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ORIGINAL ARTICLE

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Informed consent and choice in cholecystectomy

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Abstract As patients and parents seek more information and the threat of litigation increases, the process of informed consent has assumed greater importance. Data from large adult experiences indicate that the risk of bile duct injury, although small, is greater with laparoscopic cholecystectomy (LC) than open cholecystectomy. This complication has not yet been documented in pediatric practice, where cholecystectomy is relatively uncommon. What method do parents and patients choose if consent is truly informed? Of 57 consecutive children undergoing cholecystectomy, an open procedure was specifically indicated in 20 (previous major gastrointestinal surgery in 11, concomitant major abdominal operation in four, and complex biliary tract disease in five) and LC in two (cystic fibrosis, severe autism). The remaining 35 patients were counseled in a standard manner about the relative merits of LC versus mini-cholecystectomy (MC) and allowed to choose. Specifically, they were informed that LC offers better cosmesis, less postoperative discomfort, and a shorter hospital stay, but in adults is associated with a slightly increased rate of bile duct injury (0.3–0.5% vs. 0.2%). All MCs were performed through a 4-cm incision. Parents chose LC in 23 cases and MC in 12. The median age of both groups was similar. No surgical complications occurred, and there were no conversions in the LC group. No patient had retained stones. LC patients were discharged home after a mean of 1.7 days and MC patients after 2.3 days ($0.1 > p > 0.05$). If an open or laparoscopic technique is not specifically indicated and if parents/patients are fully informed, a significant minority may opt for mini-cholecystectomy.

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Introduction

Informed consent is a fundamental part of surgery. It has assumed greater importance as a paternalistic style of medical care has been replaced by the paradigm of the patient-doctor partnership. Parental desire for more information and the increasing threat of litigation have contributed to the demand for a more thorough consent process. Obtaining consent in surgery requires an open informed discussion that includes mentioning alternative surgical approaches and their relative benefits and risks.

In recent years, there has been a consistent increase in the incidence of cholecystectomy for cholelithiasis in Western children [8, 16] but the procedure still remains relatively uncommon. Data from large adult experiences indicate that the risk of bile duct injury, although small, is greater with laparoscopic cholecystectomy (LC) than open cholecystectomy [15]. There are as yet no publications that have recorded this complication in children. If consent is truly informed and parents and patients are given appropriate information about laparoscopic and open cholecystectomy, what method do they choose?

Methods

During a 10-year period (November 1994 to July 2003), 57 consecutive children underwent cholecystectomy by the author. An open procedure was indicated in 20 of them: 11 had had previous major gastrointestinal surgery, four were undergoing a concomitant major abdominal operation, and five had complex biliary tract disease. Laparoscopic cholecystectomy was indicated in two patients: one with cystic fibrosis and another with severe behavioral problems secondary to autism. Children undergoing cholecystectomy during choledochal

cyst excision, hepatic resection, hepatic artery ligation, and the like were not included in this analysis.

The remaining 35 patients were counseled in a standard manner by the author about the relative merits of LC versus open mini-cholecystectomy (MC) and allowed to choose. Specifically, they were informed that LC offers better cosmesis, less postoperative discomfort, a shorter hospital stay, and a faster recovery, but in adults is associated with a slightly increased rate of bile duct injury (0.3–0.5% vs. 0.2%). Parents chose LC in 23 cases and MC in 12. The median age of both groups was similar. All MCs were performed through a measured 4-cm right upper quadrant incision using a fundus-first dissection technique. Laparoscopic cholecystectomy was performed using a previously described standard four-port technique [12]. Abdominal drains were not used routinely with either technique.

All patients received a single dose of cefuroxime antibiotic prophylaxis at induction of anesthesia. Patients were discharged from hospital when they and/or their parents considered they were sufficiently comfortable to manage with simple nonopioid analgesics at home; LC patients were discharged home after a mean of 1.7 days and MC patients after 2.3 days ($0.1 > p > 0.05$).

Results

Two-thirds of parents/patients chose LC (Table 1). Two children underwent preoperative endoscopic retrograde cholangiography because of associated choledocholithiasis, and another two children were investigated by preoperative magnetic resonance cholangiography to exclude a stone in a sonographically dilated common bile duct. Intraoperative cholangiography was performed in seven children with multiple small stones and/or a slightly dilated common bile duct (2 LC, 5 MC), but none of there had a bile duct stone. There were no conversions to an open procedure in the LC group. All patients were well at outpatient review 3–6 weeks later. No patient has subsequently had evidence of a retained stone.

Discussion

Laparoscopic cholecystectomy has many advantages over open cholecystectomy, including better cosmesis, less postoperative discomfort, a shorter hospital stay, and faster recovery. LC usually takes longer than open cholecystectomy [1, 6]. It may also be more expensive [5, 14], but, as in this series, it typically results in a shorter hospital stay, which offsets this difference in cost [6]. However, well-designed randomized controlled trials in adults comparing LC and cholecystectomy performed through a small incision (MC) have shown few differences in outcome [7, 9]. MC through a 4-cm incision is only slightly cosmetically inferior to LC (Fig. 1). There have been no randomized controlled trials in children comparing LC and MC, only nonrandomized studies comparing LC with historical controls treated by traditional open cholecystectomy [1, 6]. The author has therefore considered it appropriate that parents (and older patients) be offered a choice as to which method of cholecystectomy they would prefer. Giving patients a choice in treatment options has recently become a topical issue, and some authorities have even argued that denying choice is a form of malpractice [11].

Patients can only choose if they are adequately informed. With cholecystectomy, this involves discussing not only the general risks of surgery and cholecystectomy common to both LC and MC and the widely accepted benefits of LC, but should also include the potential risk of bile duct injury. This is a serious complication that may be fatal [3]. In adults, LC is associated with a small but definite increased risk of bile duct injury; the published incidence of this complication is between 0.18% and 0.8% [10, 13, 15]. However, the lower incidence figures may reflect underreporting in questionnaire surveys. A more accurate figure is provided by a retrospective review of more than 114,000 patients in the United States in whom the incidence of major bile duct injury was 0.5% [15]. With open cholecystectomy the rate of bile duct injury is between 0.1% and 0.2% in most series [10]. Consequently, when counseling parents and patients about this risk, it was explained that the incidence of major bile duct injury in adults undergoing LC is 0.3–0.5%, compared with 0.2% for open cholecystectomy.

It may be argued that the risk of laparoscopic bile duct injury in children is less than in adults because children generally have less gallbladder inflammation and surrounding fat, which can obscure the anatomy. However, it is naïve to expect that children will be immune from this complication, for several reasons. First,

Table 1 Demographics and outcomes of children undergoing cholecystectomy

	Laparoscopic cholecystectomy ($n = 23$)	Open mini-cholecystectomy ($n = 12$)
Symptomatic gallstones	21	10
Other gallbladder pathology	2	2
Gender (M:F)	8:15	7:5
Median age (years)	12 (2–16)	11 (3–17)
Median weight (kg)	42 (10–78)	38 (14–74)
Surgical complications	0	0
Mean ± SD (range) postoperative hospital stay (days)	1.7 ± 0.88 (1–5)	2.3 ± 0.62 (1–3)[a]

[a] $0.1 > p > 0.05$ (unpaired t-test)

Fig. 1 The operation scar 4 weeks after mini-cholecystectomy in a 16-year-old girl

it is the laparoscopic environment that predisposes to a fundamental misperception which underlies many of these injuries [19]. Second, it is difficult for pediatric surgeons to progress beyond the learning curve of 30–50 LCs, during which there is an even higher incidence of bile duct injury [15]. Even the relatively large experiences of pediatric LC that have been reported have involved multiple surgeons and/or centers [2, 4]. Third, the focus in pediatric LC has tended to be on safe laparoscopic techniques, but a good understanding of biliary anatomy and surgery is equally important. Finally, although there are no published reports of major bile duct injury complicating LC in children, this lack may reflect publication bias. The author has recently performed a biliary reconstruction in a child who was referred after sustaining a class III injury (common bile duct transection [19]) during an elective LC for uncomplicated gallstones.

There are some patients in whom a laparoscopic or open technique is specifically indicated and for whom a choice is inappropriate. For example, previous major upper abdominal surgery is a relative contraindication to LC, whereas a laparoscopic technique is probably an advantage in patients with cystic fibrosis. It has been suggested that LC is advantageous for children with sickle cell disease requiring cholecystectomy [18], but the evidence for this conflicts with one retrospective study showing that LC did not decrease the incidence of acute chest syndrome compared with an open approach [17].

Pediatric surgeons have a duty to inform parents and patients as completely as possible about the risks and benefits of a procedure. Informed consent also requires a discussion of alternative surgical approaches. If an open or laparoscopic technique is not specifically indicated and if parents/patients are fully informed, a significant minority may opt for mini-cholecystectomy.

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References

1. Al-Salem AH, Qaisaruddin S, Al-Abkari H, Nourallah H, Yassin YM, Varma KK (1997) Laparoscopic versus open cholecystectomy in children. Pediatr Surg Int 12:587–590
2. Esposito C, Gonzalez Sabin MA, Corcione F, Sacco R, Esposito G, Settimi A (2001) Results and complications of laparoscopic cholecystectomy in childhood. Surg Endosc 15:890–892
3. Flum DR, Cheadle A, Prela C, Dellinger EP, Chan L (2003) Bile duct injury during cholecystectomy and survival in Medicare beneficiaries. JAMA 290:2168–2173
4. Holcomb GW, Morgan WM, Neblett WW, Pietsch JB, O'Neill JA Jr, Shyr Y (1999) Laparoscopic cholecystectomy in children: lessons learned from the first 100 patients. J Pediatr Surg 34:1236–1240
5. Holcomb GW 3rd, Sharp KW, Neblett WW, Morgan WM, Pietsch JB (1994) Laparoscopic cholecystectomy in infants and children: modifications and cost analysis. J Pediatr Surg 29:900–904
6. Kim PC, Wesson D, Superina R, Filler R (1995) Laparoscopic cholecystectomy versus open cholecystectomy in children: which is better? J Pediatr Surg 30:971–973
7. Majeed AW, Troy G, Nicholl JP, et al (1996) Randomised, prospective, single-blind comparison of laparoscopic versus small-incision cholecystectomy. Lancet 347:989–994
8. Miltenburg DM, Schaffer R 3rd, Breslin T, Brandt ML (2000) Changing indications for pediatric cholecystectomy. Pediatrics 105:1250–1253
9. Ros A, Gustafsson L, Krook H, et al. (2001) Laparoscopic cholecystectomy versus mini-laparotomy cholecystectomy: a prospective, randomized, single-blind study. Ann Surg 234:741–749
10. Savassi-Rocha PR, Almeida SR, Sanches MD, et al. (2003) Iatrogenic bile duct injuries. Surg Endosc 17:1356–1361
11. Smith R (2004) Abusing patients by denying them choice. BMJ 328:0 (Editor's choice, 14 February)
12. Stringer MD (2002) Gallbladder disease and cholelithiasis. In: Howard ER, Stringer MD, Colombani PM (eds) Surgery of the liver, bile ducts and pancreas in children, 2nd edn. Arnold Publishers, London, pp 189–208
13. Terpstra OT (1996) Laparoscopic cholecystectomy: the other side of the coin. BMJ 312:1375–1376
14. Ure BM, Lefering R, Holschneider AM (1999) Cost analysis of laparoscopic cholecystectomy in children. Eur J Pediatr Surg 9:8–12
15. Vecchio R, MacFadyen BV, Latteri S (1998) Laparoscopic cholecystectomy: an analysis on 114,005 cases of United States series. Int Surg 83:215–219
16. Waldhausen JHT, Benjamin DR (1999) Cholecystectomy is becoming an increasingly common operation in children. Am J Surg 177:364–367
17. Wales PW, Carver E, Crawford MW, Kim PC (2001) Acute chest syndrome after abdominal surgery in children with sickle cell disease: is a laparoscopic approach better? J Pediatr Surg 36:718–721
18. Ware RE, Kinney TR, Casey JR, Pappas TN, Meyers WC (1992) Laparoscopic cholecystectomy in young patients with sickle hemoglobinopathies. J Pediatr 120:58–61
19. Way LW, Stewart L, Gantert W, et al. (2003) Causes and prevention of laparoscopic bile duct injuries. Ann Surg 237:460–469