Surg Endosc (2000) 14: 1123–1126
DOI: 10.1007/s004640000146

Surgical Endoscopy
Ultrasound and
Interventional Techniques

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Routine vs "on demand" postoperative ERCP for small bile duct calculi detected at intraoperative cholangiography

Clinical evaluation and cost analysis

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Received: 20 May 1999/Accepted: 24 September 1999/Online publication: 28 September 2000

Abstract
Background: The detection of small and often asymptomatic gallbladder calculi within the bile duct at intraoperative cholangiography (IOC) during laparoscopic cholecystectomy (LC) frequently poses a management dilemma. Therefore, we set out to compare the outcomes and costs of two management strategies for small stones that remain in the bile duct after LC—routine postoperative endoscopic retrograde cholangiopancreatography (ERCP) vs observation alone with "on-demand" ERCP.
Methods: We studied 70 patients with bile duct stones among 922 consecutive patients who underwent LC between 1990 and 1997. Data were collected prospectively. Bile duct calculi were detected in 70 of 705 patients (9.9%) with successful IOC. Of these, 44 patients had large calculi (≥5 mm in diameter) and were subjected to a laparoscopic common bile duct exploration. The remaining 26 patients had small calculi (<5 mm in diameter); four of them had undergone preoperative endoscopic sphincterotomy and duct clearance and were therefore excluded from analysis. Patients with small duct calculi were assigned, according to individual surgeon policy, to either routine postoperative ERCP (group A, $n = 8$) or observation (group B, $n = 14$). ERCP was reserved for those who become symptomatic. The two groups were comparable for age and sex distribution.
Results: No complications developed during the follow-up period in patients assigned to observation, although four became symptomatic and underwent ERCP. In group A, ERCP demonstrated a clear biliary tree in four patients and bile duct calculi in three patients; it failed in one patient. In group B, ERCP demonstrated a clear bile duct in one patient and bile duct calculi in two patients; it also failed in one patient. Endoscopic sphincterotomy and duct clearance were achieved in all patients with demonstrable bile duct calculi at ERCP. There was no morbidity or mortality associated with ERCP. The overall hospital stay was significantly longer in group A than in group B (median 5 vs 1.5 days; $p = 0.011$); however, the number of outpatient clinic visits was significantly greater in group b (median 3 vs 5.5, $p = 0.011$). The mean hospital costs, including the costs of hospital stay, readmissions, ERCP, and follow-up, were significantly greater in group A than in group B (mean £2669 vs £1508, $p = 0.008$).
Conclusion: A "wait and see" policy of observation alone for patients with small bile duct calculi detected at IOC during LC appears to be safe, and it is more cost-effective than routine postoperative ERCP. ERCP should be reserved for post-LC patients who become symptomatic.

Key words: Cholangiography — Choledocholithiasis — Cost analysis — ERCP — Gallbladder — Laparoscopic cholecystectomy

Since the introduction of intraoperative cholangiography (IOC) to identify bile duct calculi by Mirizzi in 1931 [14], the technique has been widely used to demonstrate ductal morphology and to detect duct stones during laparoscopic cholecystectomy (LC) [16]. The detection of large calculi within a dilated biliary tree may prompt exploration of the common bile duct (CBD), or postoperative stone retrieval at ERCP and endoscopic sphincterotomy (ES). However, small asymptomatic calculi (<5 mm diameter) within a nondilated biliary system pose a management dilemma. Although laparoscopic supraduodenal CBD exploration is feasible, when it is performed on a nondilated biliary system, it

This paper was presented at the annual meeting of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), San Antonio, Texas, USA, 24–27 March 1999

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may result in significant morbidity and is therefore ill advised [24]. Transcystic exploration is a suitable and attractive alternative, but it may not be feasible in some patients [7, 20]. Furthermore, laparoscopic CBD exploration requires additional equipment and expertise, as well as adding to the operative time and cost [17].

If the surgeon elects not to explore patients with asymptomatic small calculi within an nondilated biliary system, it is still unclear whether postoperative endoscopic retrograde cholangiopancreatography (ERCP) should be carried out routinely or reserved for patients who become symptomatic. Nor is it evident whether a conservative policy of observation only is safe, and if it is, how long follow-up should be prolonged. In any case, we need to establish which policy is more cost-effective.

Therefore, the aim of the present study was to examine the two policies—routine ERCP and ERCP on demand—by studying the prospectively collected data of routine operative cholangiography during laparoscopic cholecystectomy over a 7-year period.

Patients and methods

Between July 1990 and December 1997 (90 months), 922 consecutive patients underwent laparoscopic cholecystectomy at the General Infirmary, Leeds, England, under the care of three surgeons. This series represents a policy of LC for all-comers [11]. Data, including patient details as well as operative and postoperative events, were collected prospectively and entered into a computer database.

The management policy of patients with suspected bile duct calculi during preoperative assessment (clinical, biochemical, and radiological) depended on patient age. Patients older than 45 years of age were managed by preoperative ERCP and ES, whereas younger patients were scheduled for laparoscopic bile duct exploration. The Leeds technique of LC, which employs routine liver retraction, has been described previously [4, 10, 11]. During the last 2 years, however, we have modified our technique to include lower intraabdominal pressures (7–8 mmHg).

Operative cholangiography was routine and included fluoroscopy. The shape of small filling defects within the bile duct and the direction of their migration upon tilting of the operating table into Trendlenberg and reverse Trendlenberg positions helped us to differentiate stones from air bubbles. The detection of small calculi (<5 mm diameter) within the bile duct prompted transcatheter flushing of the duct with normal saline under intravenous cover with a spasmolytic agent such as atropine or glucagon. Patients with large duct calculi (≥5 mm diameter) underwent laparoscopic exploration, whereas patients with persistent small nonobstructing calculi (<5 mm diameter) in a nondilated duct system received no further intraoperative intervention. The latter patients were nonrandomly assigned to either receive routine postoperative ERCP ("planned" ERCP) (group A) or to undergo observation (group B), with ERCP reserved for those who developed relevant symptoms or who had abnormal liver function tests ("on-demand" ERCP). The assignment of patients to each of the management options was surgeon-dependent, with the exception of those patients who underwent preoperative ERCP, endoscopic sphincterotomy (ES), and duct clearance. In these cases, the conservative approach (observation) was followed. These patients were therefore excluded from analysis.

Patients were reviewed first at 6 weeks following LC or ERCP, and at 6-month outpatient follow-up thereafter, for up to 18 months after a successful ERCP and for 3 years following a failed ERCP, or when observation alone was elected. Patients were assessed clinically and biochemically during follow-up. Abdominal ultrasound was reserved for patients in group B who became symptomatic or in whom abnormal liver function tests were recorded.

The groups were compared in terms of clinical outcome, yield of postoperative ERCP, postoperative complications of bile duct calculi and endoscopic intervention, hospital stay, readmission rate and duration, and estimated hospital cost of post-LC care. Data on costs were obtained from the finance department based on contract prices to local National Health Service purchasers.

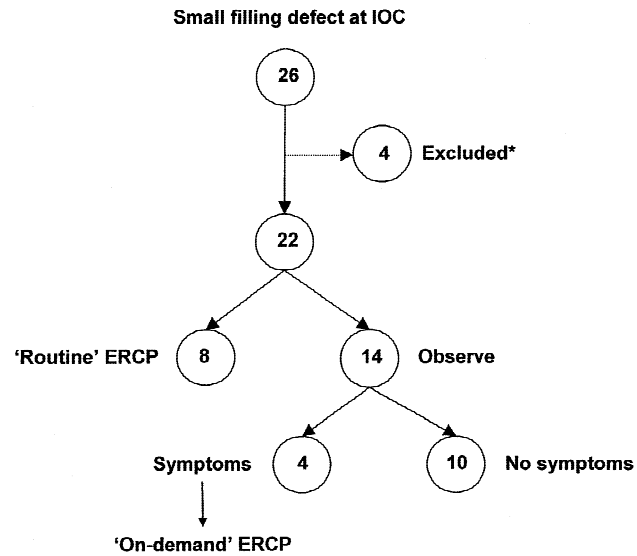

Fig. 1. Flow chart of postoperative management and outcome in 26 patients with small filling defects (<5 mm in diameter) at intraoperative cholangiography (IOC). Patients underwent preoperative ERCP and endoscopic sphincterotomy with duct clearance.

Statistical comparisons between groups were made with the Student *t*-test for continuous variables and the chi-square test to compare categorical variables. Statistical significance was accepted at $p < 0.05$.

Results

Intraoperative cholangiography was attempted in 815 patients (88%) and was successful in 705 (86.5%) of these cases. Filling defects at IOC were seen in 70 patients (Fig. 1). Forty-four patients had large filling defects (≥5 mm in diameter) and were therefore subjected to laparoscopic bile duct exploration, whereas the remaining 26 patients had small filling defects (<5 mm in diameter).

The pre- and postoperative management and outcome of the patients found to have small filling defects at IOC are summarized in Table 1. Of these 26 patients, 20 had no preoperative clinical, biochemical, or radiological features suggestive of bile duct calculi; hence, the findings at IOC were unsuspected. By contrast, the remaining six patients had undergone preoperative ERCP for suspected bile duct calculi. Preoperative ERCP confirmed bile duct calculi in four of the patients, so they underwent endoscopic sphincterotomy with stone extraction; these patients were therefore excluded from subsequent analysis. A clear duct was demonstrated by retrograde cholangiography in the remaining two patients, so no endoscopic sphincterotomy was performed.

There were eight patients in group A and 14 patients in group B. The two groups were comparable for age and sex distribution (Table 1). Follow-up was available on all patients for a median period of 18 months (range, 8–27) in group A and 33 months (range, 13–48) in group B. The median number of outpatient clinic visits was significantly greater in patients assigned to observation (group B) than in patients who learned routine ERCP (groups A) (5.5 vs 3, $p = 0.011$).

Table 1. Patients with small filling defects at intraoperative cholangiography (IOC)

	Group A ($n = 8$)	Group B ($n = 14$)
Age: median (range) yr	54 (38–86)	58 (31–79)
Sex: male/female	2/6	3/11
Postoperative ERCP	8	4
Follow-up: median (range) mo	18 (8–27)	33 (13–48)
Follow-up number of outpatient visits; median (range)[a]	3 (2–6)	5.5 (3–11)

ERCP, endoscopic retrograde cholangiopancreatography
[a] $p = 0.11$

Postoperative course

The eight patients who underwent routine postoperative ERCP (group A) remained asymptomatic during follow-up. The postoperative course of the 14 patients assigned to undergo observation (group B) is summarized in Fig. 1. Four patients developed abdominal pain that may have been due to bile duct calculi. One of these four developed liver function abnormalities, but the caliber of the biliary tree remained normal on ultrasound examination in all cases. None of the four patients developed serious complications during follow-up (e.g., pancreatitis, cholangitis, or obstructive jaundice). Urgent readmission was necessary in one patient for moderately severe abdominal pain, which resolved spontaneously. The median interval between LC and the development of symptoms was 4 months (range, 1–13). None of the four patients had undergone preoperative ERCP, but all had postoperative ERCP. The other 10 patients in group B had an asymptomatic postoperative course, and their liver function remained biochemically normal.

Postoperative ERCP

The median interval between surgery and postoperative ERCP was 4 days (range, 2–12) in group A and 29 days (range, 14–66) in group B. Postoperative ERCP findings are summarized in Table 2. "Planned" ERCP in eight patients revealed a normal biliary tree in four, bile duct calculi in three, and failed cholangiography in one. The latter patient remained asymptomatic at 29-month follow-up. "On demand" ERCP in four patients revealed a normal biliary tree in one, bile duct calculi in two, and failed cholangiography in one. The latter patient subsequently underwent magnetic resonance cholangiography that yielded normal findings; however, an upper gastrointestinal endoscopy revealed reflux esophagitis. This condition responded well to proton pump inhibitor therapy, which was maintained until 48 months' follow-up. Endoscopic sphincterotomy with stone extraction was successful in all five patients who demonstrated bile duct calculi on postoperative ERCP. Thus, calculi were detected in two of 14 patients (14%) assigned to observation and three of eight patients (37.5%) assigned to a "planned" ERCP (p = n.s). There was no morbidity or mortality associated with the postop ERCP.

Readmissions and hospital stay

The data for readmissions and hospital stay are summarized in Table 3. Although the hospital stays of readmitted patients were comparable, only four of 14 patients (29%) in group B were readmitted, as compared to five of eight patients (63%) in group A. Hence, the overall hospital stay (range), which takes into consideration all patients in each group, was significantly shorter in group B (median, 1.5 days; range, 1–7) than in group A (median, 5 days; range, 2–6) ($p = 0.011$).

Table 2. Findings at postoperative ERCP

	Clear duct	Duct stone(s)	Failed cholangiography
"planned" ERCP ($n = 8$)	4	3	1
"on demand" ERCP ($n = 4$)	1	2	1

Table 3. Postoperative hospital stay and readmission after laparoscopic cholecystectomy

	Group A ($n = 8$)	Group B ($n = 14$)
Postoperative hospital stay (day): median (range)	1 (1–5)	1 (1–2)
Number of patients readmitted	5	4
Number of readmissions: elective/urgent	5/0	3/1
Hospital stay of readmitted patients (day): median (range)	3 (2–5)	3 (3–6)
Overall hospital stay (day): median (range)[a]	5 (2–6)	1.5 (1–7)

[a] $p = 0.011$

Cost analysis

Cost comparisons are shown in Table 4. Although the cost of outpatient follow-up was significantly greater in patients assigned to observation than in those who received routine ERCP (mean, £318 vs £206; $p = 0.018$), the cost of postoperative ERCP (mean, £275 vs £763; $p = 0.003$) and the cost of hospital stay (mean, £1700 vs £914; $p = 0.016$) were significantly lower and so was the total hospital cost (mean, £2,669 vs £1,508; $p = 0.008$).

Discussion

Overall, bile duct calculi are detected more frequently when IOC is employed routinely (8–17%) [8, 15, 18, 22] rather than selectively (1–5%) [5, 19]. Half to two-thirds of detected calculi are asymptomatic and unsuspected and thus pose a management dilemma[20]. Although laparoscopic CBD exploration rather than postoperative ERCP and endoscopic sphincterotomy (ES) is our preferred treatment option for the large calculi within a dilated biliary system [12], we do not employ this technique for small calculi within a nondilated biliary tree. Transcystic bile duct exploration [13] may be a viable management option for patients with small bile ducts, but it requires additional equipment and expertise, adds to the operative cost, and may not even be necessary.

Routine postoperative ERCP and observation alone are the remaining treatment options. Though ERCP is an effec-

Table 4. Cost comparison (results expressed as mean ± SEM)

	Group A (n = 8)	Group B (n = 14)	P value
Hospital stay (£)	1,700 ± 196	914 ± 194	0.016
ERCP (£)	763 ± 55	275 ± 105	0.003
Outpatient visits (£)	206 ± 27	318 ± 29	0.018
Total cost (£)	2,668 ± 212	1,508 ± 272	0.008

tive method for the management of bile duct calculi, it is associated with a recognized risk of complications (7–11%) and mortality (≤1%) [2, 6, 20, 21]. The risk of complications is considerably increased when ES is performed in the presence of a small CBD [21]. These risks, however, should be weighed against the potential harm that retained stones may cause. In a report from Seattle, acute biliary pancreatitis developed during the follow-up period in 1.7% of patients who underwent LC for symptomatic cholelithiasis [23]. Nonetheless, observation alone appears to be a safe postoperative management strategy, since mild or no symptoms developed in the post-LC period in most other reported series [1, 5, 9, 19], including our own.

Routine postoperative ERCP in patients with small CBD calculi at IOC was associated with considerably higher costs than the policy of observation and "on-demand" ERCP. Longer follow-up, however, is required for the "wait and see" policy. Since most patients with retained bile duct calculi present within a few weeks or months (median, of 4 months in this series), and often no later than 2 years, following LC [19, 20], a follow-up period of 2 years is probably adequate. Alternatively, when a clear bile duct can be seen with noninvasive imaging on magnetic resonance cholangiography [3] at 3–6 months following LC, earlier discontinuation of follow-up is possible.

In conclusion, an expectant policy ("observation") in patients with unsuspected small calculi (<5 mm) within nondilated bile ducts detected at IOC during LC appears to be safe and cost-effective. ERCP can be reserved for those who become symptomatic.

References

1. Bonatsos G, Leondros E, Durakis N, Birbas K, Delibaltadakis G, Golematis B (1995) Laparoscopic cholecystectomy: intraoperative findings and postoperative complications. Surg Endosc 9: 889–893
2. Cotton PB (1984) Endoscopic management of bile duct stones; (apples and oranges). Gut 25: 587–589
3. Davides D, Birbas K, Vezakis A, Chang A, Dexter SPL, Larvin M, McMahon MJ (1998) Routine low pressure pneumoperitoneum during laparoscopic cholecystectomy [Abstract]. Surg Endosc 12: 35
4. de Ledinghen V, Lecesne R, Raymond JM, Gense V, Amouretti M, Drouillard J, Couzigou P, Silvain C (1999) Diagnosis of choledocholithiasis: EUS or magnetic resonance cholangiography? A prospective controlled study. Gastrointest Endosc 49: 26–31
5. Dexter SPL, Martin IG, Marton J, McMahon MJ (1997) Long operation and the risk of complications from laparoscopic cholecystectomy. Br J Surg 84: 464–466
6. Flowers JL, Zucker KA, Graham SM, Scovill WA, Imbembo AL, Bailey RW (1992) Laparoscopic cholangiography: results and indications. Ann Surg 215: 209–216
7. Freeman ML, Nelson DB, Sherman S (1996) Complications of endoscopic biliary sphincterotomy. N Engl J Med 335: 909–918
8. Hunter JG (1992) Laparoscopic transcystic common bile duct exploration. Am J Surg 163: 53–58
9. Kitahama A, Kerstein MD, Overby JL, Kappelman MD, Webb WR (1986) Routine intraoperative cholangiogram. Surg Gynecol Obstet 162: 317–322
10. Kondylis PD, Simmons DR, Agrawal SK, Ciadiello KA, Reinhold RB (1997) Abnormal intraoperative cholangiogram: treatment options and long-term follow-up. Arch Surg 132: 347–350
11. Lambert ME, Betts CD, Hill J, Faragher EB, Martin DF, Tweedle DE (1991) Endoscopic spincterotomy: the whole truth. Br J Surg 78: 473–476
12. Martin IG, Dexter SPL, Marton J (1995) Fundus-first laparoscopic cholecystectomy. Surg Endosc 9: 203–206
13. Martin IG, Holdsworth PJ, Asker J (1992) Laparoscopic cholecystectomy as a routine procedure for gallstones: results of an 'all-comers' policy. Br J Surg 79: 807–810
14. Martin IG, Curley P, McMahon MJ (1993) Minimally invasive treatment for common bile duct stones. Br J Surg 80: 103–106
15. Martin IJ, Bailey IS, Rhodes M, O'Rourke N, Nathanson L, Fielding G (1998) Towards T-tube free laparoscopic bile duct exploration: a methodologic evolution during 300 consecutive procedures. Ann Surg 228: 29–34
16. Mirizzi PL (1932) Operative cholangiography. Surg Gynecol Obstet 65: 702–710
17. Mofti AB, Ahmed I, Tandon RC, Al-Tameem MM, Al-Khudairy NN (1986) Routine or selective peroperative cholangiography. Br J Surg 73: 548–550
18. Phillips EH, Liberman M, Carroll BJ, Fallas MJ, Rosenthal RJ, Hiatt JR (1995) Bile duct stones in the laparoscopic era: is preoperative sphincterotomy necessary? Arch Surg 130: 880–886
19. Phillips EH, Berci G, Carroll B, Daykhovsky L, Sackier J, Paz-Partlow M (1990) The importance of intraoperative cholangiography during laparoscopic cholecystectomy. Am Surg 56: 792–795
20. Rhodes M, Sussman L, Cohen L, Lewis MP (1998) Randomised trial of laparoscopic exploration of common bile duct versus postoperative endoscopic retrograde cholangiography for common bile duct stones. Lancet 351: 159–161
21. Robinson BL, Donohue JH, Gunes S, Thompson GB, Grant CS, Sarr MG, Farnell MB, van Heerden HA (1995) Selective intraoperative cholangiography: appropriate management for laparoscopic cholecystectomy. Arch Surg 130: 625–630
22. Sherman S, Ruffolo TA, Hawes RH, Lehman GA (1991) Complications of endoscopic sphincterotomy: a prospective series with emphasis on the increased risk associated with sphincter of Oddi dysfunction and nondilated bile ducts. Gastroenterology 101: 1068–1075
23. Stoker ME (1995) Common bile duct exploration in the era of laparoscopic surgery. Arch Surg 130: 265–268
24. Traverso LW, Kozarek RA, Ball TJ, Brandabur JJ, Hunter JA, Jolly PC, Patterson DJ, Ryan JA, Thirlby RC, Wechter DG (1993) Endoscopic retrograde cholangiopancreatography after laparoscopic cholecystectomy. Am J Surg 165: 581–586
25. White TT, Hart MJ (1985) Cholangiography and small duct injury. Am J Surg 149: 640–643