Randomised controlled trial of laparoscopic versus open repair of inguinal hernia: early results

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Abstract

***Objective*—To establish the safety, short term outcome, and theatre costs of transabdominal laparoscopic repair of inguinal hernia performed as day surgery.**

***Design*—Randomised controlled trial. The control operation was the two layer modified Maloney darn.**

***Setting*—Teaching hospital and district general hospital.**

***Subjects*—125 men randomised to laparoscopic or open repair of inguinal hernia.**

***Outcome measures*—Morbidity, postoperative pain and use of analgesics, quality of life, and theatre costs. Outcome was assessed by questionnaires administered to patients daily for 10 days and at six weeks postoperatively and by outpatient review at six weeks. Return to normal activity was assessed by questionnaire at three months.**

***Results*—One vascular complication (2%) occurred in the group that had open repair. Seven complications (12%) including vessel injury and early recurrence arose in the group that had laparoscopic repair (difference in complication rate 10% (95% confidence interval 4% to 18%; P=0·02). Pain scores and quality of life assessed by the short form 36 showed a significant benefit to the group that had laparoscopic repair in the early postoperative period. Return to normal activity was not significantly different between the two groups. Total theatre costs were higher in the group that had laparoscopic repair (mean cost for laparoscopic repair £850 (£622 to £1078); mean cost for open repair £268 (£245 to £292)).**

***Conclusions*—Because of the greater complication rate and higher theatre costs for laparoscopic repair and the patient outcome preferences expressed, the results of larger trials of clinical and cost effectiveness using recurrence as the primary outcome measure should be known before laparoscopic herniorrhaphy is widely adopted.**

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Introduction

Laparoscopic cholecystectomy has within the past three years become the routine technique for gall bladder removal, superseding open cholecystectomy because it reduces postoperative morbidity and length of hospital stay.[1] The advantages of laparoscopic repair of inguinal hernia over open repair are less apparent. Open herniorrhaphy is already performed as day case surgery, and the operation rarely causes severe pain or morbidity. Laparoscopic herniorrhaphy requires smaller skin wounds and obviates the need for muscle or aponeurotic incision, although any resulting benefits have been disputed.[2]

Several surgical techniques for hernia repair are used in Britain. The most popular techniques are the Maloney darn and the Shouldice technique.[3] More recently open, tension free repair has been undertaken with prosthetic mesh.[4,5] Three laparoscopic techniques have been described, and all need prosthetic mesh: a transperitoneal approach in which mesh is placed directly on to the peritoneum[6]; an extraperitoneal approach in which mesh is placed in the preperitoneal space[7]; and a transabdominal approach, with incision and dissection of the peritoneum for mesh to be placed in the preperitoneal space.[8]

This study was designed as part of an evaluation of laparoscopic transabdominal preperitoneal prosthetic mesh repair—to evaluate its safety and short term outcome. Current United Kingdom targets suggest that 50% of hernias are suitable for day surgery[9]; all patients in the study had day surgery.

Patients and methods

We received ethical approval for this study from the central Oxford research and ethics committee and Milton Keynes ethics committee. Patients were eligible for the study if they had a primary, unilateral inguinal hernia on examination and met the local criteria for day surgery (American Society of Anaesthesia grade 1 or 2, age <70 years). We excluded patients who had had previous major abdominal surgery or needed overnight admission. We recorded demographic details preoperatively and classified patients by social class using the registrar general's classification.[10]

We allocated patients to open or laparoscopic surgery by unrestricted randomisation in a 1:1 ratio. All surgery was performed by four surgeons who were experienced laparoscopists of senior registrar or consultant grade. One surgeon had completed 20 laparoscopic hernia repairs before beginning the study and attended all procedures for the first six months of the study. General anaesthesia was administered to all patients in line with current local practice for day surgery. Patients received 100 mg diclofenac per rectum one hour before their operation.

OPERATIVE TECHNIQUES

The choice of open operation was determined by the need to achieve generalisability of the results. Our current standard surgical technique was therefore the appropriate choice. This consisted of a modified, two layer Maloney darn,[11] comprising a polypropylene plication of transversalis fascia and a tension free nylon darn between the inguinal ligament and conjoint tendon.

Laparoscopic repair was performed through three abdominal ports (Auto Suture): a 10 mm umbilical port was used for the laparoscope, an ipsilateral 12 mm port for the staple gun (Multifire Endo Hernia, Auto Suture), and a 5 mm auxiliary port on the contralateral side of the abdomen. Small hernia sacs were everted into the pelvis and included in the pelvic peritoneal flap which was dissected from the anterior abdominal wall in a posterior direction. Large hernia sacs were circumferentially incised and left in situ. Both direct and indirect hernias were repaired by placing a 12 cm×8 cm polypropylene mesh (Surgipro, Auto Suture) ventral to the inferior epigastric vessels. Placement was facilitated by making superior and inferior slits in the mesh to accommodate the epigastric

vessels. The mesh was stapled superiorly and medially, and the peritoneum closed over it with stapling. After the ports had been removed the deep fascia in the 10 mm and 12 mm ports was closed with interrupted braided polyester sutures.

All wounds in both groups were infiltrated with a total of 10 ml of 0·5% bupivacaine. The skin was closed with subcuticular Dexon.

Patients were given a supply of oral analgesics to take home: diclofenac (50 mg tablets) for mild discomfort, co-proxamol tablets (325 mg paracetamol and 32·5 mg dextropropoxyphene) for moderate discomfort, and pethidine (50 mg tablets) for more severe pain.

After their operation all patients were advised that they could return to work and normal activity as soon as they felt like it. Questionnaires were administered to patients for 10 days preoperatively and at six weeks postoperatively. Patients were assessed at six weeks by an investigator who had not been present at the operation. Longer term follow up by questionnaire was also undertaken.

OUTCOME MEASURES

The initial phase of the study was conducted to examine the safety of laparoscopic repair. The outcome measure used for the primary analysis was therefore the rate of short term complications. A short term complication was defined as an accidental event or secondary disease process resulting from the operative intervention and occurring within six weeks of surgery. In the absence of local data, a short term complication rate of 0·5% from open repair was assumed. The sample size and duration of follow up reported would enable the detection of an increase of 18% in the complication rate from laparoscopic repair, with a single sided α (significance level) of 0·05 and β of 0·2 (80% power).

We also performed several secondary analyses using other end points. We selected the outcome measures for these analyses so that we could assess the potential benefits that might arise from laparoscopic hernia repair. We assessed daily linear analogue pain scores (on a 0-100 scale) for seven days postoperatively. We recorded use of analgesics for the first seven postoperative days and assessed quality of life at 10 days and six weeks postoperatively using the short form 36 (SF36), a multidimensional profile measure of health status.[12] We assessed the patients' self reported general health state in the first 10 days and at six weeks postoperatively, using the linear analogue section of the Euroqol (an instrument in two parts—a linear analogue scale and a scale developed to form a single index measure of health).[13] We also used disease specific measures such as time before return to normal activity.

We calculated theatre costs as the total costs of non-varying items (perioperative consumables—gowns, gloves, intravenous transfusion equipment, sutures, and disposable laparoscopic equipment), items liable to vary between operations (anaesthetic agents, analgesics, breakages of disposable equipment), and costs per minute of operating time (staffing, theatre overheads, capital charges). Operating time was defined as the time from a patient entering the operating theatre to leaving it.

We assumed that the members of staff present in theatre for the open procedure were a G grade nurse, an E grade nurse, a consultant surgeon, and a consultant anaesthetist. We assumed that the same members of staff were present for the laparoscopic procedure but that a surgical registrar was also present as an assistant.

We costed all consumables using 1992/3 market prices including value added tax. We costed health service facilities used by the patients using 1992/3 costs generated by the finance department at the Churchill Hospital. Overheads for theatre facilities were all included. We costed the capital costs of building space according to the values attached by the district health authority's auditor. Capital charges of equipment were charged to the specialty of general surgery on the basis of use.

ANALYSIS

The difference in complication rate was assessed with Fisher's exact test. Patients undergoing the laparoscopic procedure were divided into three groups by level of "operator experience," defined as the cumulative experience of the operating team. A χ^2 test for trend was then used to assess the relation between the risk of a complication and level of operator experience.

Analysis of the postoperative pain measures (which were rank normalised) and of the patient's general self reported health state was by multivariate repeated measures analysis of variance. The short form 36 scores were analysed by repeated measures analysis of covariance, by taking the baseline score on the relevant dimension as the covariate. For these multivariate analyses a 1% significance level was taken to account for multiple testing.

The difference in time before patients returned to work or resumed normal activity between the two groups was assessed by performing a Mann-Whitney U test and by comparing survival curves for the two groups with Wilcoxon's statistic. The contribution made to the variance in this outcome by the type of operation, the type of job undertaken, and social class was assessed with multiple regression with time before returning to work or to normal activity as the dependent variable.

Differences in use of analgesics were assessed by dividing patients into four groups on the basis of the total number of painkillers consumed and by performing a χ^2 test to compare laparoscopic and open procedures.

Operating time was compared in the two groups by using Student's t test. The effect of operator experience on operating time was assessed by using Pearson's correlation and regression statistics. An unpaired t test was used to compare theatre costs in the two groups, and the mean difference in costs was calculated.

Patients randomised to laparoscopic surgery who, owing to operative difficulties, were reallocated to the group receiving open repair were termed "crossover patients" and were considered to be in the original treatment arm for analysis.

Results

ENTRY OF PATIENTS

In all, 228 consecutively referred patients with primary unilateral hernias were screened for suitability between December 1992 and December 1993. Of these, 98 were excluded: 81 patients did not meet the criteria for day surgery, seven had undergone previous major abdominal surgery, three wished to delay their treatment until after the study period, six did not wish to take part in the trial, and one did not speak English and was unable to give informed consent.

In all 130 patients were randomised, of whom 129 underwent surgery, an average of three weeks after randomisation. As only four of these patients were female, they were excluded from the analysis. One patient was found to have a femoral hernia at the time of surgery and was therefore also excluded from the analysis. Thus 66 patients randomised to open surgery and 58 to laparoscopic repair were included in the analysis. A choice of operating dates for patients contributed to a low non-attendance rate. Randomisation created balanced treatment groups with respect to

age, although a slight imbalance in the social class distribution existed between the two groups (table I). Comparison of the types of hernia between the two groups was difficult. Small direct hernias are more easily seen by the laparoscopic than the open route, and preoperative diagnosis of type of hernia is highly unreliable.[14] Two patients were crossover patients from laparoscopic to open repair as they had incarcerated hernias.

Follow up at six weeks was completed by June 1994. One patient in the open repair arm of the trial made no contact with the study group after surgery, although his wellbeing was confirmed by his family doctor. Completion rates for questionnaires varied from 98% (122) for the 10 day and six week versions of the short form 36 to 94% (117) for the postoperative pain scores.

PERFORMANCE AT FOLLOW UP

Seven (12%) patients in the group having laparoscopic repair had complications postoperatively (cord haematomas or seromas in four patients, local damage to the testicular or inferior epigastric vessels in two, and early recurrence of a direct inguinal hernia in one). One (2%) vascular complication occurred in the open repair arm of the trial, involving damage to the inferior epigastric vessels. The percentage difference in complication rate between the two groups was 10% (95% confidence interval 4% to 18%); P=0·02 with Fisher's exact test. No significant trend occurred in the likelihood of a complication in the group having laparoscopic repair with level of operator experience at this sample size and power (two complications among patients treated by a team with lowest experience, three among those treated by a team with intermediate experience, and one among those treated by a team with highest experience (χ^2 for trend=1·00, 1 df).

Linear analogue pain scores in the seven days postoperatively showed a steady and significant improvement in both groups, with a significant advantage (at 1% significance level) to the group that had laparoscopic repair on movement and on coughing but not at rest (table II). Use of analgesics also showed a significant benefit to the group that had had laparoscopic repair over seven days postoperatively (table III).

The dimensions of the short form 36 are scored on a scale of 0 to 100 (0=poorest health, 100=best health).

TABLE I—*Baseline characteristics of patient groups by treatment group. Values are numbers (percentages) of patients unless stated otherwise*

	Laparoscopic repair (n=58)	Open repair (n=66)
Median (range) age (years)	47 (20-69)	47 (20-66)
Social class*:		
I, II, III manual	27 (47)	36 (54)
III non-manual, IV, V	29 (50)	27 (41)
Student	2 (3)	3 (5)

*Registrar general's classification system.[10]

TABLE II—*Median (interquartile range) linear analogue pain scores postoperatively*

	0	1	2	3	4	5	6	7
At rest:								
Laparoscopic repair	13 (16)	10 (15)	10 (17)	7 (9)	7 (9)	5 (12)	4 (10)	4 (9)
Open repair	21 (18)	18 (19)	14 (13)	11 (12)	5 (11)	7 (11)	6 (10)	5 (8)
F value laparoscopic *v* open (df=1,116, *F*=2·45, P=0·12)								
F value operation by time (df 7,812, *F*=1·59, P=0·136)								
On movement:								
Laparoscopic repair	30 (27)	31 (27)	24 (26)	16 (17)	16 (18)	10 (17)	8 (16)	8 (12)
Open repair	38 (26)	38 (22)	35 (28)	30 (29)	23 (30)	21 (31)	18 (23)	13 (20)
F value laparoscopic *v* open (df=1,116, *F*=16·73, P<0·0001)								
F value operation by time (df=7,812, *F*=3·76, P=0·001)								
On coughing:								
Laparoscopic repair	30 (41)	30 (42)	24 (44)	18 (33)	20 (30)	18 (31)	13 (19)	10 (22)
Open repair	55 (36)	58 (34)	56 (38)	43 (43)	37 (39)	36 (39)	26 (37)	19 (29)
F value laparoscopic *v* open (df 1,116, *F*=18·29, P<0·0001)								
F value operation by time (df 7,812, *F*=1·15, P=0·331)								

TABLE III—*Use of analgesics over seven days postoperatively among patients in group that had open repair versus those in group that had laparoscopic repair. Values are numbers (percentages) of patients*

No of analgesic tablets	Open repair (n=62)	Laparoscopic repair (n=55)
0	2 (3)	11 (20)
1-10	22 (35)	23 (42)
11-20	18 (29)	14 (25)
>20	20 (32)	7 (13)

The postoperative pain score questionnaire was completed by 117 of 124 (94%) patients.
χ^2 Test with 3 df; P=0·01.

TABLE IV—*Scores from short form 36* at different times postoperatively by treatment group. Values are mean (SD) scores unless stated otherwise*

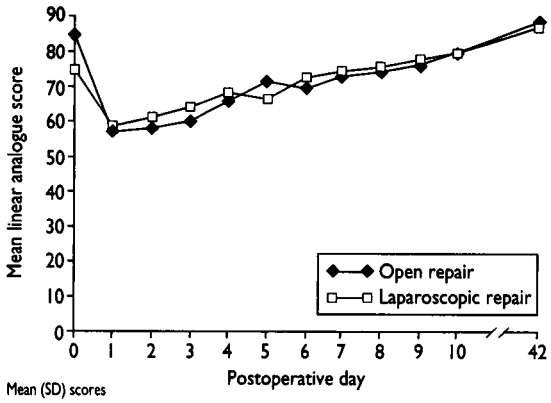
	Baseline	10 Days	Six weeks	*F* value laparoscopic *v* open repair† (P value)
General health perception:				
Open	82 (15)	77 (17)	81 (16)	0·14 (0·71)
Laparoscopic	74 (19)	71 (17)	77 (18)	
Physical mobility:				
Open	87 (14)	62 (27)	90 (13)	1·15 (0·29)
Laparoscopic	81 (21)	66 (23)	88 (16)	
Social functions:				
Open	93 (16)	64 (25)	87 (18)	5·67 (0·01)
Laparoscopic	86 (21)	70 (24)	92 (13)	
Role limitations (physical):				
Open	82 (32)	13 (25)	54 (40)	4·13 (0·04)
Laparoscopic	69 (38)	25 (35)	64 (41)	
Role limitations (mental):				
Open	90 (24)	74 (38)	83 (33)	2·16 (0·14)
Laparoscopic	88 (29)	66 (42)	76 (38)	
Pain:				
Open	74 (21)	44 (20)	77 (21)	15·3 (0·0001)
Laparoscopic	68 (23)	61 (20)	81 (18)	
Mental health:				
Open	81 (18)	82 (18)	84 (14)	1·38 (0·24)
Laparoscopic	77 (17)	82 (14)	84 (15)	
Energy:				
Open	69 (20)	56 (20)	66 (16)	9·24 (0·003)
Laparoscopic	65 (18)	62 (17)	72 (16)	
Change in health:				
Open	51 (16)	46 (20)	58 (22)	0·82 (0·366)
Laparoscopic	50 (18)	50 (18)	57 (17)	

*Scale 0 to 100 (0=poorest health, 100=best health).
†Df 1,120; operation by time not significant except for pain dimension (*F*=9·15, P=0·003).

Scores at 10 days and six weeks postoperatively showed that pain receded most rapidly, and with a significant advantage, in the group that had had laparoscopic repair. Postoperative social function and energy were dimensions in which a relative advantage to the patients in the laparoscopic arm of the trial also achieved significance (table IV). Both groups showed improvement on these and other dimensions from 10 days to six weeks. The other dimensions did not show significant differences between the two groups. Notably, both groups sustained a consistent level throughout the study on their general perception of health.

The two groups did not differ in their self reported general health state in the first 10 days postoperatively, as recorded on the linear analogue scale of the Euroquol. Both groups showed a significant progressive temporal improvement, but there was no difference in the rate of recovery (fig 1).

The median time before return to work or normal activity was 22 days (range 2-99 days) in the group that had laparoscopic repair and 28 days (1-103 days) in the group that had open repair (P=0·13 on a Mann-Whitney U test). Curves for the two procedures did not achieve a significant difference between the two groups (Wilcoxon's statistic=1·91, df=1, P=0·17) (fig 2). The type of operation undertaken did not explain a significant amount of the variation in time to normal activity (r^2=0·01, *F*=0·18). Social class explained 4% of the variance (r^2=0·04, *F*=0·04). The type of work undertaken (sedentary or physically active) did not explain a significant amount of variation in time to normal activity (r^2=0·04, *F*=0·11).

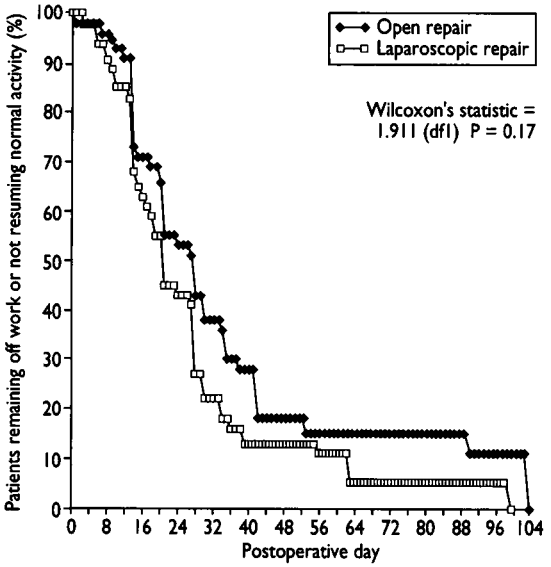


Mean (SD) scores

Day	0	1	2	3	4	5	6	7	8	9	10	42
Open	85(13)	57(23)	58(22)	60(23)	66(20)	71(16)	70(19)	73(18)	74(17)	76(16)	79(14)	89(11)
Laparoscopic	75(14)	58(21)	61(18)	64(18)	68(17)	67(20)	72(15)	74(15)	76(14)	77(13)	79(15)	88(12)

Difference between operations (effect of operation) $F = 2.00$, $P = 0.162$
Improvement over time (effect of time) $F = 96.9$, $P = <0.001$
Difference in rate of recovery (operation by time interaction) $F = 0.71$, $P = 0.686$

FIG 1—*Linear analogue health assessment analysed by repeated measures analysis of variance*



Median No of days before returning to work or resuming normal activity: Open repair, 28; laparoscopic repair, 22

FIG 2—*Time before returning to work or resuming normal activity*

A subgroup of 100 patients entered in the trial were asked at three months postoperatively whether they considered the traditional outcome measure of recurrence of hernia or the speed of recovery as the most important outcome. Seventy four of these patients regarded recurrence as the most important outcome.

COSTS

Mean operating time was significantly different in the two groups—72 minutes (95% confidence interval 67 min to 75 min) in the group that had laparoscopic repair and 32 minutes (30 min to 34 min) in the group that had open repair ($P<0·0001$ on Student's t test). A significant correlation was found between operating time and cumulative operator experience in the group that had laparoscopic repair (Pearson's correlation=0·39, significance of correlation=0·005), with operator experience explaining 15% of the variation in operating time ($r^2=0·15$, $F=0·003$).

Mean total theatre costs were £850 in the group that had laparoscopic repair (£622 to £1078) compared with £268 (£245 to £292) in the group that had open repair. The significant difference between the two groups ($P<0·001$) largely arises from differences in standard theatre consumables (non-varying costs), and from differences in the variable costs of staff and overheads owing to differences in operating time (table V).

Three patients in the group that had laparoscopic repair and two in the group that had open repair had to be admitted overnight.

Discussion

The possibility that laparoscopic hernia repair may introduce new risks to the repair of inguinal hernias and the need to evaluate its safety provided the rationale for this ongoing study. So far we have demonstrated that this approach to laparoscopic repair can be performed with reasonable safety in the hands of experienced laparoscopists, but is not without short term risks. In our study these risks were slightly greater than for a conventional open repair.

SHORT TERM MORBIDITY

The need to convert two laparoscopic repairs to the open technique suggests that laparoscopic repair of an irreducible hernia is ill advised. Placement of the mesh anterior to the inferior epigastric vessels provided excellent apposition of the mesh to surrounding tissues and reduced kinking of the mesh but may have contributed to vessel damage on two occasions. The occurrence of four cord haematomas or seromas may be related to the eversion of large hernial sacs. Circumferential incision of such sacs may be more appropriate. The learning curve for the new procedure may be a contributory factor in the complication rate, and differences in the reporting of complications in the follow up period may be a potential source of bias. The relative contribution of these factors needs longer term follow up in larger scale studies with adjustment for operator experience by its use as a covariate in the analysis.

POSTOPERATIVE PAIN

Laparoscopic hernia repair conferred an advantage to patients in terms of their early postoperative pain. The advantage was evident on movement and on coughing but not at rest, suggesting that the pain that laparoscopic repair induces is muscular in origin.

Despite such differences in specific aspects of health state, they do not seem to be reflected either in the general perceptions of health on the short form 36—which showed little change postoperatively in either group—or in the scores on the linear analogue self measurement, which were similar and showed steady improvement in both groups during the first 10 postoperative days. There were only small differences in time to return to work or normal activity in the two groups. Factors other than operative technique seem to explain most of the variance in this measure. The

TABLE V—*Theatre costs (£) for open versus laparoscopic repair of inguinal hernia*

	Consumables		Staff and overheads	Total theatre costs
	Non-varying	Varying		
Mean (SD) cost:				
Open repair	41	82 (55)	145 (42)	268 (76)
Laparoscopic repair	417	94 (81)	339 (79)	850 (77)
Mean (SE) difference in laparoscopic v open (95% confidence interval)	376 (0; NA)	12 (82; −150-175)	194 (62; 70-318)	582 (114; 355-809)
Significance of difference			P<0·01	P<0·001

Key messages

- This study shows that laparoscopic repair of inguinal hernia reduces postoperative muscular pain and causes less disruption to quality of life in the immediate postoperative period than open repair
- Laparoscopic repair was associated with a higher risk of complication than open repair
- Return to normal activity was not significantly different between the two groups, with social class explaining more of the variance in this outcome than the type of operation received
- Theatre costs were higher for the group that had laparoscopic repair owing to the cost of laparoscopic consumables and the increased operating time (only 15% of costs were explained by the surgeons' learning curve)
- Seventy four per cent of patients regarded long term recurrence as the most important outcome, and the results of larger scale, long term trials examining this outcome should be awaited before laparoscopic repair is widely adopted

contribution of a range of other socioeconomic and cultural factors to this outcome is consistent with previously published work.[15]

Although differences in these measures might become apparent if the sample size and power of the study is increased, the clinical importance of any such difference may be questionable. Also, information is needed on the value that patients attach to different health states.

COSTS

Laparoscopic hernia repair increased costs by increasing operating time and the costs of consumable equipment. The pronounced difference in theatre costs means that open repair would have remained cheaper even if reusable laparoscopic equipment had been used. Further investigation is required to distinguish the relative contribution made to variations in operating time by the surgeon's learning curve for the procedure from the inherent difficulty of the operation. In our study operator experience explained only 15% of the variance.

CONCLUSIONS

Our results show that this laparoscopic approach to hernia repair may increase the short term risks of an established procedure. This result is at variance with the only previously published randomised trial of laparoscopic hernia repair, which showed a higher complication rate with open repair than with laparoscopic repair.[16] The finding that theatre costs were increased in the laparoscopic repair arm and that postoperative pain was reduced is, however, consistent with this previous work. In this present study patients in both groups seem similar in their self reported general health in the early postoperative period and are generally more concerned with longer term recurrence. Recurrence therefore seems to be the appropriate outcome measure for sample size calculations and for the primary analysis of trials of effectiveness of laparoscopic hernia repair. A sample size of thousands rather than hundreds is needed to provide adequate power in a trial designed to detect differences in recurrence rates. In this study recurrent and bilateral hernias were excluded, but laparoscopic repair may hold particular advantages in such cases and these types of hernia should be included in larger trials of effectiveness and cost-effectiveness. In such studies a more pragmatic trial design could also be used, with greater flexibility in the use of general or local anaesthetic in the control arm of the trial.[17]

These larger trials of the various techniques described for laparoscopic hernia repair, with recurrence as the primary outcome measure, are currently under way, and our data will be available for cumulative meta-analysis.[18] In view of the increased risks and costs shown by our early results and the outcome preferences expressed by our patients, the results of these studies should be known before this technology is widely adopted.

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Correction

Association of *Helicobacter pylori* and *Chlamydia pneumoniae* infections with coronary heart disease and cardiovascular risk factors

An editorial error occurred in this paper by Dr P Patel and colleagues (16 September, pp 711-4). "Factor VIIa" was spelt out incorrectly as "factor VII antigen." It should have been spelt out as "activated factor VII." This is important because factor VII antigen is the inactive form and its concentration in plasma (measured as % of normal) is not a particularly good marker of clotting activation.