Day surgery laparoscopic cholecystectomy: comparative analysis in two consecutive periods in a cohort of 1132 patients

F. Docobo Durántez[a], M. Arance García[b], A. Navas Cuéllar[a], J. Mena Robles[a], J.M. Suárez Grau[a], F. J. Padillo Ruiz[a]

Abstract

Aim: To evaluate factors preventing discharge in patients scheduled for laparoscopic cholecystectomy (LC) in a day Surgery Unit in a University Regional Hospital.

Methods: *Selection criteria:* Adult patients, American Society of Anesthesiology (ASA) physical status classification class I-II or III compensated, and BMI < 35, uncomplicated acute cholecystitis. Between 1997 and 2002 (Group A) and between 2003 and 2010 (Group B) a total of 1132 patients underwent LC. Clinical characteristics, Substitution Day Surgery Index, causes for inpatient, postoperative complications, pathological studies, patient satisfaction index and 3 months clinical results were compared.

Results: 306 patients in the group A and 826 in group B were selected for day-case laparoscopic cholecystectomy. In group A only 1.31% were day cases and in group B 82.5% were day cases. Symptoms such as abdominal pain or nausea and/or vomiting were less frequent in group B. The incidence of complications was low and similar in both groups of patients. There were no differences in the presence of events in the three months following surgery. Satisfaction rates were high in both groups but higher in the group B.

Conclusions: Outpatient laparoscopic cholecystectomy is a safe and reliable procedure with a high level of patient acceptance.

Keywords: Laparoscopic cholecystectomy, Day Surgery, Inpatient, Substitution Day Surgery Index.

Authors' addresses: [a]General and Digestive Surgery Department. [b]Anesthesiology Department. University Hospital Virgen del Rocío. Sevilla. Spain.

Corresponding author: F. Docobo Durántez. *Tel:* +34 629548336 *E-mail:* fdocobod@yahoo.es

Introduction

Laparoscopic cholecystectomy (LC) is now the treatment of choice for non-complicated cholelithiasis, especially on a short stay or day case basis [1.2].

Despite this, several questions remain unsolved. Is LC safe as an ambulatory procedure? Is it a cost-effective procedure? Are both surgical and anaesthetic teams involved in this ambulatory procedure? What are the views of patients and relatives regarding LC as a day surgery procedure? What is the implication to hospital administrators?

If this surgical activity is going to be carried out in Sort Stay Surgical Units (SSSU) as well in Day surgery Units (DSU), safety and efficacy of the procedure are necessary. Therefore, any LC ambulatory programme requires appropriate patient selection according to clinical, biochemical, ultrasonography and social criteria, with the establishment of protocols for each phase of the patient pathway, and formal evaluation of the service. If appropriate pathways are present in both (short stay surgical units) SSSU's and (day surgery units) DSU's, which factors determine hospital stay and contribute to the observed differences between the programmes?

The aim of this study is to evaluate the incorporation of LC in an ambulatory surgery unit and to identify clinical and surgical factors which could be determinants in the decision to discharge patients on same day or after an overnight stay.

Methods

Patients. A prospective study of patients undergoing LC for chronic cholecystitis from 1997 to 2010 was conducted.

The study groups were composed of patients followed-up for 3 months postoperatively. Patients were selected according to the following criteria: patient adherance to the ambulatory programme after previous personal interview, signed consent information, own phone, support of a responsible adult, and a home distance less than 1 hour from the hospital. Patients were classified following the American Society of Anesthesiology (ASA) physical status classification class I-II or III compensated, and BMI < 35. Patients with cholestasis, choledocholithiasis, acute cholecystitis, treated or drained by percutaneous approach, or recent acute pancreatitis, were not included.

Two consecutive groups were compared. Group A patients received their operation between 1997 and 2002, and group B between 2003 and 2010, and time to discharge noted (same day or overnight stay). The following clinical characteristics were recorded in both groups: Substitution Day Surgery Index (SSDI), reason for inpatient stay, postoperative complications, histopathology, patient satisfaction index, and 3 months post-operative clinical results.

Anaesthetic and surgical technique. Patients were admitted in the morning of the day of surgery. The procedures were performed before 12 noon to allow a postoperative recovery period of about 8 hours.

The anaesthetic procedure was as follows: premedication with oral midazolam (0.1 mg/kg) in the 30 min before surgery. Induction was performed with propofol (3–5 mg/kg) and muscular relaxation with a non depolarizing muscle relaxant (cisatracurium 0.3-0.5 mg/kg). Anaesthesia was maintained with a continuous infusion of propofol, 2–4 µg/ml Target Controlled Infusion (TCI) and remifentanyl (0.3 µg/kg/min) or fentanyl (3 µg/kg) as an ultra short-acting analgesic drug. Intravenous ketorolac (60 mg) was injected at the end of the procedure. Nausea and vomiting, and thromboembolism prophylaxis

were given when risk factors were present. No routine antibiotic prophylaxis was done.

Surgical procedures were performed by 2 trained-surgeons assisted by surgical residents in a teaching-programme. Surgical technique involved the creation of a pneumoperitoneum (10 mm Hg) using a Verress needle inserted into the left hypochondrium with 3 or 4 ports as necessary. No routine drains were inserted.

Postoperative analgesia consisted of: ketorolac 60 mg/8 h, and paracetamol 1g, if necessary and omeprazole 20 mg/12 h. If pain persisted, tramadol (50–100 mg, i.v.) was used as analgesic rescue.

Oral liquids were normally taken 2 h after the procedure. Postanaesthetic Discharge Scoring System (PADSS) [3] (Appendix 1) was selected for discharge criteria. The surgeon discharged the patients and managed their expectations in the post-operative period. In particular they were informed about possible warning signs of complications (several abdominal pain, abdominal distension, nausea and/or vomiting, fever, etc.). All patients were contacted by phone 24 after surgery and interviewed using a standardized questionnaire. Patients were clinically evaluated one and three months after discharge.

Statistical analysis. Statistical comparative analyses were performed using Chi-Square and Student t- tests. A p value < 0.05 was considered significant.

Results

The study group consisted of a total of 1132 patients undergoing LC for chronic gallstone cholecystitis, and followed-up for 3 months postoperatively between 1997 and 2010.

Between 1997 and 2002 (group A) 306 patients (27.04%) were included and between 1998 and 2010 (Group B) 826 (72.96%) were selected for LC in a DSU.

The characteristics of the patients are shown in Table 1. Mean BMI was 29±1.47 kg/m^2 in group A and 28±0.82 kg/m^2 in group B ($p<0.001$). Mean total bilirrubin was 0.69±0.03 mg/dl in group A and 0.57±0.03 mg/dl in group B ($p<0.001$).

Average surgical time was 39±10 minutes in group A and 28±7 minutes en group B ($p<0.001$).

Number of ports, 3 in 35/306 (11.4%) group A and 825/826 (99.88%) group B ($p<0.01$).

The length of hospital stay of each patient, as well as the rate of substitution for both study groups is shown in Table 2. The percentage of patients who were discharged the same day of surgery was higher in the group B compare to the group A (82.5% vs 4%) substitution index of both groups ($p< 0.01$).

All patients selected for surgery were scheduled to be discharged home on the same day of surgery. The reasons for hospital stay in both groups are shown in Table 3. In Group A, only 4 of 306 patients (1.31%) were discharged on the day of surgery. The reasons for failed discharge in the other 302 patients were as follows: abdominal pain 84 patients (27.4%), nausea and/or vomiting 69 patients (22.5%), general discomfort 68 patients (22.2%), social criteria and/or patient preference 48 patients (15.6%) and a further 33 patients failed to go home due to conversion to the open procedure. (10.7%). In group B, 144 (17.43%) patients were admitted due to: abdominal pain 30 (3.63%), nausea and/or vomiting 25 (3.02%), general discomfort 38 patients (4.6%), social criteria 40 (4.8%) and 11 open conversions (1.33%).

The readmission rate was 2/306 (0.6%) in group A and 3/826 (0.36%) in group B (p= ns). Symptoms after 3 months was also uncommon in both groups with 291/306 (95.09%) asymptomatic in group A and 809/826 (97.94%) asymptomatic in group B. Occasional abdominal pain was present in 7/306 (2.28%) in group A and 9/826 (1.08%) (p= ns). Histopathology findings were similar in both study groups with chronic cholecystitis present in 244/306 (79.7%) of

Table I Characteristics of the patients distribution in relation both groups.

	Group A (1997–2002)		Group B (2003–2010)	
	n = 306	(27.04%)	n = 826	(72.96%)
Gender (p< 0.05) Female : Male	247:59	80.71:19.28	663 : 163	80.26 : 19.73
Age (p < 0.05) 20 – 39 40 –59 60 – 79	 49 128 129	 16.01 41.83 42.15	 193 323 310	 23.36 39.10 37.53
ASA (p < 0.05) I II III	 51 206 49	 16.66 67.33 16.01	 184 543 99	 22.27 65.73 11.98
Mean BMI (Kg/m^2) (p<0.001)	29±1.47		28±0.82	
Mean total bilirubin (mg/dl) (p<0.001)	0.69±0.03		0.57±0.03	
Average surgical time (min) (p<0.001)	39±10		28±7	
Number of ports (p< 0.01)				
3 4	35 271	11.4 88.6	825 1	99.88 0.12

Table 2 Discharge time and substitution index distribution in both groups.

	Group A (1997–2002)		Group B (2003–2010)	
	n = 306	(27.04%)	n = 826	(72.96%)
Discharge time (hours) (p< 0.001)				
No overnight	4	1.31	682	82.5
< 24	186	60.78	129	15.6
24 – 28	106	34.64	7	0.84
≥ 48	10	3.26	8	0.96
Sustitution DS index	4 : 306	1.30	686 : 826	83.05

Table 3 Reasons for failed discharge discharge. Major complications. Histopathological studies. Clinical and quality 3 months distribution in both groups.

	Group A		Group B	
Causes of no DS discharge (p<0.05)	n	%	n	%
Abdominal pain	84	27.4	30	3.63
Nausea and/or vomiting	69	22.5	25	3.02
Discomfort	68	22.2	38	4.6
Social criteria	48	15.6	40	4.8
Open conversion	33	10,7	11	1.33
Total	302/306	98,69	144/826	17.43
Mayor complications (p ns)				
Biliary leakage	2/306	0.6	3/826	0.36
Hemoperitoneum			1/826	0.1
Readmission rate	2/306	0.6	3/826	0.36
After 3 months (p ns)				
Asymptomatic	291/306	95.09	809/826	97.94
Sporadic abdominal pain	7/306	2.28	9/826	1.08
Diarrhea	2/306	0.65	2/826	0.24
Subhepatic collection	3/306	0.98	5/826	0.6
Umbilical hernia	1/306	0.32	-	-
Infection surgical wound	1/306	0.32	1/826	0.12
Retained stone	1/306	0.32	-	-
Histopathological study (20 days) (p ns)				
Unspecific chronic cholecystitis	244/306	79.7	633/826	76.63
Cholesterolosis	44/306	14.4	140/826	16.94
Adenomiomatosis	18/306	5.9	53/826	6.41
Satisfaction Index (p < 0.001)				
High	178/306	58.16	569/826	68.88
Moderate	117/306	38.23	245/826	29.66

group A patients and 633/826 (76.63%) of patients in group B (p=ns). Patient satisfaction was high in 178/306 (58.16%) in group A and 569/826 (68.88%) in group B. (Table 3)

Discussion

Day Surgery is a predefined pathway requiring shorter and less intensive postoperative care. Therefore patients do not need to remain in the hospital and can be discharged a few hours after surgery [4]. Laparoscopic cholecystectomy has, over time, become readily achievable through SSSU's and DSU's for the treatment of non-complicated cholelithiasis [1,4].

In Spain, most of the LCs are performed as part of an inpatient SSS programme. The experience in day surgery laparoscopic cholecystectomy (DSLC) is very limited even today. Perhaps there are several outstanding questions which must be addressed in this country before widespread adoption can occur:

Is LC safe as an ambulatory procedure? To be included in a DSU programme, LC must be both safe and effective. Therefore patient comorbidity needs to be controlled with patients selected according to clinical, biochemical, ultrasonography and social criteria. Reddick and Olsen published in 1990 the first LC outpatient series [5]. Thereafter, several other series confirmed that LC is a safe and effective procedure in DSU with a substitution index between 80% and 92.7%. Nowadays, laparoscopic cholecystectomy (and indeed laparoscopic groin hernia repair) is a well-recognised and safe day case procedure [6,7].

Clinical pathways must be defined from both the surgical and anaesthetic points of view with appropriate postoperative evaluation, including an assessment of quality [8,9]. Several series have demonstrated the safety and efficacy of outpatient LC in selected patients [10–13]. However, comparative studies are infrequent. In this present study, 1132 patients were included for day case LC between 1997 and 2010. Anaesthetic and surgical procedures were standardised to obtain a short hospital stay with the same level of safety and quality as those patients who did not receive DS.

The study showed that the need for hospitalization decreased in Group B compared to Group A (82.5% vs 4% : $p< 0.01$). This difference could be explained by the development of a learning curve for surgeons and anaesthetists resulting in fewer complications and/or side-effects. Other authors show that these early postsurgical events are factors that most commonly determine the need of admission [14–18]. However the incidence of major complications after LC in large series are between 1-5% [17], with most (bile leakage or intestinal perforations) diagnosed 24–36 hours after surgery, when the patients are already home, even in an inpatient programme [17–19]. In our series, major complications were infrequent in both groups. Biliary leakage for bile duct damage was detected in only 0.6% of cases in Group A and 0.3% in Group B. These results are similar to previous series, where bile duct lesions were recorded in 0.3–0.5% of cases. The recognised incidence of bleeding in the immediate post-operative period is between 0.05–0.1% [17,18]. In our series, one patient in Group B suffered this complication with no long term effects.

Is LC a cost-effective procedure? A DSU permits an increase in surgical activity which is not limited by bed numbers, while reducing the costs through shorter length of stay [20]. but maintaining safety. 25-30%(6,10,14,15).

A further question relates to clinical willingness, by both surgeon and anaesthetist, to undertake day case LC. The reasons for this are complex and sometimes obscure. Nevertheless, there are those who do not wish to undertake the perceived greater workload of day surgery or perhaps loss of surgical esteem or administrative power by operating on less invasive cases.

To minimize the unplanned overnight admission rate, potential complications must be avoided. In our study, the inclusion of multimodal model of analgesia and prophylaxis for nausea and vomiting in Group B patients resulted in a significant reduction in postoperative complication rate from 27.4% to 3.63% and abdominal pain, from 22.5 % to 3.02% for postoperative nausea and vomiting, which is similar to results in other series. [1,6,8,16].

Are patients and relatives prepared for day surgery? Some authors suggest that over 70% of cholecystectomies can be performed as day cases [14,21,22]. Even so, many patients choose an inpatient stay for no apparent reason. Could it be that they are reassured by the presence of health care professionals overnight? Since they prefer the direct observation and care of professionals. This "social" reason for staying in hospital is a factor that significantly increases unplanned admissions in a DSU and may account for 18–30% of unexpected stays [23–26]. In our study 15.6% in Group A and 4.8% in Group B overnight admissions occurrred for this reason. In our study, 83.05% of the patients in Group B were same-day discharges, a level similar to that reported in other series [27–29]. However, this figure may be biased as patients with acute cholecystitis and recent acute pancreatitis were excluded. Relaxation of our criteria to include ASA grade III compensated patients, was not associated with any increase in the incidence of postoperative complications and others have shown that exclusion criteria such as age >65 years or BMI >30 or 35 kg/m^2, have shown no relationship to the incidence of major complications after LC [26,30–34].

An operating time >60 minutes correlates with day case failure [4,7,16]. In our study, the average operating time was 39±10 minutes in the A Group and 28±7 minutes in Group B ($p<0.001$). Open conversion where Calot's Triangle could not be readily identified was only 1.33% in Group B versus 10.7% in Group A, and was similar to that of other studies [9,10,20].

Safe discharge requires clear patient instructions for their return home with appropriate follow-up if required [35] and low rates of readmission. In our study, the readmission rate was low in both study periods, 0.6% in first 4 years and 0.36% in the last period. This rate was lower than that reported by others [7,20,36]. The low incidence of adverse postoperative events in the short and medium term did not allow statistically significant conclusions.

Conclusions

Outpatient laparoscopic cholecystectomy is a safe and reliable procedure with a high level of acceptance. In general, events emerging in the early postoperative period can be considered similar to inpatients. Variables such as the doubt or insecurity of patients at discharge can be important factors when it comes to deciding on unplanned admission. Comprehensive patient may reduce admissions for 'social' reasons. We believe that same-day discharge is the treatment of choice for uncomplicated LC.

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Appendix 1 Postanesthetic Discharge Scoring System (PADSS).

Vital signs	
2	Whitin 20% of preoperative value
1	20%-40% of preoperative value
0	40% of preoperative value
Activity, mental status	
2	Oriented and steady gait
1	Oriented or steady gait
0	Neither
Pain, nausea, vomiting	
2	Minimal
1	Moderate
0	Severe
Surgical bleeding	
2	Minimal
1	Moderate
0	Severe
Intake and output	
2	Per os fluids and voided
1	Per os fluids or voided
0	Neither