Outpatient laparoscopic cholecystectomy: a prospective study on 250 patients

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SUMMARY

Background — Patient selection, postoperative monitoring and discharge criteria after outpatient laparoscopic cholecystectomy (LC) are not clearly defined.

Methods — Patients scheduled for elective LC who fulfilled socioeconomic requirements for ambulatory surgery were enrolled in an open prospective study. Cholecystolithiasis, ASA IV and unstable ASA III patients were excluded. Discharge was allowed after at least 6 hours if patients were conscious, asymptomatic, ambulant, with normal vital signs, no evidence of bleeding, spontaneous micturition and tolerating soft diet.

Results — Of the 250 patients included, 10.4% were admitted due to intraoperative causes. Of the remaining, 92% were discharged on the same day and 8.0% were admitted for pain control or postoperative anxiety/discomfort. Neither mortality or major complications were observed. Ninety-five percent of patients declared themselves satisfied. History of jaundice, common bile duct dilatation on ultrasound, microlithiasis, abnormal preoperative alkaline phosphatase levels and surgeon’s experience were independent predictors of admission due to intraoperative causes. No predictor of postoperative admission was identified. Cost analysis showed a benefit for ambulatory LC compared to overnight stay.

Conclusion — Outpatient LC is feasible and safe with high patient satisfaction even with broad selection criteria. Improvements may be achieved in postoperative pain management.

Introduction

Laparoscopic cholecystectomy (LC) is considered the gold standard in surgical treatment of benign gallbladder disease.

Advantages over the conventional open approach have been widely demonstrated [1]. Besides reduced postoperative pain, LC allows quicker recovery and shortening of hospital stay, which is highly favoured by health care administrators. Several authors reported in large series that outpatient LC may be safely performed [2-14] with high patient satisfaction and lower cost [15-20]. Economic issue is the most relevant factor promoting outpatient LC. Only one randomized trial reported no difference between day-case and overnight LC, which was mainly attributed to the cost of home nursing service which might not be essential to these patients [21].
A matter of concern for ambulatory LC is the risk of potentially severe complications which may become clinically evident beyond the first 1-24 hours [22]. Though, complications which become evident after the first 48 hours would not be detected within the average in-hospital stay [8, 9, 23, 24].

The widest experience in outpatient LC comes from North America, Australia and Northern Europe. Yet, patient selection, postoperative nursing protocols and discharge criteria have not been clearly defined. In Italy, experience with "true" outpatient LC is lacking and no studies have been published at present from our country. This open prospective trial was designed in order to state reliability of discharge criteria and to identify the predictors of unplanned admission.

Patients and methods

This open prospective non-controlled study was carried out at the dedicated Day Surgery Unit located within a large acute care community hospital in an urban area south of Milan. The Unit has its own recovery room and dedicated personnel (anesthesiologists and nursing staff). It is open five days a week from 7 a.m. to 8 p.m., and an operating room is available for general surgery twice a week from 6 a.m. to 6 p.m. Operations which require general anesthesia are scheduled in the morning whereas procedures under local anesthesia and/or peritumoral surgery requiring overnight stay are performed in the afternoon. The study was approved by the local ethics committee.

Patient selection

Candidates for elective LC aged over 18 who gave their consent to outpatient procedure were enrolled. Those with proven or suspected choledocholithiasis were excluded, as well as American Society of Anaesthesiologists ASA class IV and unstable ASA III patients. Stable ASA II patients (adequate therapy and no interference of surgery on the underlying disease and/or its treatment), elderly age, morbid obesity, previous abdominal surgery and history of gallstone disease complications (such as acute cholecystitis, pancreatitis and common bile duct stones) were not considered exclusion criteria. Patients had to fulfill socioeconomic requirements for outpatient surgery, such as residence within 1 hour from the hospital, full comprehension of instructions and prescriptions, adult accompanying person available for the first 24 hours and easy access to a telephone line.

Preoperative protocol

Preoperative workup consisted of upper abdominal ultrasound performed within 3 months before surgery, blood test screening including liver function tests and serum amylose, electrocardiogram and anaesthesiologist consultation. Chest x-ray and consultation by a cardiologist were scheduled if age was over 45 years, in presence of abnormal liver function tests or high serum amylose levels, further imaging of the biliary tree with ultrasonography or magnetic resonance cholangiography was obtained in order to rule out common bile duct stones.

Informed consent to surgery, anaesthesia and study trial were obtained. Patients were asked to state and sign-up for full comprehension of instructions and prescriptions, adult accompanying person available for the first 24 hours and easy access to a telephone line.

Nursing protocol consisted of hourly monitoring of arterial blood pressure, heart rate, diuresis and cognitive function. Patients were also assessed hourly for pain on a visual analogic scale (VAS), nausea, vomiting, headache, dizziness and discomfort. State of wound dressing, subcutaneous emphysema and body temperature were recorded. Early mobilization and feeding with soft diet were encouraged. Aldrete score was used to allow discharge [23]. Criteria were the following: patient conscious and fully orientated, asymptomatic (no nausea, vomiting, hear dach or pain), normal vital signs, no evidence of bleeding, wound, spontaneous migration, tolerating soft diet. These parameters were checked hourly and discharge was authorized by surgeon and anesthesiologist after a minimum 6-hour observation.

Home prescriptions included low-fat diet, avoid heavy duty, ketorolac tromethamine 60 mg i.v. before the end of surgery and a further 30 mg dose upon discharge if needed. Metoclopramide 10 mg i.v. was administered for postoperative nausea and vomiting treatment if needed.

Surgical technique

LC was performed with standard 4-trocar technique. Pneumoperitoneum was achieved through open umbilical access and carbon dioxide insufflation was set at 12 mmHg. Port sites were infiltrated with 10 mL anaesthetic solution (ropivacaine 50 mg and saline 5 mL) before incision. Two 10 mm and two 5 mm ports were used. Retrograde cholecystectomy was carried out with monopolar coagulation and identification and ligation of cystic artery and duct. Intraoperative cholangiography was performed on a routine basis. The gallbladder was extracted from the umbilical incision in a specimen bag to avoid spillage of bile or particle contamination. Complete dissection was obtained at the end of the procedure and no intraoperative local anaesthetic was used. Fascia was sutured at 10 mm port sites.

Postoperative management

Patients were monitored in the recovery area and considered for same-day discharge unless any of the following conditions had occurred: bleeding over 500 mL, need for associated major surgical procedures, detection of common bile duct stones, placement of an abdominal or biliary drainage, visceral and/or vascular lesion regardless of treatment, conversion to laparotomy, anaesthesiologic complications (respiratory failure, persistent electrocardiogram and/or hemodynamic changes). According to the Italian Society of Anaesthesiology guidelines duration of surgical procedure >90 min was also considered as a contraindication to same-day discharge even if the procedure had been uneventful.

Patients were administered 500 mL of 0.9% saline solution postoperatively. Analgesia was obtained with ketorolac tromethamine 60 mg i.v. before the end of surgery and a further 30 mg dose upon discharge if needed. Metoclopramide 10 mg i.v. was administered for postoperative nausea and vomiting treatment if needed.

Cost of in- and outpatient LC was calculated by Hospital administration.
Outcome

Outcome measures were: number of patients who met discharge criteria; intraoperative time (from skin incision to closure), and actual time left the hospital on the same day of surgery; time elapsed between end of the operation and full fluid intake; discharge criteria, morbidity, mortality and rehospitalization during the first postoperative week; patient satisfaction index; hospital costs.

Statistical methods

To assess the number of samples required for this phase II study, p0 (percentage of patients free from complications with CL) was determined at 95%; and p1 (percentage of patients free from complications with CL in DS) at 95%. As a precaution against type I or II error, p was fixed at 5% and 1-0.9590. Based on this, the number of patients necessary to assess differences in success rates in the two groups is 236, calculated according to Simon test.

The percentage of success rates was calculated on an "intention to treat" principle, by dividing the number of successes observed by the total number of patients enrolled.

A patient who is discharged on the same day and who has no complications during the first 48 hours after surgery was considered a success.

We used the Chi-Square test to compare two variables measured in the sample, that are dichotomous in nature, and the Mann-Whitney U test to compare two independent groups of sample data (StatSoft, Inc., Tulsa, OK, USA).

We considered P<0.05 as statistically significant.

Results

From February 2002 to September 2005, 250 outpatient LC were planned. There were 71 males and 179 females with a mean age of 46 years (SD=19.7). Twenty-six patients (10.4%) were excluded from same day discharge and admitted to inpatient ward for the following intraoperative reasons: duration of procedure >90 min (11 pts); finding of common bile duct stones at cholangiography (10 pts) and eight cholecystitis requiring abdominal drainage (5 pts); one patient with cholecystitis required conversion to open surgery due to difficult dissection (conversion rate 0.4%). The remaining 224 patients were monitored in the recovery area. Postoperative VAS score showed adequate pain control (VAS≤5) in 70.3% of patients since the first post-surgical hour, reaching 92.8% (median VAS=1) after four hours (figure 1). Two hundred and six patients (92%) were discharged in the afternoon after a median observation of 430 minutes (iq range 398.5-472.5 min).

Eighteen patients (8%) were admitted because of inadequate pain control (4 pts, 1.8%) or postoperative anxiety/discomfort (14 pts, 6.2%). Patients admitted for pain were discharged after 1 day (2 pts) or 2 days (2 pts). All patients admitted for anxiety or discomfort were discharged within 24 hours. Neither mortality or major complications were observed in the outpatient group.

Six minor wound complications occurred at the umbilical port site (4 hematomas and 2 serous discharge) and were diagnosed on 7th postoperative day at follow-up visit. None of these complications required earlier consultation. No hospital re-admission was necessary during the study follow-up period.

Five patients requested for unscheduled medical advice on the first or second postoperative day. One of them was given phone prescription for fever. Three reported abdominal pain and were asked to return to outpatient clinic for consultation: abdominal ultrasound was performed in one case and further postoperative course was uneventful in all. Another patient was seen for headache and discharged with appropriate treatment. Postoperative pain control evaluated at scheduled phone interviews and on pain monitoring cards showed adequate (VAS≤5) in 184/204 patients (90.1%).

Of the 206 patients discharged on the same day of surgery, 180 (87.4%) returned the satisfaction questionnaire. One hundred seventy-one patients (95%) declared themselves satisfied with the outpatient procedure and 161 (89%) stated they would suggest outpatient LC to a friend or relative. Reasons for not advising outpatient LC mainly concerned pain management and fear of complications. Twelve patients (6.6%) would have preferred an overnight stay, mainly because of difficult pain management. In these patients, VAS scoring on phone interviews and self-reports was always below 5 and no statistical difference was found in median VAS score between this group and fully satisfied patients.

Patients resumed normal activities of daily living after a median of 1 day. Twenty-five patients (12.3%) had resumed work by the first postoperative week and 40 (24%) planned to go back to work within a week from follow-up visit.

Patients were divided into groups according to timing and reason for hospital admission, and data were compared in order to identify predictive factors for failure of discharge. Data from

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26 patients in whom conversion to inpatient procedure was decided at surgery were compared to all 224 patients monitored in the recovery area for potential same-day discharge. Factors predicting common bile duct stones were history of jaundice (P=0.011) and common bile duct dilation on ultrasound (P=0.018). No statistical difference was found in the rate of previous biliary complications (choledocholithiasis, common bile duct stones, pancreatitis, liver function tests and serum amylase abnormalities. Eight out of ten patients with intraoperative finding of common bile duct stones had no detectable preoperative risk factor. Preoperative predictors of duration of operation >90 min were common bile duct dilation on ultrasound (P=0.03) and micro lithiasis (P=0.002). Surgeon's experience was also a predictive factor of duration of operation: the number of uncomplicated procedures lasting longer than 90 minutes was significantly higher among residents within the learning curve (first 50 procedures) than among senior surgeons (8.16% vs 2.21%; P=0.044). No differences were found in age, BMI, history of cholecystitis, pancreatitis or jaundice, thickening of gallbladder wall or common bile duct dilation on ultrasound and abnormal liver function tests/serum amylase.

The sole prognostic factor related to intraoperative finding of acute cholecystitis requiring inpatient observation was abnormal preoperative alkaline phosphatase levels (P=0.032).

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Discussion

Several reports indicate that LC may be safely performed as an outpatient procedure without any adverse effect on clinical outcome [2-20]. Although some authors define "ambulatory" or "outpatient" surgery when postoperative hospital stay is less than 24 hours [26-29], these terms should be used only when patients are discharged a few hours after the operation on a same-day basis [30-33].

This is the first report of "true" outpatient LC from Italy. Success of outpatient LC may be measured in terms of feasibility (unplanned admission/readmission rates), safety (morbidity and mortality), patients' satisfaction and cost saving. Although ambulatory LC proved to be safe in high risk patients [33], results heavily depend on selection criteria: the more restrictive they are, the lower the risk of complications and need for in-hospital observation [34]. As for patients' satisfaction, socioeconomic and cultural aspects play an important role in acceptance of ambulatory surgery [8, 35-37] although studies addressing quality of life measures demonstrate no difference between ambulatory and overnight stay [16, 17, 20].

In this study, we could not identify any preoperative parameters as exclusion criteria would have reduced the incidence of unplanned admission. Nevertheless, 134 patients were successfully treated as outpatients despite history of jaundice (2 pts), common bile duct dilation on ultrasound (3 pts), previous cholecystectomy (10 pts), elevated serum alkaline phosphatase levels (26 pts), micro lithiasis (56 pts) and operation carried out by a younger surgeon (37 pts). Therefore, as stated by others [7, 33, 34, 43], including patients with potential risk factors does not jeopardize patients' comfort and safety, provided access to hospital admission is easily and rapidly available. Our Day Surgery Department is an independent Unit located within a large hospital and therefore shift is easy and immediate whenever needed. In such situation, "unplanned" admission does not represent a drawback or complication but simply a better option for postoperative management. Conversely, careful patient selection is much more critical in free-standing Units where the need for hospital admission implies patient transfer to another facility [3, 14], may be stressful for patient, surgeon and nursing staff and may have financial implications [44].

In this study, we could not identify any preoperative parameters related to admission for inadequate pain control, anxiety or discomfort. Some studies [7, 9, 14, 31, 45] pointed out a significant correlation between length of operation and admission rate. Others [10] stated that duration of operation is not a contraindication to same-day discharge. No conclusion can be drawn from our study since duration of surgical procedure beyond 90 min was considered a reason for prehospital observation. Age, ASA class and starting of surgical procedure in the afternoon have been demonstrated that surgeon's experience [24] and use of a predetermined clinical pathway [39] can improve success of ambulatory LC. In our Department we deal with an average of 250 LCs every year. Access to the Day Surgery Unit is limited to two days per week and most of the time is dedicated to hernia and proctologic procedures. According to the Italian Society of Anaesthesiology guidelines we observe patients operated on under general anaesthesia for a minimum of 6 hours before discharge, therefore these procedures have to be completed by noon. No ambulatory laparoscopic procedure would ever be scheduled in the afternoon. Moreover, laparoscopic hernia repair is often performed on an outpatient basis, thus further limiting the number of LCs that may be scheduled in the Day Surgery Unit to 60-70 per year. All other LCs had to be performed in the main operating theatre, where this protocol was not applied. This figure has not changed over time and improvement may be achieved only by modifying internal Hospital organization and shifting resources to the Day Surgery Unit.

Over 10% of patients enrolled were excluded from potential same-day discharge due to intraoperative findings of common bile duct stones, acute cholecystitis or technical difficulties requiring prolonged operative time. Studies attempting at identifying predictors of common bile duct stones yielded controversial results [40, 41]. In our study, history of jaundice and common bile duct dilation on ultrasound were predictors of choledocholithiasis, whereas previous cholecystitis and abnormal preoperative alkaline phosphatase levels were related to intraoperative finding of acute cholecystitis. In other studies, age, preoperative endoscopic sphincterotomy and thickened gallbladder wall were found to be related to operating time [42]. In our series, common bile duct dilation, micro lithiasis and surgeon's experience were considered unimportant.

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Conclusion

In conclusion, our study confirms that outpatient LC is feasible and safe, especially in dedicated Units with specially trained personnel. Easy access to inpatient is essential, too. If these requirements are fulfilled, patient satisfaction is high. Still, improvements may be achieved in postoperative pain management which remains a core issue in ambulatory surgery. Since an economic benefit is demonstrated, outpatient LC should be preferred wherever full patient safety can be guaranteed. A future challenge will be further reduction of hospital stay and extension of its benefits even if full patient safety can be guaranteed. A future challenge will be further reduction of hospital stay and extension of its benefits. Moreover, VAS scoring in patients who would have preferred an overnight stay for pain management was always below 5 at home monitoring. This indicates that other factors play a role in patients’ anxiety and acceptance for ambulatory surgery. Still, more effort may be concentrated on patient education in order to improve symptom control after discharge.

Although patient well-being is the most important medical outcome in ambulatory surgery, an economic benefit is evident, too. Our cost analysis shows that ambulatory LC allows almost 20% saving compared to overnight stay when surgery is performed in the dedicated Day Surgery Unit. Benefit is even higher if we consider cost of LC performed in the main operative theatre. Although a more intensive nursing assistance is needed in ambulatory surgery, its cost is largely overcome by lower charges of a less specialized operative theatre. In the Day Surgery Unit, most procedures are performed under local or locoregional anaesthesia, therefore full-time presence of anaesthesiologists is not required. Moreover, there is no need for 24-hour availability of medical and nursing staff for emergencies, which is committed to the main operative theatre. Costs due to amortization are also reduced, since equipment for major cases, which is committed to the main operative theatre. Costs due to amortization are also reduced, since equipment for major cases, which is committed to the main operative theatre. Costs due to amortization are also reduced, since equipment for major cases, which is committed to the main operative theatre. Costs due to amortization are also reduced, since equipment for major cases, which is committed to the main operative theatre. Costs due to amortization are also reduced, since equipment for major cases, which is committed to the main operative theatre. Costs due to amortization are also reduced, since equipment for major cases, which is committed to the main operative theatre. Costs due to amortization are also reduced, since equipment for major cases, which is committed to the main operative theatre.

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REFERENCES


