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A Single-Blinded, Randomized Comparison of Laparoscopic Versus Open Hernia Repair in Children

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The authors have indicated they have no financial relationships relevant to this article to disclose.

What's Known on This Subject

Pediatric laparoscopic IH repair is feasible. It remains unclear whether laparoscopic surgery offers any advantages for children.

What This Study Adds

Laparoscopic surgery offers no advantages over conventional open repair of pediatric IH.

ABSTRACT

OBJECTIVE. The role of laparoscopic surgery in pediatric inguinal hernia repair is unclear. We aimed to compare day-case laparoscopic hernia repair with open repair.

METHODS. A prospective, single-blinded randomized study in children aged 4 months to 16 years with unilateral inguinal hernia was performed. The primary outcome measure was the time to normal daily activities after surgery. Secondary outcome measures included postoperative pain, time in the operation room, results, and complications.

RESULTS. Eighty-nine patients were enrolled (laparoscopic hernia repair: 47, open repair: 42). The mean number of days to normal activity after laparoscopic hernia repair and open repair was 2.4 and 2.5, respectively. Thirty-seven (79%) patients with laparoscopic hernia repair and 20 (42%) with open repair required rescue analgesia postoperatively. The median pain score in the second postoperative morning was significantly higher after laparoscopic hernia repair. The median times in the operation room for laparoscopic hernia repair and open repair were 63 and 38 minutes, respectively. Surgical and cosmetic results were similar at up to 2 years' follow-up.

CONCLUSIONS. Recovery and outcome were similar after open repair and laparoscopic hernia repair in children. Laparoscopic hernia repair was associated with increased theater time and postoperative pain. *Pediatrics* 2009;123:332–337

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All the authors contributed to the manuscript and have seen and approved the final version. Drs Koivusalo and Pakarinen performed all the operations, created the study protocol, and had primary responsibility for enrollment, outcome assessment, and writing the manuscript.

This trial has been registered at www.clinicaltrials.gov (identifier NCT00597194).

Key Words

children, inguinal hernia repair, laparoscopy, outcome, complications

Abbreviations

IH—inguinal hernia
OR—open hernia repair
LR—laparoscopic hernia repair
OPS—objective pain scale

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LAPAROSCOPIC INGUINAL HERNIA (IH) repair in adults has the advantages of diminished postoperative pain, faster recovery, and better cosmesis compared with open hernia repair (OR).^{1–4} Laparoscopic hernia repair (LR) may be associated with a higher incidence of serious complications, longer operation times, and higher costs.⁵ The feasibility LR among children has been demonstrated in descriptive series.^{6–7} Whether LR offers any advantages in the treatment of uncomplicated pediatric IH remains unclear. To elucidate this, we performed a randomized, single-blinded, prospective comparative study between LR and OR in day-case surgery. We hypothesized that LR would result in faster recovery, diminished need for pain medication and a shorter hospital stay.

MATERIALS AND METHODS

The study was approved by the ethical committee of the Hospital for Children and Adolescents. The aim was to randomize 100 patients to LR and OR arm. Patient enrollment started on October 1, 2002, and follow-up ended on February 1, 2007.

The primary outcome measure was the time to normal daily activities after surgery. According to sample-size calculation, 100 cases were required for each arm to achieve 90% power to detect statistically significant difference ($P < .05$) of at least 1-day difference in the recovery time. Secondary outcome measures included degree of postoperative pain, amount of postoperative analgesia, duration of the procedure, number of days caregivers were absent from work, surgical complications, cosmetic results, and patient satisfaction. Outcome was recorded at outpatient visits 10 days, 6 months, and 2 years after the surgery. Cosmetic result was scored (unsatisfactory = 0,

satisfactory = 1, good = 2, and excellent = 3) by patients or parents, the attending nurse, and the surgeon (maximum points = 9). Patient satisfaction was scored similarly (unsatisfactory = 0, satisfactory = 1, good = 2, and excellent = 3). The long axis of the testes was measured.

Participation was proposed to patients referred to day-case IH repair. Inclusion criteria included unilateral IH, age between 4 months and 16 years, and no history of abdominal or inguinal operations. The age range was based on the day surgery criteria of our hospital. Of male patients, only those with completely descended testes were included. The parents were asked to give an informed written consent. Randomization was performed by operating surgeons with the closed-envelope method. Operative approach was revealed to the operative team on the morning of the operation and to patients and their parents on the first outpatient visit.

All operations were performed under general anesthesia. Anesthesia was induced with sevoflurane-air (8%) gas mixture or with propofol 3 to 4 mg/kg with 1% bicaine (0.5 mg/kg) and maintained with propofol (10 mg/kg per hour) together with 1% to 2% sevoflurane and with dose(s) of fentanyl 1 to 2 μ g/kg. Mivacur (0.2 mg/kg) was given as muscle relaxant. Acetaminophen (60 mg/kg) was given rectally. This acetaminophen dose effectively reduces postoperative pain after OR in children.⁸ The airway was maintained by laryngeal mask or with endotracheal intubation. Anesthesia time started at the induction and ended when the patient was fully conscious.

Postoperative pain was recorded on a modified objective pain scale (OPS) from 0 to 9.⁹ For postoperative pain, rescue fentanyl (1 μ g/kg) and for nausea ondansetron (0.1 mg/kg) were given as judged necessary by the attending nurse blinded to the operative approach. OPS score was recorded before each administration. After discharge, parents were instructed to give ibuprofen 20 mg/kg twice daily until needed. The next morning, a nurse specialist blinded to the operative approach phoned the families and recorded the level of pain on a scale from 0 to 3 (no pain = 0, mild pain = 1, moderate pain = 2, severe pain = 3) and the occurrence of nausea, vomiting, headache, shoulder pain, and voiding problems. Thereafter, pain, nausea, headache, shoulder pain, and the amount of administered medication were recorded by the participants on structured follow-up forms until the third postoperative morning.

OR was performed according to standard methods.¹⁰ LR was performed transabdominally with three 5-mm ports (Versaport, Auto Suture [Tyco Healthcare, Norwalk, CT]). The maximum insufflation pressure was 8 mm Hg below 18 months of age, 10 mm Hg below 10 years of age, and 12 mm Hg in older children. The internal inguinal orifice was closed using unabsorbable suture (Ti-Cron) as described by Schier.⁶ An open asymptomatic contralateral orifice was not closed. All incisions were closed in layers with 4-0 (PDS [Johnson & Johnson International, St Stevens-Woluwe, Belgium]), 5-0 (Monocryl [Johnson & Johnson International]) and Steri-Strips (3M Healthcare, Neuss, Germany). Local anesthetic (mepivacain: 2.5 mg/kg) was infiltrated into the

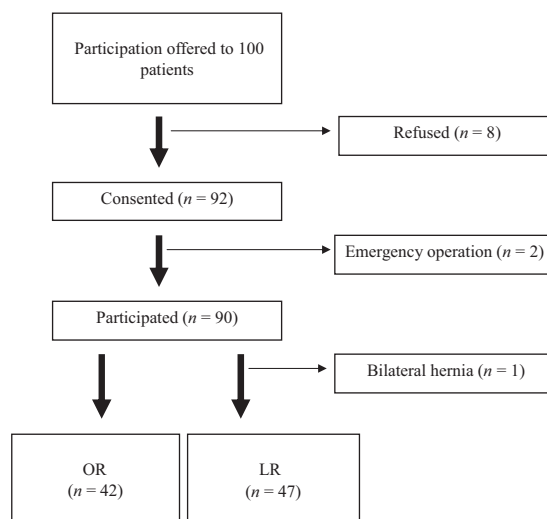


FIGURE 1
Patient enrollment.

wound edges. The total length of the closed incisions and the long axis of the testes in males were measured with a flexible ruler. Dressings were applied to cover a groin incision and the sites of port incisions regardless of whether the incisions were actually made to blind the operative approach. Parents were specifically instructed to leave the dressings on for at least 2 days.

The operating room time started when patient entered the operating room and ended when the patient was transported to the recovery room. The operative time started at the first incision and ended when wound dressings were applied. The time of the hospital stay started when patient arrived into operating room and ended when he or she was discharged.

Frequencies were compared with Fisher's exact test. Continuous variables were compared with the Mann-Whitney *U* test. Correlations were tested with a simple regression analysis. *P* values of <.05 were considered significant.

RESULTS

Patient Enrollment

Enrollment of patients was discontinued after an interim analysis showing that LR required significantly more analgesia while only 89 patients (47 LR and 42 OR) had been enrolled. The study was offered to a total of 100 patients: 90 patients were randomly assigned and 89 patients completed the study (Fig 1). Clinical data of the patients were comparable between LR and OR groups (Table 1). The age distribution of the patients is shown in Fig 2.

Short-term Outcomes

Recovery From Operations

The respective median and mean time to restore normal daily activities after surgery was 2 (range: 0–8) and 2.4 (SD: 1.4) days in the LR group and 2 (range: 1–8) and 2.5 (SD: 1.8) days in OR group (*P* = not significant). The

TABLE 1 Clinical Data

Variable	All (n = 89)	LR (n = 47)	OR (n = 42)	P
Age, median (range), y	6.0 (0.65–15)	6.0 (0.65–15)	6.1 (1.6–15)	NS
Male/female, n/n	66/23	36/11	30/12	NS
Weight, median (range), kg	23 (9.9–64)	24 (9.9–62)	23 (10–64)	NS
Time from diagnosis to operation, median (range), mo	7.9 (2.0–60)	6.8 (2.0–24)	9.2 (2.0–60)	NS
Side, right/left, n/n	54/35	31/16	23/19	NS
Parents working, 1/both, n/n	30/59	19/28	11/31	NS

NS indicates not significant.

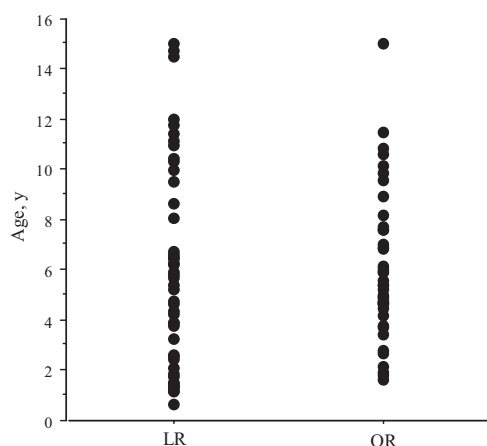


FIGURE 2

Age distribution of the 89 patients (LR: $n = 47$; OR: $n = 42$).

time to restore normal activities similarly correlated with patient age both in the LR ($R = 0.53$; $P = .0001$) and in the OR group ($R = 0.51$; $P = .001$). In patients aged <6 years, the restoration of the activities occurred faster than in those aged 6 years or more both in the LR group (median: 2; range: 0–4 vs 3 days; range: 1–8 days, $P = .01$), and in the OR group, (median: 2; range: 1–7 vs 3; range: 1–8 days, $P = .02$). When both parents were working the median duration of their absence from work was 1 (range: 0–3) days after LR and 2 (range: 0–3) days after OR ($P < .05$).

Postoperative Pain Before Discharge

The percentage of patients who required rescue analgesia (fentanyl) for postoperative pain was significantly ($P < .05$) higher after LR (79%) than after OR (42%; Table 2). Two or more doses of fentanyl was required by 34% after LR and by 10% after OR ($P < .05$). The median OPS score immediately before fentanyl administration was 4 (range: 2–7) after LR ($n = 37$) and 4 (range: 2–5) after OR ($n = 20$; $P =$ not significant). Duration of the operation and the patient age were not related to the number of fentanyl doses either after LR ($R = 0.01$, $P = .53$; $R = 0.17$, $P = .27$, respectively) or after OR ($R = 0.05$, $P = .76$; $R = 0.08$, $P = .62$, respectively).

The postoperative OPS score was recorded 30 and 60 minutes after surgery in all conscious patients and at

TABLE 2 Intraoperative and Rescue Analgesia Dosage of Fentanyl

Variable	LR (n = 47)	OR (n = 42)	P
Intraoperative fentanyl dose, median (range), $\mu\text{g}/\text{kg}$	3.0 (1.1–5.0)	2.9 (1.1–5.9)	NS
Patients requiring postoperative rescue analgesia (1 $\mu\text{g}/\text{kg}$ fentanyl), n (%)	37 (79)	20 (48)	$<.05$
OPS (0–9) before administration of rescue analgesia, median (range)	4 (3–7)	4 (2–6)	NS

NS indicates not significant.

discharge. At 30 minutes, the median OPS score was 2 (range: 0–5) after LR ($n = 12$) and 0 (range: 0–5) after OR ($n = 13$). The respective figures at 60 minutes were 2 (range: 0–6; $n = 31$) and 1 (range: 0–4; $n = 34$). At discharge, OPS scores were 1 (range: 0–5; $n = 47$) after LR and 0 (range: 0–4; $n = 42$) after OR. There were no statistically significant differences in the OPS scores between the groups. Shoulder pain occurred in 4 patients (9%) and transitory voiding difficulties in 2 patients (5%) after LR. The incidence of postoperative nausea, vomiting, headache, shoulder pain, and voiding difficulties did not differ significantly between the groups (data not shown).

Postoperative Pain After Discharge

Pain scores and the amount of ibuprofen doses (20 mg/kg) administered at home during the first, second, and third postoperative day are shown in Table 3. The median pain score in the second postoperative morning was significantly ($P < .05$) higher after LR than after OR. The highest incidences of nausea (11% after LR and 7% after OR), vomiting (11% after LR and 2% after OR), and headache (4% after LR and 2% after OR) occurred in the evening of the first postoperative day. Thereafter, only 1 patient in each group reported nausea, vomiting, or headache. After discharge, the overall incidence of shoulder pain was 17% (8 of 47) after LR whereas shoulder pain did not occur after OR ($P < .05$).

Operative Data

The operative time, time in the operating room, and duration of the anesthesia and postoperative stay in the day surgery unit were significantly longer after LR (Table 4). All 89 patients could be treated as day surgery cases.

The contralateral inguinal orifice was open in 12 (26%) of 47 patients (boys: 9 of 36 [25%]; girls: 3 of 11 [27%]; $P =$ not significant) who underwent LR. Filling of the hernia sac with gas during pneumoperitoneum was observed in none of the patients. Medial inguinal or femoral hernias were not encountered. The total median length of incision(s) after LR (3 port incisions), was 24 (range: 17–41) mm, and after OR 19 (range: 15–30) mm ($P < .05$).

With LR, there was no correlation between the patients number of order (from 1–47) and the operative time ($R = 0.08$; $P = .61$), indicating that no significant learning curve effect occurred.

TABLE 3 Pain and Analgesia After Discharge

Variable	Postoperative Day 1			Postoperative Day 2			Postoperative Day 3		
	LR	OR	P	LR	OR	P	LR	OR	P
Pain score, median (range)									
Morning	1 (0–2)	1 (0–2)	NS	1 (0–2)	0 (0–1)	<0.05	0 (0–1)	0 (0–2)	NS
Evening	1 (0–2)	1 (0–1)	NS	0 (0–2)	0 (0–1)	NS			
Doses of ibuprofen (20 mg/kg), median (range)	1 (0–3)	1 (0–5)	NS	0 (0–2)	0 (0–2)	NS	0 (0–2)	0 (0–2)	NS

NS indicates not significant.

Long-term Outcomes

Eighty-7 (98%) patients (LR: 47; OR: 40) were seen after 6 months and 75 (84%) (LR: 44; OR 31) 2 years after the operation.

Recurrent Hernia

Three (3%) patients (LR: 2; OR: 1) had a hernia recurrence. All 3 recurrent hernias manifested before the follow-up visit at 6 months.

Contralateral Inguinal Hernia

A metachronous contralateral inguinal hernia occurred in 5 patients between 1 and 2 years after surgery (LR: 3 of 47; OR: 2 of 42). Three patients were males. In all 3 LR patients (2 boys and 1 girl) with a metachronic contralateral inguinal hernia, a patent processus vaginalis was observed in the previous laparoscopic operation.

Testicular Atrophy and Position

The long axis and the position of the testes were assessed in all 66 male patients (LR: 36; OR: 30) at the 6-month follow-up and in 56 patients at the 2-year follow-up (LR: 33; OR: 23). A 20% decrease of the long axis of the testis was considered significant. None of the patients had postoperative testicular atrophy or testicular ascent.

Cosmesis and Patient Satisfaction

Six months and 2 years postoperatively the median cosmetic score was 7 (range: 3–9) for both groups, and 7 (range: 5–9) after LR and 9 (range: 5–9) after OR ($P = .06$), respectively. The median patient satisfaction score 6 months and 2 years postoperatively was 2 (range: 2–3) after LR and 2 (range: 1–3) after OR and 2 (range: 2–3) for both groups, respectively ($P =$ not significant).

TABLE 4 Operative Time, Length of the Anesthesia, Time Spent in the Operating Room, and Length of Stay in the Day Surgery Ward

Variable	LR (n = 47), Median (Range), min	OR (n = 42), Median (Range), min	P
Operative time	33 (15–59)	15 (8–35)	<.001
Length of anesthesia	55 (25–95)	30 (20–60)	<.001
Operating room time	63 (29–110)	38 (21–65)	<.001
Length of stay in day surgery ward	300 (185–635)	230 (145–432)	<.001

DISCUSSION

Nearly identical times for the children to resume their normal daily activity after LR and OR indicated that recovery after these procedures is very similar. Among the secondary outcome measures, several clinically and statistically significant differences between LR and OR groups occurred. Compared with OR, LR required significantly longer operating time and hospital stay. In addition, the patients who underwent LR needed more pain medication immediately after the surgery, had postoperative shoulder pain, and reported themselves less often as painless in the second morning after surgery. These findings were contrary to our initial hypothesis. The 1-day difference in parents' absence from work is difficult to explain based on these findings.

In a randomized study, Chan et al¹¹ found that the mean time to resume full activities did not statistically differ between LR (48 hours) and OR (58 hours). The respective figures were 58 and 60 hours in the present study. These findings clearly indicate that recovery after LR is not faster than after OR in children.

Contrary to our results, Chan et al suggested that postoperative requirement of pain medication is reduced after LR. However, they employed a surprisingly small dosage of acetaminophen (15 mg/kg) without reporting the level of pain before each dose or the percentage of patients who actually received acetaminophen. We assessed postoperative requirement of analgesia as the number of patients receiving rescue doses of fentanyl. Amount of intraoperative analgesia did not differ between the groups, and OPS scores were similar before administration of fentanyl indicating that the level of pain was comparable at the time of rescue analgesia. Still, the number of children requiring rescue analgesia was significantly higher after LR. The need for rescue analgesia reliably reflects postoperative pain after inguinal surgery in children.^{8,9} Increased postoperative pain after LR in children is an unexpected finding contradicting previous results from adult series.^{2,3} The number of postoperative fentanyl doses were not related to operative time, indicating that longer operative time did not essentially contribute to increased pain after LR. In addition, postoperative fentanyl requirement was independent of patient age in both groups.

Our operative time of 33 minutes for unilateral LR is somewhat longer than reported previously by Schier⁶ (22 minutes) and Chan¹¹ (23 minutes). In the present study, operative time included the closure of the port

incisions including fascia, injection of local anesthetic and wound dressing. All hernia repairs were conducted by 2 senior pediatric surgeons with considerable experience in laparoscopic surgery.¹²⁻¹⁴ Both the study of Chan et al and the present study found that the operative time of LR is statistically significantly longer than that of OR. In the present study LR lasted twice longer than OR (33 vs 15 minutes), whereas Chan et al¹¹ reported a 5-minute difference (23 vs 18 minutes). These findings clearly indicate that cost-effectiveness of LR is adversely affected by increased time in the operating room.

In the present study, cosmetic results after short and long-term follow-up were similar after LR and OR. Two years after surgery the scores for scar cosmesis tended to favor OR, although the difference did not reach statistical significance. Contrary to our findings Chan et al¹¹ reported that the scores given by parents for wound appearance were slightly but significantly higher after LR. At the time of the outset of the present study, 5-mm video cameras were the smallest available, and we chose to use 5-mm instruments uniformly in the study population. Whether employment of smaller instrument ports as in the studies of Chan¹¹ and Schier⁶ would have affected recovery and cosmesis remains speculative.

In the present study, the incidence of recurrent hernias after laparoscopic repair was relatively high (4%) but comparable to previous descriptive series.^{6,7,15,16} The prospective study protocol and high rate of compliance with long-term follow-up may have increased the rate of detection of recurrence. Both patients with hernia recurrence after LR had associated events within 6 postoperative weeks (a junior motocross accident with dislocation of the femoral head in an 8-year-old boy and bronchopneumonia with cough in a 14-year-old boy), which may have contributed to the recurrence. These recurrences may also reflect higher degree of tension, especially in older children, when the repair is conducted laparoscopically by suturing the inner orifice of the inguinal canal instead of transecting and closing mobilized hernia sac from above.

A recent meta-analysis estimated the risk of a meta-chronous contralateral inguinal hernia at 7.2%.¹⁷ In the present study, the incidence of contralateral inguinal hernia was 6%. Of the 12 patients in whom an open contralateral inguinal orifice was detected but not surgically closed, 3 (25%) developed a contralateral inguinal hernia in 2 years. The incidence of an open contralateral orifice has previously been reported to be between 25% and 40%.^{11,18,19} It is, however, not known whether all laparoscopically detected open inguinal orifices develop into clinical hernias. Our study indicated that LR did not cause testicular atrophy.

During the last 10 years, laparoscopic surgery has rapidly invaded the pediatric surgical practice. So far, in children, only few randomized studies have assessed medical and economical justification of laparoscopic procedures in relation to open ones.^{20,21} Inguinal hernia repair is one of the most common pediatric surgical procedures worldwide. It is of paramount importance to critically assess laparoscopic techniques in children before changes of surgical practice that are based on studies

in adult patients. We found that LR in children results in increased postoperative pain and costs because of longer theater time when compared with OR. The rate of complications, patient satisfaction, and cosmetic results were similar after LR and OR. Whether LR offers an advantage over open operation by allowing simultaneous identification and closure of contralateral open inguinal orifice remains to be proven.

CONCLUSIONS

This randomized, single-blinded, prospective study between elective laparoscopic and open repair of unilateral inguinal hernia in children showed that recovery and surgical outcome were similar. Laparoscopic repair significantly increased the degree of postoperative pain and operation room time.

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SMELLY SLEEP: RESEARCHERS FIND HYDROGEN SULPHIDE CAN LOWER METABOLISM

“The odour may be horribly familiar from stink bombs and sewage, but new research suggests the foul fumes might not be all bad. Low doses of hydrogen sulphide, a gas which smells like rotten egg, can safely reduce the metabolism of mice, putting them into a state of suspended animation. Earlier experiments had demonstrated this effect, but it was unclear whether the gas was doing this itself or was acting indirectly by lowering body temperature, which also reduces metabolism. Warren Zapol, of the Massachusetts General Hospital and a professor of anaesthesia at Harvard Medical School, along with his colleagues, monitored the vital signs of mice exposed to low-dosages (80 parts per million) of hydrogen sulphide for several hours. The mice were split into 2 groups. Half were exposed to the gas at room temperature and half in a warm environment to keep their body temperatures from dropping. The mice’s consumption of oxygen and production of carbon dioxide dropped 10 minutes after they began inhaling hydrogen sulphide and remained extremely low as long as the gas was administered. In spite of reduced respiration, oxygen levels in the blood of the mice did not change, suggesting that no part of the body was at risk of being starved of oxygen. Heart rates also fell by nearly half without much effect on blood pressure or the strength of the heart-beat. When the mice were given pure air again, they returned to normal within less than 30 minutes. Mice in both the normal and warm environments responded similarly, suggesting that the gas is directly responsible. The finding, reported in the (April 2008) edition of *Anesthesiology*, has a number of potential applications. Stasis induced by hydrogen sulphide could, for instance, help save the lives of severely injured people if medical treatment is not readily available.”

The Economist. March 29, 2008

Noted by JFL, MD

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