



Prospective randomized trial of laparoscopic (transabdominal preperitoneal) vs open (mesh) repair for bilateral and recurrent inguinal hernia

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Abstract

Background: Laparoscopic hernia repair excites controversy because its benefits are debatable and critics claim it is attended by serious complications. The one group of patients in whom benefits may outweigh the perceived disadvantages are those with bilateral or recurrent inguinal hernias.

Method: One hundred twenty patients with bilateral or recurrent hernias were randomized to either laparoscopic transabdominal preperitoneal (TAPP) or open mesh repair. Patients completed a well-being questionnaire prior to and following surgery together with a visual analog pain score. Patients were followed up clinically at 1 and 3 months and thereafter by their general practitioner.

Results: Age and sex distribution was similar in the two groups. Laparoscopic TAPP hernia was quicker (40 vs 55 min; $p < 0.001$), less painful (visual analog pain score, 2.8 vs 4.3; $p = 0.003$) and allowed earlier return to work (11 vs 42 days; $p < 0.001$) compared to open mesh repair.

Conclusion: This trial demonstrates that laparoscopic hernia repair via the TAPP route offers significant benefit to patients undergoing bilateral or recurrent inguinal hernia repair.

Key words: Laparoscopic hernia

Inguinal hernia is a very common complaint, with approximately 80,000 patients undergoing surgical repair in England per year [16]. Long-term follow-up shows that 15–30% of all hernia repairs will fail and 60% of these recurrences will cause symptoms [2]. Ten percent of patients undergoing hernia repair present with recurrent inguinal hernia and 7.5% present with bilateral inguinal hernia [14].

Minimal access surgery has rapidly become established in many areas of general surgery, and by 1996 laparoscopic hernia repair accounted for 10% of all hernia surgery. Potential benefits of laparoscopic repair include a reduction in postoperative pain [11] and a shortened recovery period [10]. However, it has been slower to gain acceptance, perhaps because of reports of rare but serious complications.

It seems logical that if such benefits occur for patients undergoing primary inguinal hernia repair, there may be an even greater benefit to patients undergoing bilateral inguinal hernia repair since an open approach requires two incisions. In addition, there could also be greater benefit to patients undergoing recurrent inguinal hernia repair because a second groin exploration via an open route would necessitate cutting through scar tissue and additional trauma is to be expected. Retrospective or consecutive comparisons have been made by several investigators that show that laparoscopic repair is a safe and effective alternative to conventional repair in such patients [9, 13].

The National Institute for Clinical Excellence in the United Kingdom recently published Guidance on the Use of Laparoscopic Surgery for Inguinal Hernia [15]. It recommended that laparoscopic surgery be considered for recurrent and bilateral hernias only. This guidance will be reviewed in 2003. Despite this advice, most published trials provide data on groups containing a mixture of patients, with only one trial considering patients with recurrent hernias alone [1].

Materials and methods

This study was performed in the general surgical department of a single large institution under the care of a single surgical team. The local ethics committee approved the study and all patients gave informed consent. All patients aged 16 years and older were eligible for inclusion into the study; however, patients with irreducible hernias and those unfit for general anesthesia were excluded.

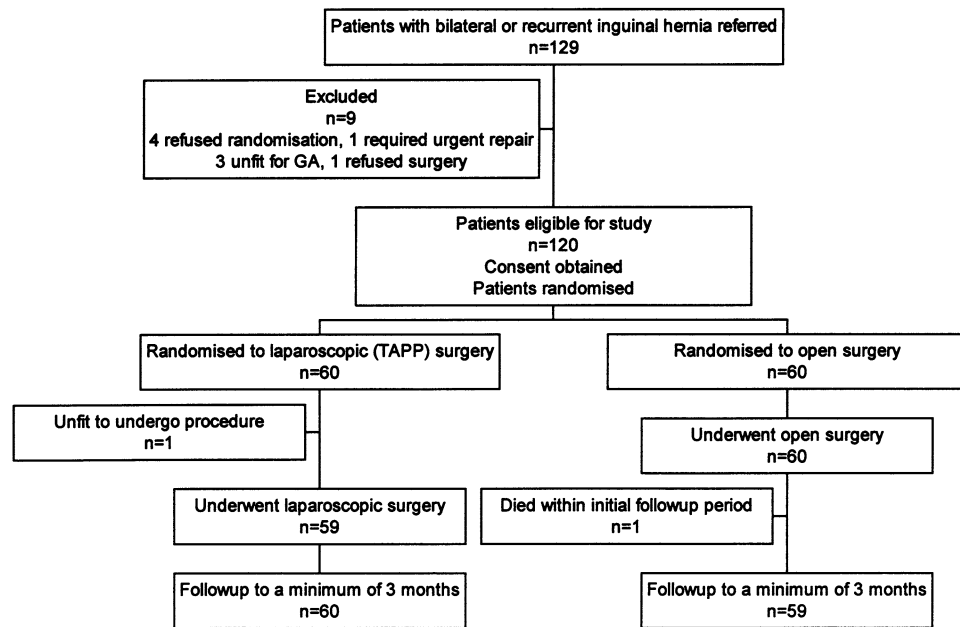


Fig. 1. Flow of participants through randomization, surgery, and follow-up.

Table 1. Patient demographics^a

	Laparoscopic (<i>n</i> = 60)	Open (<i>n</i> = 60)	<i>p</i>
Median age, years (range)	61.5 (20–80)	61 (25–88)	0.33
Sex			
Male	59	60	1 ^b
Female	1	0	1 ^b
Hernias	101	97	
Recurrent	19	23	0.444 ^c
Bilateral	37	34	0.711 ^c
Bilateral and recurrence	4	3	1 ^b
Median follow-up, months (range)	29 (4–43)	28 (5–43)	0.898

^a Statistical tests performed with Mann–Whitney *U*-test unless otherwise indicated

^b Fisher's exact test

^c Pearson's chi-square test

After the surgeon confirmed the diagnosis in the outpatient department and explained both procedures, written consent for the trial was obtained. Randomization was performed using pregenerated random numbers.

From September 1997 to December 2000, 129 patients were seen in the clinic with recurrent or bilateral inguinal hernia. One hundred twenty patients gave consent and were randomized (Fig. 1). Four patients refused to be randomized because of a preference—2 for laparoscopic surgery and 2 for open surgery. Three patients were deemed unfit to undergo general anesthesia, 1 patient elected not to undergo surgery, and 1 patient required an urgent repair of his obstructed hernia. The two patient groups are shown in Table 1.

Prior to surgery, patients completed a well-being questionnaire. This questionnaire is a combination of those produced by Dupuy [7] Dimenas [6], and Svedlund et al. [19] and we have previously used it in other trials involving patients with abdominal symptoms [5]. It includes 15 questions about gastrointestinal symptoms and 22 questions addressing psychological well-being. The combined maximum score is 177.

In the case of open inguinal hernia repair, the method of anesthesia was chosen by the anesthetist in consultation with the patient. All except six patients undergoing open repair opted for general anesthesia (three opted for local anesthesia and three opted for spinal/epidural anesthesia). All patients undergoing laparoscopic inguinal hernia repair underwent general anesthesia. Patients were given antibiotic prophylaxis using 500 mg flucloxacillin (or 1.5 g cefuroxime if allergic to penicillin) intravenously at the time of induction.

The laparoscopic technique was performed by the transabdominal preperitoneal (TAPP) route. We inserted a Hasson trocar at the um-

bilicus under direct vision and positioned two additional trocars, one in each side. Initially, we used one 5-mm and one 10- or 11-mm trocar for our additional ports; however, we altered our technique during the study to use two 5-mm trocars because we now believe this may reduce the chance of a port-site hernia. The hernial orifice was dissected using scissors and diathermy and a 13 × 8-cm polypropylene mesh (Surgipro, Tyco, CT, USA) was placed overlapping the defect and fixed into position using staples to the pectineal ligament and to the anterior abdominal wall. In the case of a bilateral hernia, both hernias were dissected and either a large 30 × 8-cm mesh was placed across the midline or two 13 × 8-cm centrally overlapping meshes were used.

Open inguinal hernia repair was carried out by the Lichtenstein [12] technique using 13 × 8-cm polypropylene mesh (cut to size) and 2–0 ethilon suture material. Data on operative time and the type of hernia were collected prospectively by the surgeon. Operative time was recorded from the computerized theater system and measured as the time from entering the theater to the time when leaving the theater. In the private sector, the anesthetic chart was used to measure the time of the anesthetic.

Patients were given postoperative pain relief on a PRN basis with oral analgesia for mild/moderate pain and intramuscular morphine for more severe pain. Patients were seen by a surgeon the day following surgery and the wound was inspected for complications. Patients were asked to complete a 10-cm visual analog pain score the morning following surgery.

Patients were seen by a surgeon in the outpatient department and clinically examined after 4 and 12 weeks. Data were collected on the time to mobilization without pain, time off work, visits to general practitioner, and overall satisfaction with the surgery as well as the

Table 2. Operative details and postoperative pain^a

	Laparoscopic	Open	<i>p</i>
Operating time, min (range)	40 (20–130)	55.5 (28–148)	<0.001
Hospital stay, days (range)	1 (0–41)	1 (0–20)	0.750
Pain score, (0–10) (range)	2.8 (0–9.4)	4.3 (0–10)	0.003
Time to pain-free mobilization, days (range)	7 (0–60)	7.5 (1–90)	0.012
Number working	29	26	0.583 ^b
Days off work (range)	11 (1–60)	42 (2–90)	<0.001

^a Mann-Whitney *U*-test of statistical significance used unless otherwise indicated

^b Pearson's chi-square test

presence of any complications. At 12 weeks patients were again asked to complete the well-being questionnaire. Further clinical follow-up was by the patients' general practitioner with referral back to the hospital if any problems developed.

Our primary outcome measurements was postoperative pain, and sample size was calculated with this end point in mind. Secondary outcome measures of well-being, post-operative mobilization, return to work, recurrence rate, chronic pain, and complications were also studied. Statistical analyses were performed with the Mann-Whitney *U*-test, Pearson's chi-square test, and Fishers exact test. $p < 0.05$ was considered statistically significant.

Results

Of the 60 patients randomized to laparoscopic surgery, 59 had the repair initiated. One patient (with bilateral hernias) developed high blood pressure and his operation was postponed. One was converted to open surgery. Of the 60 patients randomized to open surgery, all had surgery. A total of 196 hernias were repaired—42 recurrent, 70 bilateral, and 7 both bilateral and recurrent. Two patients had concurrent procedures performed along with their hernia repair. One patient undergoing laparoscopic hernia repair had a transurethral removal of bladder stone. One patient undergoing open hernia repair had a transurethral resection of prostate. Follow-up to 90 days was obtained in all 119 patients who underwent surgery.

All 59 patients undergoing laparoscopic repair underwent general anesthesia. Of the 60 patients undergoing open mesh repair, 3 (5%) chose to have local anesthesia, 2 (3.3%) chose to have spinal anesthesia, and 55 (91.7%) chose to have general anesthesia.

The median duration of surgery was significantly shorter for those undergoing laparoscopic repair. Patients in the laparoscopic group had significantly less postoperative pain the day after surgery and were also mobile without pain significantly earlier. Almost all patients (102 of 119) were discharged the morning following surgery or earlier (< 24 h). Because the average age of patients in this trial was more than 60 years, many patients had retired from work; however, for those employed, laparoscopic repair allowed return to work in approximately one-fourth of the time required for those patients undergoing an open procedure (Table 2).

Overall, there were more complications in the open group (Table 3); however, there were two bowel injuries in the laparoscopic group. The first was an injury to the cecum by a 5-mm port placed under direct vision. Initial laparoscopy revealed dense adhesions from a previous appendectomy for perforated appendicitis. Indenta-

tion of the site chosen for port insertion was performed and a 5-mm port inserted. It was immediately apparent that it had caught the edge of the cecum and the procedure was converted to open surgery, the cecum repaired, and an open hernia repair undertaken. The patient stayed in the hospital for 7 days and made an uncomplicated recovery. The second injury occurred when the protective sheath on a disposable 5-mm port failed to deploy and a 3-mm puncture of normal small bowel occurred. This was recognized and sutured laparoscopically with 3–0 PDS. We proceeded with a laparoscopic hernia repair because there had been no soiling of the peritoneum and the patient went home 36 h postsurgery, having opened bowels normally and showing no signs of ileus. This patient also made an uncomplicated recovery.

One patient in the open group died within 90 days of surgery, although the death was not attributable to the operation. No patients required removal of the mesh due to infection. Four patients undergoing laparoscopic hernia repair suffered a recurrence. One patient who had open mesh hernia repair suffered from a recurrence. We recorded no significant difference in quality of life scores between the two groups. However, of the patients undergoing recurrent hernia repair, more of those undergoing laparoscopic repair thought the overall experience of their second operation was superior to that of their original operation (Table 4).

Discussion

This trial demonstrates that laparoscopic hernia repair via the TAPP route offers significant benefit to patients undergoing bilateral or recurrent inguinal hernia repair. Postoperative pain is reduced and the length of postoperative recovery is shortened. For those patients who are employed, time to return to work is almost one-fourth that required for an open procedure. Previous reports found that laparoscopic inguinal hernia repair takes longer than an open inguinal hernia repair; however, for recurrent and bilateral hernias we have found that the laparoscopic approach is significantly quicker. This obviously reduces the additional cost that has been associated with performing hernia repair laparoscopically in patients with primary unilateral hernia.

We believe this trial provides a valid result because it was conducted in a prospective randomized fashion. A representative sample of the community was used be-

Table 3. Complications following surgery^a

	Laparoscopic (<i>n</i> = 59)	Open (<i>n</i> = 60)	<i>p</i>
Hematoma	4	2	0.439
Seroma	2	0	0.244
Wound infection	2	8	0.095
Chronic pain	1	8	0.032 ^b
Retention of urine	1	4	0.364
Recurrence	4	1	0.21
Orchidectomy	0	1	1
Port-site hernia	2	0	0.244
CVA	0	1	1
Death within 90 days	0	1	1
Cecum injury (1)	1	0	0.496
Small bowel injury (2)	1	0	0.496
Orchalgia	1	0	0.496
Neuralgia	0	2	0.496
Chest infection	1	1	1
Hemospermia	0	1	1
UTI	1	0	0.496
Total No. of patients with complications	17	23	0.272 ^c

^a Some patients suffered more than one complication. Probability calculated using Fisher, exact test unless otherwise indicated

^b Significant difference

^c Pearson's chi-square test

Table 4. Postoperative well-being and patient satisfaction^a

	Laparoscopic	Open	<i>p</i>
Preoperative well-being score (range)	153 (113–175)	153 (101–175)	0.375
Postoperative well-being score (range)	153 (98–174)	158 (68–173)	0.392
Patients satisfied with operation	46 (<i>n</i> = 59)	44 (<i>n</i> = 60)	0.556 ^b
Patients who preferred this operation to their previous repair	19 (<i>n</i> = 23)	14 (<i>n</i> = 26)	0.032 ^b

^a Mann–Whitney *U*-test of statistical significance used unless otherwise indicated

^b Pearson's chi-square test

cause a very narrow set of exclusion criteria were employed; in particular, patients who had undergone previous open abdominal surgery were not excluded. There was a very small refusal rate, with only a small minority of patients expressing a preference for either open or laparoscopic surgery.

Published recurrence rates for TAPP (under the auspices of randomized trials) vary between 0 and 15%. However, a randomized controlled trial specifically examining recurrent inguinal hernia repair reported a recurrence rate of 12.5% in the TAPP group [1]. Published recurrence rates for open mesh repair (under the auspices of randomized trials) vary between 0 and 5%. In our series, the recurrence rates for both TAPP (4%) and open mesh repair (1%) compare favorably with those previously published.

The majority of laparoscopic recurrences (75%) occurred in patients undergoing bilateral repairs, and in all these patients we used a single large mesh placed across the midline. At reoperation, we noticed creasing of the mesh across the midline with medially located recurrences. We changed our practice and currently use two smaller centrally overlapping meshes; since this change in practice, we have had no more recurrences.

We noted two occurrences of bowel injury in the laparoscopic group. One patient had a previous appendectomy and a trocar injury was made in the cecum. This was recognized and a transverse incision was made in the right iliac fossa to repair the injury. The hernia

was repaired by the open route and the patient spent 6 days in the hospital making an uneventful recovery. The second was a trocar injury to the small bowel that was recognized and sutured laparoscopically within 5 min using 3–0 PDS. Laparoscopic hernia repair proceeded uneventfully, and the patient went home at 36 h and made an uncomplicated recovery. Although these both occurred within the trial, these are the only trocar injuries in a series that now includes 600 patients.

A significant chronic complication of inguinal hernia repair is long-term groin pain, with some surgeons considering division of the ilioinguinal nerve to help prevent it [18]. Although initially reported as infrequent, recently this has been reported in up to 30% of patients undergoing open inguinal hernia repair [17]. Ten percent of patients may suffer with pain that causes significant morbidity 2 years following surgery [4]. It is also noted that the frequency of chronic pain in those undergoing repair of a recurrent hernia is higher than that in primary repairs [3]. In this study, in which 35% of patients underwent recurrent surgery, 13% of patients undergoing open repair had persistent groin pain at 3 months. This number is significantly reduced to 1% using a laparoscopic approach.

The laparoscopic TAPP technique for inguinal hernia repair offers several advantages compared to open mesh repair in patients with recurrent or bilateral hernias and should be considered as a valuable alternative to open mesh repair.

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