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**Abstract Reproduction Form B-1**

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Title (type in  
CAPITAL  
LETTERS)**LAPAROSCOPIC VERSUS OPEN COLPOSUSPENSION – EARLY  
RESULTS OF A SINGLE BLIND PROSPECTIVE RANDOMIZED  
CONTROL TRIAL****Aims of Study**

The Burch colposuspension is an effective operation for the treatment of stress incontinence with a long-term objective cure rate exceeding 80%. In 1990 the laparoscopic Burch colposuspension was described and has gained wide popularity in recent years. With the exception of two small series, introduction of this laparoscopic procedure has proceeded without appropriate randomized trials (1,2). Both studies were prospective RCT's and reported poorer outcome with the laparoscopic approach based on post-operative urodynamic cure. Burton reported a failure rate of 7% for the open colposuspension compared to 27% for the laparoscopic approach (1). Tsung-Hsien et al reported a success rate for the open procedure of 95.6% and 80.4% for the laparoscopic approach [p=0.04] (2).

The perceived benefits of the laparoscopic colposuspension, including shortened hospitalization, reduced analgesic requirements and pain, and early return to normal activities have not been evaluated by methods that eliminate the bias created by patients and staff knowing which procedure has been performed. Two prospective single-blinded, randomized studies comparing laparoscopic cholecystectomy and appendicectomy with small incision open procedures failed to demonstrate any short-term benefits (3,4).

This study aimed to evaluate the short-term benefits and long-term success of the laparoscopic compared with the traditional open Burch colposuspension. We also aimed to develop a validated questionnaire assessing patient satisfaction with surgical treatment.

**Methods**

All patients with genuine stress incontinence who were recommended a colposuspension, had no contraindications for laparoscopy and no major prolapse were offered participation in the study. A total of 201 patients were recruited and underwent surgery. Patients were randomized to either open or laparoscopic colposuspension. The 2 senior authors, together, performed approximately 70 laparoscopic colposuspensions before commencing the study. Surgery was performed at 9 hospitals by 6 surgeons of different expertise levels. The surgical technique for the laparoscopic approach aimed to mimic the open procedure with the exception of the incision. The suture material and the number and degree of tension of suspending sutures were the same for both open and laparoscopic procedures. The wounds were dressed identically so that the patient and nursing staff were blinded to the incision used. The anaesthetic, post-operative pain management protocol, catheter regimen, discharge policy and instructions in the post-operative period were the same for both groups.

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Patients were assessed at 6 weeks and 6 months by staff blinded as to which operation had been performed. At 6 months, an independent assessor performed urodynamics. Patients completed the Short Form 36, Incontinence Impact Questionnaire and Urogenital Distress Inventory before surgery and 6 months post-operatively. A patient satisfaction questionnaire was developed, validated and administered 6 months after surgery.

### Results

Between January 1997 and December 1998, 201 women were randomized and underwent surgery. By March 1999, 141 women had completed their 6 month review.

Outcomes are summarized in the table.

<u>Variable</u>	<u>Open</u>	<u>Laparoscopic</u>	<u>p-value</u>
<u>Age (mean)</u>	<u>52.8 yrs</u>	<u>51.6</u>	<u>0.42</u>
<u>Parity (mean)</u>	<u>2.5</u>	<u>2.7</u>	<u>0.19</u>
<u>BMI (mean)</u>	<u>29.9</u>	<u>29.13</u>	<u>0.45</u>
<u>Operating time (mean)</u>	<u>35 mins</u>	<u>78</u>	<u>0.01</u>
<u>Hospital stay (mean)</u>	<u>3.9 days</u>	<u>3.7</u>	<u>0.32</u>
<u>High satisfaction</u>	<u>86.9</u>	<u>87.5</u>	<u>0.60</u>
<u>Subjective success (%)</u>	<u>95</u>	<u>100</u>	<u>0.12</u>
<u>Urodynamic cure (%)</u>	<u>77.8</u>	<u>70.1</u>	<u>0.34</u>

Intraoperative blood loss and postoperative pain were significantly less for the laparoscopic procedure (p0.05).

### Discussion

The early results from this study suggest that the laparoscopic colposuspension is as effective as the traditional open procedure. Patients reported high satisfaction with treatment for both procedures. The laparoscopic approach was associated with less post-operative pain and an earlier return to normal activities but hospital stay was the same for both procedures. The operating time for the open procedure was less but was associated with more blood loss than the laparoscopic approach.

In this study, success rate based on patient satisfaction scores was higher than urodynamic cure rate. High patient satisfaction with treatment should be aimed for rather than a urodynamic cure.

### References

1. Proceedings RACOG ASM, 1996
2. Acta Obstet Gyn Scan 1997;76:576-82
3. Lancet, 1996; 347:989-994
4. Anesthesiology, 1996; 84: 801-805