Indian J Surg (January–February 2013) 75(1):22–27
DOI 10.1007/s12262-012-0452-5

ORIGINAL ARTICLE

Routine Sub-hepatic Drainage versus No Drainage after Laparoscopic Cholecystectomy: Open, Randomized, Clinical Trial

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Received: 13 August 2011 / Accepted: 5 March 2012 / Published online: 16 March 2012

Abstract Surgeons are still following the old habit of routine subhepatic drainage following laparoscopic cholecystectomy (LC). This study aims to compare the outcome of subhepatic drainage with no drainage after LC. This prospective study was conducted in two phases. Phase I was open, randomized controlled trial (RCT), conducted in Civil Hospital Karachi, from August 2004 to June 2005. Phase II was descriptive case series, conducted in author's practice hospitals of Karachi, from July 2005 to December 2009. In phase I, 170 patients with chronic calculous cholecystitis underwent LC. Patients were divided into two groups, subhepatic drainage (group A: 79 patients) or no drainage (group B: 76 patients). The rest 15 patients were excluded either due to conversion or elective subhepatic drainage. In phase II, 218 consecutive patients were enrolled, who underwent LC with no subhepatic drainage. Duration of operation, character, and amount of drain fluid (if placed), postoperative ultrasound for subhepatic collection, postoperative chest X-ray for the measurement of subdiaphragmatic air, postoperative pain, postoperative nausea/vomiting, duration of hospital stay, and preoperative or postoperative complications were noted and analyzed. Duration of operation and hospital stay was slightly longer in group A patients (*P* values 0.002 and 0.029, respectively); postoperative pain perception, nausea/vomiting, and postoperative complications were nearly same in both groups (*P* value 0.064, 0.078, and 0.003, respectively). Subhepatic fluid collection was more in group A ($P=0.002$), whereas subdiaphragmatic air collection was more in group B ($P=0.003$). Phase II results were nearly similar to group B patients in phase I. Routine subhepatic drainage after LC is not necessary in uncomplicated cases.

Keywords Subhepatic drainage · Drains versus no drains · Cholecystectomy · Laparoscopic cholecystectomy

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Introduction

Cholecystectomy without subhepatic drainage was first described in 1913, and since then surgeons were divided whether to use it as a routine drainage or not in uncomplicated cases [1]. Most surgeons continue to use routine subhepatic drain for the fear of bile leak and bleeding [2–4]. Such complications invariably occurred in spite of subhepatic drainage [3]. Easier convalescence, decreased rate of complications, and shortened hospital stay were the advantages of no drainage [3]. Laparoscopic cholecystectomy (LC), after its advent in 1987, rapidly established itself as the gold standard treatment of gallstones. Arguments of drainage from open era continues into the laparoscopic era, with another factor, that is, pneumoperitoneum being questioned. Pneumoperitoneum is considered the causative factor for postoperative nausea/vomiting, and postoperative pain, especially shoulder tip pain, following LC [5]. This study, therefore, aims to determine the role of routine subhepatic drainage, after uncomplicated LC, and its effect on postoperative nausea/vomiting, pain, and wound complications.

Patients and Methods

This prospective study was conducted in two phases. Phase I was conducted at Surgical Unit I, Civil Hospital, Karachi (tertiary care teaching institution), from August 2004 to June 2005. Phase II was conducted at Fatima Hospital (tertiary care teaching institution), and Shamsi Hospital, Moazzum Hospital, and Atique Medical Centre (secondary care hospitals) of Karachi, from July 2005 to December 2009.

Phase I was prospective, analytical, comparative study using randomized controlled trial (RCT). Blocked randomization was used for allocation of patients to two groups (groups A and B). The patients are divided into blocks of two, and within each block the first patient was allocated in group A and the second in group B. The whole process of generation, allocation (sealed envelopes), and implementation of randomization, as well as assessment were done by different groups of interns who were posted in surgery department for 2–6 months rotation. The study was open as patients, interns (assessors), and surgeons cannot be blinded. A total of 170 patients were enrolled in phase I. Group A, 79 patients, underwent LC with subhepatic drainage. Group B, 76 patients, underwent LC without subhepatic drainage. Phase II was a prospective, descriptive case series; 218 consecutive patients (group C) were enrolled, who underwent LC with no subhepatic drain placement.

All the patients with chronic calculous cholecystitis were included in the study. The exclusion criteria were as follows: acute cholecystitis, choledocholithiasis, acute pancreatitis, previous upper abdominal surgery, patients who require conversion and elective subhepatic drainage, cases with incomplete patients' data, and patients who were lost to follow-up.

An informed written consent was taken and patients were counseled about the merits and demerits of subhepatic drainage or no drainage. A thorough record of patients' data was maintained, including the history and clinical examination. Investigations included blood complete picture (CP), fasting blood sugar (FBS), liver function tests (LFTs), hepatitis B surface antigen (HBsAg), anti-hepatitis C virus (anti-HCV), X-ray chest, and ultrasound abdomen. The preoperative ultrasound findings recorded were as follows: thickness of gallbladder wall, number of stones present, any pericholecystic fluid or adhesions, CBD diameter, and liver parenchyma. Endoscopic retrograde cholangiopancreatography (ERCP) was performed in cases with choledocholithiasis and acute pancreatitis.

All the patients were operated under general anesthesia. Antibiotic prophylaxis was done, using 1.5 g of intravenous cefuroxime at the time of induction of anesthesia; the dose was repeated once after 12 h postoperatively. Operative details recorded included operating time (from first port incision to last port closure), operative findings (i.e., gallbladder size, adhesions, number of stones), complication, conversion, and subhepatic drainage. Complete hemostatis was achieved in each case. In cases of gallbladder perforation and stone spillage, attempt was made to retrieve stone as far as possible and subhepatic area was irrigated and sucked out completely. At this stage, sealed envelope was opened to randomize the patients into group A or B. Drains (if placed) were brought out through one of the 5-mm ports; they were removed when the discharge was less than 20-ml in last 24 h.

Postoperative ultrasound for the detection of subhepatic fluid collection was done at the following times: first scan 24 h after removal of drains (group A) or 24 h postoperatively (group B), and second scan 96 h after the first scan. Similarly, postoperative X-ray chest, in erect posture, for the measurement of subdiaphragmatic air bubble was done at the following times: just after removal of drain (group A) or 24 h postoperatively (group B). Severity of pain was defined using verbal rating scale. All patients received diclofenac suppository 50 mg at the induction of anesthesia, and bupivacaine (0.2%) was infiltrated into the gallbladder bed and 10-mm ports to decrease postoperative pain; diclofenac 75 mg intramuscular injection was given 12 hourly for 24 h, followed by diclofenac oral 50 mg 8 hourly for the next 24 h. Patients were discharged on 5th–7th postoperative day in phase I, and within 48 h in phase II. Skin sutures were removed between 8th–10th postoperative days. The follow-up schedule included initial weekly follow-up in the 1st month, and then monthly follow-up for 3 months, and a quarterly follow-up for one year; the patients were then advised to come in case of any problem/complication related to the operation.

The hypothesis tested in this study was that the omission of routine subhepatic drainage would be better than drainage in terms of postoperative nausea/vomiting, postoperative pain, and wound complications. Primary outcome variable was the subdiaphragmatic air volume, calculated by measuring its size on postoperative X-ray chest. Its mean given by Nursal et al. [5] was used to calculate the sample size by G-power software; based on 0.90 power and 0.5398 effect size, to detect a significant difference (P=0.05, two-sided), 74 patients were required in each study group. This was raised by 11 patients in each group, considering in anticipation the cases that would be lost to follow-up. Secondary outcome variables were drainage volume, subhepatic fluid collections, and preoperative and postoperative complications. Statistical analysis was done using SPSS 16. The inferential statistics were calculated using Pearson's chi-square and Student's t tests. A P value of <0.05 was considered significant.

Results

Flow of patients through each stage of phase I was given in Fig. 1. The patients were enrolled from August 2004 to June 2005 (phase I) and July 2005 to December 2009 (phase II),

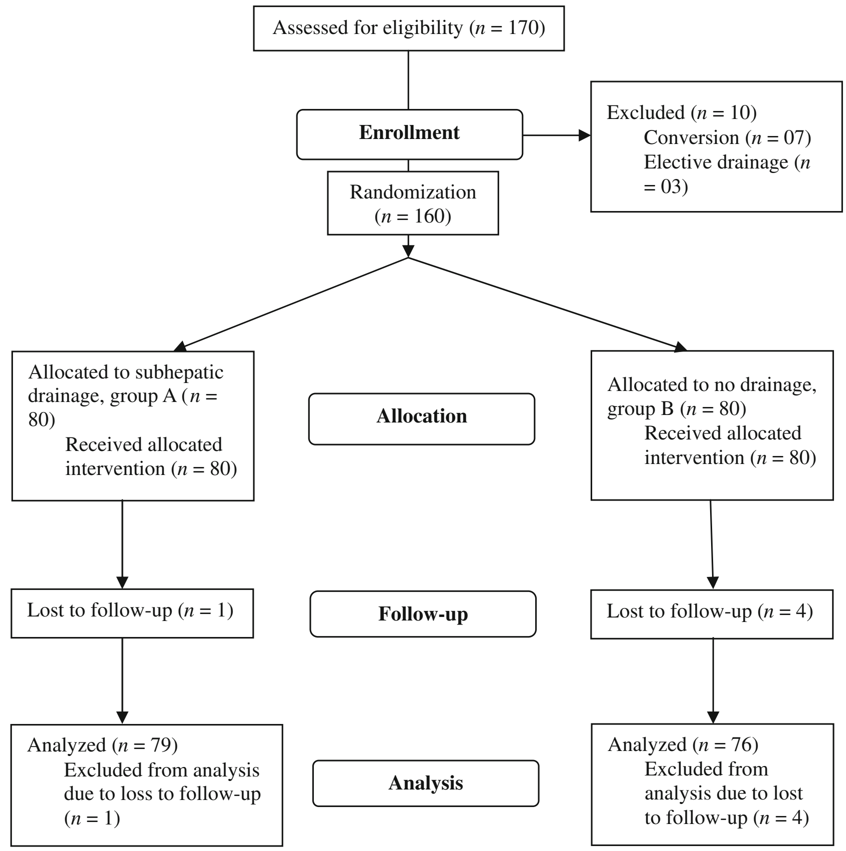

Fig. 1 Flow diagram of phase I, open RCT of subhepatic drainage versus no drainage after uncomplicated laparoscopic cholecystectomy

with strict one-year follow-up period. There were no significant demographic differences between the three groups. The mean age of the patients in group A, B, and C were 41.35, 41.07, and 39.45 years, respectively. The sex distribution were as follows: 68 females and 11 males in group A, 68 females and 8 males in group B, and 192 females and 26 males in group C.

The subdiaphragmatic gas volume was significantly lower in group A patients than in group B and C patients (Table 1). But, the subhepatic fluid collection on the first

Table 1 Comparative analysis of primary and secondary outcome variables

Study groups	Variable	Number	Mean ± SD	*P* value*	95% CI	
					Lower	Upper
Group A (Phase I)	Subdiaphragmatic gas (cm^2)	79	4.23±2.12	0.000	3.7044	4.6573
	Drain volume in 24 h (ml)	79	3.99±5.28	0.000	2.75	5.12
	Subhepatic fluid,1st US (cm^3)	79	3.13±3.63	0.000	2.268	3.895
	Subhepatic fluid, 2nd US (cm^3)	79	0.26±1.18	0.116	−0.054	0.478
Group B (Phase I)	Subdiaphragmatic gas (cm^2)	76	7.60±3.94	0.000	6.6529	8.4555
	Drain volume in 24 h (ml)	0				
	Subhepatic fluid,1st US (cm^3)	76	2.85±3.64	0.000	1.973	3.638
	Subhepatic fluid, 2nd US (cm^3)	76	0.05±0.45	0.960	−0.102	0.107
Group C (Phase II)	Subdiaphragmatic gas (cm^2)	218	6.93±2.63	0.000	6.5340	7.2372
	Drain volume in 24 h (ml)	0				
	Subhepatic fluid,1st US (cm^3)	218	2.01±3.05	0.000	1.548	2.365
	Subhepatic fluid, 2nd US (cm^3)	218	0.01±0.14	0.000	−0.059	0.021

* = Student's *t* test

SD = Standard deviation

95% CI = 95% confidence interval of the difference ultrasound at 24 h was significantly higher in group A patients than in group B and C patients (Table 1). The difference was insignificant on subsequent ultrasound at 72 h (Table 1).

Statistically significant difference was observed in postoperative complications between the three groups (Table 2). Preoperative complications were comparable between the three groups (P value=0.952); gallbladder perforation (with or without stone spillage) occurred in 8 group A, 8 group B, and 16 group C patients, whereas bleeding from gallbladder bed or cystic artery occurred in 3 group A, 3 group B, and 7 group C patients. The post hoc power analysis showed Power (1-β err prob) of 0.999845, calculated from mean of subdiaphragmatic air volume (primary variable) with effect size 0.9000000 and α err prob 0.05.

Discussion

Subhepatic drainage after cholecystectomy, open or laparoscopic, is still an unsolved debate. Lewis et al. [6] in an analysis of 1920 open cholecystectomies showed no significant difference in the complication rate between the drained and non-drained group. In this study, the complication rate is comparable between the drain group (26.58%) and the non-drain group in phase I, that is, initial study period (21.05%), but decreases markedly in non-drain group in phase II (8.72). Routine subhepatic drainage is not recommended after cholecystectomy if the gallbladder bed remains dry and there is no leakage from the biliary system, as found in both phases of this study [7–9]. An example can be taken from appendicectomy for appendicitis where drainage is of no help and, in many cases, increases the chance of complications, especially wound infection and dehiscence [7]. But many surgeons still continue drainage for reasons based on traditional teaching and anecdotal complications and not on reliable facts and figures [7]. The major reason for drainage is the fear of bile leakage that may lead to bile peritonitis; this is usually due to an aberrant bile duct and not slippage of the cystic duct ligature [3]. Fear of blood collection requiring intervention is another reason for routine drainage after LC [10]. Drainage also allows CO_2 insufflation during laparoscopy to escape via the drain site, thereby decreasing the shoulder pain [10–14].

Prevention of intra-abdominal collections after LC is the main reason of drainage. The peritoneal cavity usually absorbs serous fluids rapidly, but blood and bile are absorbed more slowly[8]. Postcholecystectomy collections in the subhepatic space are on the whole small, rapidly reabsorbed, and essentially similar in size and number whether a drain is used or not [1]. Fraser et al. [2] found that the amount of fluid drained was on average twice as large as the volume of subhepatic fluid measured. They also suggest that drain provokes leakage from superficial biliary ductules damaged by dissection and contend that without drainage it would rapidly wall off [1]. Thiebe and Eggert [15] reported that the total number of abdominal collections was higher in the drain group (44%) compared with the no drain group (4.1%). They performed routine ultrasound on the fourth postoperative day, as compared with first and fourth day in this study [15]. The subhepatic fluid collection on first ultrasound at 24 h was significantly higher in drained group than in non-drained groups (Table 1). Further, the difference became insignificant on subsequent ultrasound at 72 h (Table 1). Intraperitoneal collection of blood may cause postoperative pyrexia, prolong the hospital stay, and increase the incidence of wound infection, while the presence of bile in the peritoneal cavity produces peritoneal irritation [8]. However, only some clinically significant abdominal collections may need intervention, while other abdominal collections may not be clinically significant [16, 17]. The only patient requiring intervention in the two trials mentioning treatment of the abdominal collections was in the drain group [18, 19]. The drain may also give false sense of security as it may get blocked and the patient continue to bleed internally and later presenting with signs of shock, as reported in one study [8]. Another study reported laparotomy for postcholecystectomy bile peritonitis in patients who had drains placed, suggesting that drain placement does not

Table 2 Comparative analysis of postoperative complications

Complications	Group A (Phase I) No. (%)	Group B (Phase I) No. (%)	Group C (Phase II) No. (%)
Nausea	5 (6.33)	4 (5.26)	6 (2.75)
Vomiting	3 (3.80)	3 (3.95)	0
Shoulder tip pain	7 (8.86)	6 (7.90)	7 (3.21)
Port site pain (wound infection)	1 (1.27)	2 (2.63)	2 (0.92)
Ileus	2 (2.53)	0	2 (0.92)
Fever and cough (chest infection)	3 (3.80)	1 (1.32)	2 (0.92)
Complication rate	21 (26.58)	16 (21.05)	19 (8.72)
Total	79 (100)	76 (100)	218 (100)
P value*	0.017		

* = Pearson chi-square

guarantee prevention of this complication [20]. It is assumed that the use of a drain might be helpful for early detection of postoperative bleeding. However, significant bleeding can also be easily detected by clinical and ultrasonographic signs of intra-abdominal hemorrhage in the event that there is no drain [20]. If there is doubt as to the significance of the collection, the ultrasonographic study can be repeated in a few days. An enlarging collection associated with persistent fever or worsening pain will suggest an abscess [17]. However, one cannot eliminate the possibility that the drain, acting as a foreign body, stimulates the formation of this fluid. Whatever the mechanism, the result is a fluid accumulation, most probably serous, adjacent to a drain [17]. The drain may prove dangerous after simple cholecystectomy as infection introduced along a drain may render an otherwise harmless collection of bile a cause of peritonitis [1, 3, 17]. Also drain may rapidly becomes walled off, and then merely provokes an exudate in response to its own presence [1]. Even if complications do occur in non-drain cases, minimally invasive interventions such as percutanenous and/or endoscopic techniques can be applied to solve the problem according to minimally invasive principles [20]. It would be reasonable, however, to leave a drain if there is a worry about an unsolved or potential bile leak, that is, imperfect closure of the cystic duct or bile staining in the lavage fluid or gallbladder bed, suggesting the possibility that an accessory duct has been missed. In these cases, a drain can be selectively used, bearing in mind that drain placement, although sometimes providing a false sense of security, guarantees neither prevention nor treatment of postoperative bile or blood collections [20].

The advantages of not inserting a drain are reduction of hospital stay, patient comfort, and lower incidence of postoperative complications [8, 10, 15, 19, 21]. On the other hand, drainage results in higher wound infection rate and longer hospital stay [15, 21]. Gurusamy et al. [16] reported lower wound infection rate in the no drain group than in the drain group, maybe because of the presence of a foreign body. Johansson et al. [22] safely performed day-case LC with low rates of re-admissions. However, the insertion of drain can delay the discharge and, thus, decrease any saving in costs of day-case LC [16].

Further, drain-related pain may negate one of the most important advantages of the laparoscopic approach, that is, less pain [20]. Postoperative pain and postoperative nausea/vomiting are important problems after a procedure that is designed for minimal discomfort. In fact, these are the most common cause of delayed discharge after laparoscopic procedures [5]. Carbonic acid that results from CO_2 insufflations and gas that separates the liver from the diaphragm causing the stretch of the attachments of the liver result in the postoperative pain, especially shoulder tip pain [13]. Nursal et al. found subdiaphragmatic drain effective in reducing the incidence and the amount of subdiaphragmatic gas bubble[12]. Another study in which residual gas was removed by active aspiration through the trocars rather than drains documented a decrease in opioid use, but not in VAS scores [14]. Another study used irrigation with relatively large amounts of saline, which presumably replaced the subdiaphragmatic gas and finally absorbed, and this proved effective in reducing pain [23]. In this study, subdiaphragmatic gas volume was significantly lower in group A patients than in group B and C patients (Table 1). Both active aspiration of CO_2 through the trocar as well as saline lavage and suction had been used more efficiently during phase II, resulting in lesser subdiaphragmatic gas volume. This greatly reduces postoperative nausea/vomiting and shoulder tip pain from 18.99% (group A) and 17.11% (group B) to 5.96% in group C. Gurusamy et al. in a meta-analysis reported decreased early postoperative shoulder pain in the drain group, that was not significant and reversed in the later postoperative period. This would not suggest that drainage of residual CO_2 or peritoneal fluid is of value in reducing the pain of LC [16]. They also noted lower nausea rate in the drain group compared with the no drain group [16]. Gurusamy et al. noted that drain use after open or LC increases the wound infection, but chest complications occurred only in open cholecystectomy [16].

One study of open cholecystectomy reported wound infection at 1.6% for non-drained cases and 8.4% for drained cases, with chest infection in 31% of cases and the great majority of these were in the group that had been drained (21 of the 22 cases)[7]. Similarly in this study, wound infection was comparable in both groups occurring in 1.27% cases in drained group and 1.36% in non-drained groups, but chest infection occurred in 3.80% in drained group and 1.02% in non-drained groups. It would seem that the presence of the drain and the extra pain resulting cause a splintage of the lower right chest and predispose to atelectasis and chest infection [7]. They also reported reoperation for collections more common after drainage, as well as the drain fever on removing or manipulating a drain that has been in situ for more than 48 h [7].

Finally, the timing of randomization is important in evaluation of these studies. If the randomization was performed toward the end of the surgery (after the gallbladder dissection and hemostasis is complete), the dropouts and crossovers can be kept to a minimum. For example, a surgeon may obtain meticulous hemostasis if he knew that the patient was randomized to the 'no drain' group [16]. In this study, the randomization was done at the end of surgery, thus reducing the bias introduced by the surgeon.

Conclusion

Routine subhepatic drainage after LC is not necessary in uncomplicated cases.

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