patients with pre-existing detrusor overactivity (Table 1).

Comparing the laparoscopic and open groups, the mean operating time was significantly longer in the laparoscopic group (47.80 vs 37.95 min; p=0.002), while the mean blood loss was significantly less in the laparoscopic group (117.86 vs 279.52 ml; p<0.001). There were one (1.2%) bladder injury in the open group and two (2.4%) bladder injuries in the laparoscopic group. One bladder injury was repaired laparoscopically without sequelae. The other patient required conversion

Table 3. Postoperative details

Details	Mean (SD) No. of days		p Value
	Open colposuspension	Laparoscopic colposuspension	
Bladder training	4.07 (3.27)	4.32 (4.64)	0.687
Hospital stay	9.21 (3.60)	9.15 (5.39)	0.933
Sick leave	9.26 (13.04)	5.58 (9.19)	0.036
Return to normal activity	29.79 (24.39)	19.40 (18.15)	0.002

Table 4. Success rates at 1 year and 3 years of open and laparoscopic colposuspension

	At 1 year			At 3 years		
	Open (n=84)	Laparoscopic (n=82)	p Value	Open (n=71)	Laparoscopic (n=69)	p Value
Subjective success	82 (97.6%)	78 (95.1%)	0.389	68 (95.8%)	67 (97.1%)	0.672
Objective success	77 (91.7%)	71 (86.6%)	0.292	56 (78.9%)	49 (71.0%)	0.283

Table 5. Preoperative versus postoperative pad test at 1 year

	Mean (SD) [g]		p Value
	Preoperative	1-Year postoperative	
Open colposuspension	31.85 (57.67)	4.13 (19.48)	<0.001
Laparoscopic colposuspension	33.11 (42.53)	6.93 (18.29)	<0.001

to laparotomy for bladder repair. The rate of bladder injury was not statistically significant between the two groups. Other immediate postoperative complications were similar between the two groups (Table 2).

The number of patients requiring epidural or patient-controlled analgesia was significantly less in the laparoscopic group (19.0% in laparoscopic group vs 84.5% in open group; p<0.001). There was no significant difference in the duration of bladder training and length of hospital stay between the two groups. The mean duration of hospital stay was around 9 days in both groups, which was quite different from other studies[9]. This could be due to the subsidisation for the financial costs for hospitalisation from the government, and different expectation from patients. However, patients in the laparoscopic group had a significantly shorter duration of sick leave and earlier return to normal activity (Table 3).

First-year Assessment

All 84 patients in the open group were assessed within 1 year after the operation, while only 82 (97.6%) patients in the laparoscopic group attended the 1-year assessment. The two missing patients had been contacted via phone or mails but could not be reached. The subjective and objective success rates were similar between the two groups (open vs laparoscopic: 97.6% vs 95.1%, p=0.389; 91.7% vs 86.6%, p=0.292, respectively) [Table 4]. There was a statistically significant difference in the 1-hour pad test when comparing the preoperative results and the 1-year postoperative results (31.85 g vs 4.13 g in the open group, p<0.001; 33.11 g vs 6.93 g in the laparoscopic group, p<0.001) [Table 5]. There were also no differences in the overall patient satisfaction, rate of de-novo detrusor overactivity, voiding dysfunction (peak flow rate <15 ml/sec), enterocele or dyspareunia after operation between the two groups (Table 6).

Third-year Assessment

71 (84.5%) patients in the open group and 69 (82.1%) patients in the laparoscopic group attended the third-year assessment. For those 28 patients who defaulted follow-up, two of them died after the first-year assessment (1 in the open group and 1 in the laparoscopic group). The other 26 patients defaulted further follow-

Table 6. Patients' satisfaction and complications at 1 year and 3 years

	At 1 year			At 3 years		
	Open (n=84)	Laparoscopic (n=82)	p Value	Open (n=71)	Laparoscopic (n=69)	p Value
Satisfied	57 (67.9%)	56 (68.3%)	-	40 (56.3%)	44 (63.8%)	-
Not satisfied	2 (2.3%)	4 (4.9%)	-	3 (4.2%)	2 (2.9%)	-
De-novo detrusor overactivity	20 (23.8%)	24 (29.3%)	0.426	20 (28.2%)	19 (27.5%)	0.933
Obstruction (peak flow rate <15 ml/sec)	29 (34.5%)	25 (30.5%)	0.579	17 (23.9%)	18 (26.1%)	0.770
Enterocele	2 (2.4%)	1 (1.2%)	0.574	2 (2.8%)	1 (1.4%)	0.576
Dyspareunia	5 (6.0%)	4 (4.9%)	0.760	1 (1.4%)	1 (1.4%)	0.984

Table 7. Preoperative versus postoperative pad test at 3 years

	Mean (SD) [g]		p Value
	Preoperative	3-Year postoperative	
Open colposuspension	34.86 (62.27)	7.14 (24.80)	<0.001
Laparoscopic colposuspension	32.81 (43.30)	9.42 (24.45)	<0.001

up and could not be contacted via phone or mails.

The objective and subjective success rates were similar between the two groups (open vs laparoscopic: 95.8% vs 97.1%, p=0.672; and 78.9% vs 71.0%, p=0.283, respectively) [Table 4]. There seems to be a trend that the objective success rate in the open group was higher than that of the laparoscopic group, the difference was not statistically significant. There was a statistically significant difference in the 1-hour pad test when comparing preoperative results and 3-year postoperative results (34.86 g vs 7.14 g in open group, p<0.001; and 32.81 g vs 9.42 g in laparoscopic group, p<0.001) [Table 7]. As in the first-year assessment, there were no significant differences in the proportion of patients having de-novo detrusor overactivity, voiding dysfunction, enterocele or dyspareunia between the two groups (Table 6).

Discussion

Since the first trial by Burton[10] in 1997, there were many ongoing studies comparing open and laparoscopic colposuspension. The first Cochrane review of laparoscopic colposuspension was published in 2002 and was further updated in May 2006[11]. According to the report, currently available evidence suggested that laparoscopic colposuspension might be as good as open colposuspension at 2 years after surgery. However, long-term performance of laparoscopic colposuspension remained uncertain. Patients who underwent laparoscopic colposuspension recovered quicker, although the operation itself took a longer time to perform when compared with open colposuspension. Two large randomised controlled trials have been published since the last update of Cochrane review — one from Australia, Carey et al[9], and the other from the United Kingdom, COLPO (Colposuspension; is Laparoscopic Preferable to Open?) Study Group[12]. Carey et al[9] recruited 200 women who were randomised and operated on. The study was designed to blind the nursing staff and patients to the type of surgery performed by placing betadine-soaked dressing over all possible incision sites. There were no significant differences in the objective and subjective measures of cure, as well as patients' satisfaction, at 6 months, 24 months, or 3 to 5 years (mean, 3.7 years) of follow-up between laparoscopic and open groups. Kitchener et al[12], on behalf of the COLPO Study Group, published the results of a randomised controlled trial which involved 291 women. The study concluded that there were no significant differences in the subjective and objective outcomes at 24 months between the two groups (open vs laparoscopic: 70.1% vs 79.7%; 54.6% vs 54.9%, respectively). There was, however, some evidence of 'loss of cure' when measured by pad test

at 6, 12, and 24 months. Both trials were included in a recently published meta-analysis[13], and a conclusion similar to that of the Cochrane review was reached.

In our study, laparoscopic colposuspension was shown to be as effective as open colposuspension in treating urodynamic stress incontinence, at both 1 year and 3 years after surgery, if performed by experienced hands. Furthermore, it was associated with less blood loss, reduced postoperative pain, quicker recovery, and earlier return to work, which would be welcomed by most of the patients nowadays.

With the recent introduction of tension-free vaginal tape (TVT) procedure, which was first described by Ulmsten et al[14] in 1999, the role of laparoscopic colposuspension is being challenged. Tension-free vaginal tape is associated with less morbidity and faster recovery. It is also easy to perform, with a shorter learning curve than laparoscopic colposuspension. Clinical trials[15] had been carried out, showing that the short-term success rates were comparable between the two procedures. Longer-term data from follow-up studies between 3 and 5 years have confirmed that cures of TVT appeared to be maintained. This further establishes the role of TVT as the first-line treatment for urodynamic stress incontinence, which imposes great challenge on the role of colposuspension.

Conclusion

This study shows that laparoscopic colposuspension is not clinically inferior to open colposuspension during follow-up at 1 and 3 years. In addition, it carries the advantages of less blood loss and faster recovery. However, with the evolvement of TVT, which is another minimal invasive technique, further long-term trials will be required to establish the true value of laparoscopic colposuspension.

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