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A PROSPECTIVE RANDOMISED CONTROLLED TRIAL OF OPEN AND LAPAROSCOPIC COLPOSUSPENSION

Hypothesis / aims of study

To date, there have been no studies published which have compared laparoscopic and open colposuspension with a robust design including sufficient patients with 2 year follow up. This multicentre study was designed to compare the effectiveness of open and laparoscopic colposuspension in the treatment of stress urinary incontinence.

Study design, materials and methods

Women with urodynamically proven stress urinary incontinence requiring surgery in the form of a colposuspension were invited to participate in this six centre, (Manchester, Glasgow, Leeds, Wolverhampton, Basingstoke and London) prospective, randomised trial. Cases who had undergone previous retropubic surgery were excluded. Randomisation was performed by an external centre and stratified by centre, age and previous bladder neck surgery. Each centre included surgeons with extensive experience in both surgical techniques. Pre-operatively, in addition to urodynamics, women completed UK version Short Form 36, Bristol Female Lower Urinary Tract Symptom (BFLUTS) Questionnaire, Kings Health Questionnaire, Sabbatsberg Sexual Rating Scale and Symptom Severity and Symptom Impact Index. No attempt was made to blind the women to the type of surgery. Standard surgical procedure included antibiotic prophylaxis, skin preparation, supra-pubic catheterisation, and patient controlled analgesia post-op. In all cases a minimum of two ethibond sutures were inserted on each side. Following surgery questionnaires were completed at 6 weeks, and 6, 12, and 24 months. A pad test was performed at each visit, a positive result being defined at > 1.0g/hr. Urodynamic studies were performed routinely at 6 months but only repeated thereafter if the pad test was positive.

Primary outcomes at 2 years were both subjective; a question of satisfaction with outcome ("perfectly happy / pleased" Q33 in BFLUTS) and objective; a negative 1 hour pad test. Secondary outcomes were levels of operative morbidity, time to return to work and health economic costs to the NHS and patient.

The study was powered to demonstrate non inferiority, i.e. that the absolute cure rate of laparoscopic colposuspension did not differ by more than 15% compared with open colposuspension.

Results

Between April 1999 and February 2002, 291 women were recruited into the trial. Two year data was completed in June 2004. Data on subjective and objective outcomes was available in 88% and 82.5% respectively. The intention to treat analysis indicated no significant difference in cure rates between open and laparoscopic surgery. The objective cure rates for open and laparoscopic were 82% and 79.7% respectively. Subjective cure rates by satisfaction were 54.6% and 54.9% and by symptoms 53.1% and 55.4% respectively. There was a significant decrease in cure in both arms over time when assessed objectively but not subjectively. Significantly fewer (23%) of the laparoscopic surgery women suffered 24 hour pain levels >6 compared to those after open surgery (40%). The mean length of hospital stay was 5 days and 6 days in the laparoscopic and open groups. The mean time to return to work was 9 weeks and 11 weeks respectively although only about half of the women were working. Neither of these post-operative time differences was statistically significant. Bladder and bowel injury were uncommon but were seen more frequently in the laparoscopic group. Wound infection was seen significantly more frequently in the open group. Although there were observed differences in treatment effects between centres, these were no more than could be expected by chance.

Interpretation of results

This is the first reported series which has the power and length of follow up to make a judgement on the outcome of laparoscopic colposuspension compared to open colposuspension. Laparoscopic colposuspension, when performed by experienced surgeons, is not inferior to open colposuspension in terms of curing stress urinary incontinence when assessed objectively and subjectively. Laparoscopic colposuspension is associated with less post-operative pain and wound infection but confers no significant benefit in terms of length of hospital stay or return to work. The finding of non-inferiority in this study infers that surgical experience may have contributed to the lower success rates seen for laparoscopic colposuspension in other series. Furthermore, adherence to a standard technique, whether performing open or laparoscopic surgery, may also help to maintain an acceptable outcome.
The length of post-operative stay in hospital may have been determined more by voiding problems than by other aspects of recovery from surgery. The lower pain scores and reduction in wound infection associated with laparoscopic surgery might allow for a shorter hospital stay if voiding problems were managed in a different way.

The discrepancy seen between objective and subjective results has been reported in other studies of stress incontinence surgery. Qualitative outcome measures for surgery clearly need further study.

Concluding message

Laparoscopic colposuspension, when performed by experienced surgeons, produces a similar cure rate to open colposuspension.

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