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Prospective randomised controlled trial comparing laparoscopic and open colposuspension

比較腹腔鏡和開放式陰道懸吊手術的預期隨機控制測試

Objective. To compare the efficacy, safety, complications, and short-term outcome of laparoscopic and open colposuspension in women with genuine stress incontinence.

Design. Randomised controlled trial.

Setting. Urogynaecology unit in a public hospital, Hong Kong

Subjects and methods. Ninety patients with urodynamically proven genuine stress incontinence. Forty-three patients were randomly allocated to receive open colposuspension and 47 to undergo laparoscopy. All patients had reassessment within 1 year of the operation.

Main outcome measures. Objective and subjective measures and complication rates.

Results. There was no significant difference in the duration of stress incontinence, mean preoperative pad test results, or proportion with pre-existing detrusor instability. Among patients in the laparoscopic group, the mean operating time was significantly longer (42.0 minutes versus 29.3 minutes; $P < 0.0001$), while the mean blood loss was significantly less (124.7 mL versus 326.9 mL; $P = 0.001$). Subjective and objective success rates within 1 year were similar for patients in the open and laparoscopic groups (86.0% versus 80.9%; $P = 0.58$, and 86.0% versus 85.1%; $P = 1.00$, respectively). There was no significant difference in the rate of complications, including de novo detrusor instability and an obstructive voiding pattern, enterocele, or dyspareunia.

Conclusion. Laparoscopic colposuspension is a feasible alternative to the open approach. The operating time is longer but the short-term cure rate is comparable with that of the open approach.

目的：在患上應力性失禁的婦女中，比較腹腔鏡和開放式陰道懸吊手術的功效、安全性、併發症率和短期結果。

設計：隨機控制測試。

安排：香港一所公立醫院的婦女泌尿科。

患者與方法：經尿動力學證實患上應力性失禁的90名患者。隨機分配結果讓43名患者接受開放式陰道懸吊手術治療，另47名患者進行腹腔鏡陰道懸吊手術治療。所有患者進行手術後一年內再接受檢查。

主要結果測量：客觀及主觀的測量和併發症率。

結果：尿失禁期、平均術前墊托試驗結果、或逼尿肌已有不穩定比率沒有顯著差別。接受腹腔鏡陰道懸吊手術治療的患者中，手術的平均時間明顯較長(42.0分鐘比29.3分鐘； $P < 0.0001$)，而平均失血亦明顯較少(124.7毫升比326.9毫升； $P = 0.001$)。對於接受開放式和腹腔鏡治療的患者，一年內的主觀及客觀成功率相似(分別是86.0%比80.9%； $P = 0.58$ ，和86.0%比85.1%； $P = 1.00$)。此外，併發症率(包括更新逼尿肌不穩定和排尿困難，後陰道垂脫或性交困難)沒有顯著差別。

結論：利用腹腔鏡陰道懸吊手術代替開放式陰道懸吊手術是可行的。腹腔鏡陰道懸吊的手術時間相對較長，而短期治癒率則與開放式陰道懸吊手術相約。

Key words:

Laparoscopy;

Urinary incontinence, stress

關鍵詞：

腹腔鏡；

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Introduction

Colposuspension has been considered the 'gold standard' in the surgical treatment of genuine stress incontinence without intrinsic sphincter deficiency.

Long-term studies have shown cure rates of 80% five years after open colposuspension.^{1,2} In recent years, however, many complicated surgical procedures have been modified and simplified. Video laparoscopy has made more complex and extensive surgery possible through the laparoscope. Laparoscopic colposuspension has also become possible, with the first procedure being described in 1991.³ Laparoscopic surgery emulates the open operation. The place of this procedure has yet to be established and, as for all new techniques, only case reports and small randomised studies have been reported so far. Larger randomised studies with adequate power have yet to be performed. This study aimed at comparing the results of laparoscopic and traditional colposuspension in the treatment of genuine stress incontinence.

Methods

The research protocol was approved by the Ethics Committee at the Queen Elizabeth Hospital, Hong Kong. The study was a 1-year prospective randomised controlled trial. The principal outcome measures were subjective and objective cure rates and operation-related complications.

From July 1999 to August 2001, ninety patients with urodynamically proven genuine stress incontinence were recruited. Forty-three patients were randomly allocated to undergo open colposuspension and the other 47 to have the laparoscopic procedure. Each patient who was enrolled gave informed consent and agreed to each procedure that would be performed. 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. This included 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. Resting urethral pressure profilometry and Valsalva leak point pressure were also performed to exclude intrinsic sphincter deficiency. All terms used were in accordance with International Continence Society standardisation. Thereafter, the examinations were repeated within 1 year of the operation (ranging from 6 to 12 months). Patients who had pathological conditions that might have limited the flexibility of the vaginal wall such as reduced vaginal capacity or fibrosis were excluded. Patients who had undergone previous anti-incontinence surgery or intrinsic sphincter deficiency (resting maximum urethral closure pressure <20 cm H₂O or Valsalva leak point pressure <60 cm H₂O) were also excluded. Seven (14.9%) patients in the laparoscopic group and 16 (37.2%) patients in the open colposuspension 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. Objective results were assessed by urodynamic tests. A patient who was dry during severe cough on urodynamic testing was defined as being successfully treated. Otherwise, the procedure was deemed to have failed. Subjective outcome measures were defined by the women's description of cure or improvement. Student's *t* and Chi squared tests were used for statistical analysis, and *P*<0.05 was considered statistically significant.

Operative techniques

Traditional Burch open colposuspension, as described by Stanton et al,⁶ was performed in the usual manner with a transverse skin incision 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 2 x 1-0 unabsorbable polybutylate-coated polyester sutures (Ethibond; Ethicon, Brussels, Belgium) were inserted into the fascia at the level of the urethrovesical junction, 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 Bonarno 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 pubis and two 5-mm lateral trocars 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. Access 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 with 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 urines of less than 100 mL). The time required for bladder training was recorded. All patients preferred to stay in hospital until the indwelling catheters were removed. All women were then

Table 1. Patients' characteristics

	Open colposuspension, n=43	Laparoscopic colposuspension, n=47	P value
Mean age (SD) [years]	50.4 (9.2)	51.1 (9.2)	NS [‡]
Mean parity (SD)	2.9 (1.2)	2.7 (1.2)	NS
Mean No. of vaginal deliveries (SD)	2.6 (1.3)	2.7 (1.2)	NS
Mean duration of SI* (SD) [years]	5.1 (5.6)	5.7 (4.8)	NS
Mean preoperative pad test (SD) [g]	35.9 (60.8)	29.0 (36.0)	NS
Pre-existing DI [†] /No.	13.0 (30.2%)	7.0 (14.9%)	NS

* SI stress incontinence

† DI detrusor instability

‡ NS not significant

Table 2. Immediate complications of the procedure

	Open colposuspension No. (%)	Laparoscopic colposuspension No. (%)	P value
Conversion	-	1 (2.1)	-
Bladder injury	0	2 (4.3)	NS*
Fever	11 (25.5)	5 (10.6)	NS
Urinary tract infection	3 (6.9)	1 (2.1)	NS
Wound complication	1 (2.3)	1 (2.1)	NS
Deep vein thrombosis	0	1 (2.1)	NS

* NS not significant

Table 3. Postoperative details

	Open colposuspension Mean No. of days (SD)	Laparoscopic colposuspension Mean No. of days (SD)	P value
Bladder training (days)	3.7 (2.8)	3.0 (1.6)	NS*
Hospital stay (days)	9.6 (3.9)	9.7 (5.0)	NS
Leave (days)	15.4 (13.2)	8.5 (9.3)	0.03
Return to normal activity (days)	29.3 (19.8)	22.2 (15.9)	NS

* NS not significant

asked to return for evaluation 6 to 12 months after surgery. Urodynamic measurements, pad test, and physical examination were performed and patients completed a visual analogue scale and questionnaire.

Results

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

In the laparoscopic group, the mean operating time was significantly longer (42.0 minutes versus 29.3 minutes; $P < 0.0001$) while the mean blood loss was significantly less (124.7 mL versus 326.9 mL; $P = 0.001$). There were two (4.3%) bladder injuries in the laparoscopic group. One bladder repair was performed laparoscopically without sequelae. One patient required conversion to laparotomy for bladder repair. There were no injuries in the open operation group. The difference was not statistically significant. One patient in the laparoscopic group developed hydronephrosis 6 months after discharge and required re-implantation of the left ureter. There was no conclusive evidence that the stricture in the left ureter was related to the operative procedure. A congenital cause was suspected. There was one (2.1%) conversion to laparotomy. The conversion was due to a larger bladder perforation which was repaired by open laparotomy. Other immediate postoperative complications were similar between the groups (Table 2).

The number of patients requiring epidural or patient-controlled analgesia was significantly less in the laparoscopic group (10.6% versus 48.8% in the open operation group; $P < 0.001$). The mean sick leave was significantly less for patients in the laparoscopic group. There was no significant difference in the duration of bladder training between the groups (Table 3). The subjective and objective success rates were similar between the groups (86.0% for open operation versus 80.9% for laparoscopy; and 86.0% for open operation versus 85.1% for laparoscopy, respectively) [Table 4]. There was a statistically significant difference in the 1-hour pad test when comparing preoperative results and 1-year postoperative results (35.9 g versus 4.4 g for open operation; $P = 0.001$; and 29 g versus 3.6 g for laparoscopy; $P < 0.001$) [Table 5]. There was no difference in the overall patient satisfaction between groups. There was also no significant difference in the rate of de novo detrusor instability, proportion with voiding dysfunction (peak flow rate < 15 mL/sec), enterocele, or dyspareunia after the operation (Table 6).

Discussion

Since the first description of laparoscopic colposuspension in 1991,³ there have been many reports of outcome following the procedure. Some of the methods used have emulated the open procedure but, overall, there has been a large variation in the techniques used so direct comparisons with the open approach have been difficult. Therefore, evaluation of the procedure in the form of appropriately designed, randomised studies in the hands of experienced urogynaecologists was needed.

Table 4. One-year success rate

	Open colposuspension No. (%)	Laparoscopic colposuspension No. (%)	P value
Subjective success	37 (86.0)	38 (80.9)	NS*
Objective success	37 (86.0)	40 (85.1)	NS

* NS not significant

Table 5. Preoperative pad test versus postoperative pad test at 1 year

	Preoperative pad test Mean (SD)	Postoperative pad test Mean (SD)	P value
Open colposuspension (g)	35.9 (60.8)	4.4 (20.3)	0.001
Laparoscopic colposuspension (g)	29.0 (36.0)	3.6 (11.1)	<0.001

Table 6. Patients' satisfaction and complications at 1 year

	Open colposuspension No. (%)	Laparoscopic colposuspension No. (%)	P value
Very satisfied	13 (30.2)	14 (29.8)	-
Satisfied	28 (65.1)	32 (68.1)	-
Not satisfied	2 (4.7)	1 (2.1)	-
De novo DI*	5 (11.6)	12 (25.5)	NS†
Obstruction (PFR†<15)	16 (37.2)	13 (27.7)	NS
Enterocoele	2 (4.7)	1 (2.3)	NS
Dyspareunia	4 (9.3)	3 (6.4)	NS

* DI detrusor instability

† PFR peak flow rate

‡ NS not significant

To date, there have been two randomised studies, which have demonstrated that the laparoscopic success rate was lower than the open success rate.^{7,8} Burton's⁷ study was conducted early in the learning curve of the author, and absorbable sutures were used for the procedure. In addition, this author used a very small needle for the laparoscopic group. The report of Su et al⁸ did not compare like with like and was not properly randomised. One suture was inserted on each side for the laparoscopic group and two to three sutures for the open operation group. Five reviews specifically related to laparoscopic surgery have been reported.⁹⁻¹³ The paper by Miklos and Kohli¹¹ reported on their technique in 171 women. The results with laparoscopic colposuspension were similar to those expected for an open procedure. One recent randomised study compared laparoscopic with open colposuspension.¹⁴ The same technique was used for both groups, although only one suture was used on each side. Subjective and objective results were reported with cure rates of 87.9% and 85% for patients in the laparoscopic and open operation groups, respectively, after 18 months. These differences were not significant. In this study, the technique was standardised and two sutures were applied to each side in an exact manner in both approaches. The subjective and objective success rates, patient's satisfaction, and pad test improvement were similar for both groups.

The apparent increased complication rate associated with laparoscopic colposuspension, particularly in relation to lower urinary tract injury, has been highlighted by several authors.^{15,16} Other authors referred to lower morbidity with the laparoscopic approach.¹⁰ Speights et al¹⁷ reported that previous studies showed injury rates that varied from 0% to 25%, with the more recent papers quoting

figures of approximately 3%. The apparent reduction in injuries in more recent series may be related to improved surgical technique. In this study, the rate of bladder injury was 4.3%. The two senior surgeons had performed at least 15 laparoscopic colposuspensions prior to the commencement of the study. Although the laparoscopic procedure required more time, the mean duration was 42 minutes, which is considered acceptable for any major procedure.

These results also demonstrated that the laparoscopic procedure was associated with reduced postoperative pain and decreased need for analgesia, quicker recovery, and earlier return to work. This may, however, be related to both doctors' and patient's expectation rather than the actual effect. Recently, a well-designed randomised blinded study cast doubt on the alleged advantages after laparoscopic cholecystectomy. Moreover, early mobilisation of the patient may carry a risk of suspension rupture because of weak scarification, which may affect the long-term success rate for continence procedures.

Conclusion

This study showed that laparoscopic colposuspension was a feasible alternative to the open operation approach, with the advantages of reduced blood loss and earlier return to normal activity. There was a slight increase in operating time. The short-term cure rate was comparable with the open operation approach. Further long-term results will be presented later. The authors believe that adherence to traditional surgical principles and adoption of the procedure by those surgeons with combined laparoscopic and urogynaecological skills will enable the true place of this operation to be established.

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