

Day surgery laparoscopic cholecystectomy: initial experience in 43 consecutive patients



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Day Surgery laparoscopic cholecystectomy: Initial experience in 43 consecutive patients

AIM: Analyze the results of an early experience in day-case LC (laparoscopic cholecystectomy) in a single laparoscopic unit, in terms of clinical outcome, unexpected admissions, readmissions, patients satisfaction.

MATERIALS AND METHODS: During three years, 200 consecutive patients underwent LC. Emergency procedures (32pts) and patients scheduled for cholecystectomy plus other surgical procedures (21pts) were excluded. Thus, 147 patients underwent elective LC and 43 were scheduled for DSLC (day-surgery laparoscopic cholecystectomy).

RESULTS: Six patients (13,9%) were considered not eligible for a same day discharge and admitted to the inpatients ward for overnight observation. The re-admission rate was 2,3% and 41 patients (95.3%) were completely satisfied.

DISCUSSION: Patients satisfaction was complete in 95.3% of cases, related to a correct preoperative information and the reduction in hospital costs amounted approximately to 41%. Despite the evidence of feasibility and safety of the day-case procedure, the Italian cultural background is nowadays inadequate for a clean acceptance of the DSLC. The provision of adequate staff education and training prior to full DSLC introduction is mandatory to the success of this organizational model.

CONCLUSIONS: LC can be performed safely in an outpatient setting if there's a careful education of patients and the surgical and anesthesiologist team is well-trained. Besides, good results can be achieved considering inclusion criteria. For the admission to be kept to a minimum, postoperative pain and nausea management has to be carefully planned such as discharge criteria evaluated. For selected patients, day-case LC is feasible and safe and can provide a reduction in hospital costs.

KEY WORDS: Cost effectiveness, Day surgery, Laparoscopic cholecystectomy.

Introduction

Laparoscopic cholecystectomy (LC) has rapidly replaced open surgery for patients with symptomatic gallstone disease. Day Surgery cholecystectomy (DSL) is a well-established practice in the United States where routine

day-case LC is increasingly replacing inpatient treatment and the trend is similar in other developed countries¹. Early positive outcomes and results of DSL were described by Reddick and Olsen in 1990² and it is now well accepted as a cost-effective and safe procedure for the treatment of symptomatic gallstones^{3,4}.

Many Authors have suggested that careful patient selection through strict selection criteria such as age, ASA score and the availability of a responsible adult to take care of the patient after discharge, contributes to improving the success rate of DSL^{1,3,5}.

Furthermore, the development and diffusion of the "day surgery model" permits rapid bed turn-over and reduces total costs with obvious advantages for the healthcare system. Indeed, ambulatory and day surgery may be amongst the options for decreasing the use of hospital resources and saving costs⁶.

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However, apart from being safe and cost-effective, the conversion of an inpatient to an outpatient procedure cannot be to the detriment of patient satisfaction: patients must be properly informed about the procedure, postoperative course and pain control and the possibility of hospital admission, if needed.

Despite the increasing number of reports on the cost-effectiveness and positive outcomes of day-case LC, the concept is still controversial in many countries, including Italy, where it is yet to become part of routine clinical practice. During 2010, of the 7232 LCs performed in the Emilia-Romagna region, only 49 cases (0.67%) were day-case LC (report by the Emilia-Romagna Agency for Health).

The aim of this paper is to prospectively analyse the results of an early day-case LC experience in a single laparoscopic unit of a university hospital, in terms of clinical outcome such as unexpected admissions, readmissions, postoperative complications and patient satisfaction.

Material and methods

During the two and half year period between January 2009 and December 2011, 200 consecutive patients underwent LC in a single minimally-invasive surgical unit at Policlinico of Modena. Emergency procedures (32 cases) were excluded, as were patients scheduled for cholecystectomy plus other surgical procedures (for example splenectomy and inguinal hernia repair) (21 cases). Therefore, a total of 147 patients underwent elective LC as a sole procedure. Of these, 43 were scheduled for DSLC. All procedures were performed by the same surgeon.

INCLUSION CRITERIA

The inclusion criteria for DSLC were general health status with American Society of Anaesthesiologists (ASA) score 1 or 2, age of between 18 and 70 years, a body mass index (BMI) less than 35 and a diagnosis of uncomplicated gallstone disease (clinical criteria); moreover, home within 1 hour of the hospital, availability of a responsible adult to take care of patient after discharge until the following morning, availability of a telephone line and full comprehension of instructions and prescriptions (social criteria) were considered mandatory⁷.

EXCLUSION CRITERIA

The exclusion criteria were emergency admission, high risk of common bile duct stones and acute cholecystitis, previous open upper abdominal surgery and clotting disorders⁷.

PREOPERATIVE PROTOCOL

Patients were examined by the operating surgeon in the outpatient department and scheduled for a DSLC if all

inclusion criteria were satisfied. Information about the operation, expected postoperative course, possible complications and symptoms were discussed thoroughly. The possibility of unexpected ordinary hospitalisation after surgery was also discussed. All information was given both verbally and in writing and informed consent to day surgery and LC was collected.

The preoperative work-up consisted in an upper abdomen ultrasound performed in the 3 months prior to surgery, blood tests including liver and pancreatic function, chest X-ray and electrocardiogram and anaesthesiologist evaluation. In the presence of abnormal liver function test results, an MRI- cholangiography study was performed. If this was normal, the patient was considered eligible for the day-case procedure.

Patients were admitted to the day surgery ward at 7:00 am on the day of surgery, having been nil-by-mouth since midnight. No more than two DSLC were scheduled for the same morning to assure patients adequate recovery time before discharge.

ANAESTHETIC TECHNIQUE

Antibiotic prophylaxis with cefazoline 2gr iv was administered prior to surgery and no premedication was given.

The surgical procedure was performed with oro-tracheal intubation under total anaesthesia with propofol infusion, fentanyl, rocuronium and sevoflurane with air and oxygen.

OPERATIVE TECHNIQUE

A standard four-port laparoscopic technique was adopted using a 10-12 mm umbilical trocar (open approach) and three further 5mm operative cannulas – one epigastric and two right upper quadrant; pneumoperitoneum was set at 10-11 mmHg. A retrograde cholecystectomy was performed using monopolar coagulation plus 5mm endoclips placed on the cystic artery and duct or with an ultrasound forceps as the sole instrument. The gallbladder was extracted from the umbilical port into a specimen bag to avoid parietal contamination. Intraoperative cholangiography was never performed and no drain was placed in any case. Complete pneumoperitoneum deflation was obtained and all port sites were injected with ropivacaine hydrochloride (10mg/ml) at the end of the procedure.

POSTOPERATIVE MANAGEMENT

Patients were monitored in a rented recovery ward; they were encouraged to mobilise as soon as possible and offered oral fluids as tolerated. Postoperative pain was controlled with paracetamol or non-steroidal anti-inflammatory drugs and nausea and vomiting prevented by the administration of metoclopramide. On discharge, patients were provided with a supply of analgesic therapy (ibuprofen 600 mg, 1 tablet twice a day for two days) and a booklet providing information about wound care, symp-

toms to be worried about (fever, chills, bile drainage from the incision, significant nausea or vomiting, abdominal pain) and telephone number to contact if necessary.

DISCHARGE CRITERIA

Patients were discharged by 8 pm, after 8 or more hours' observation. Patients who were able to take fluids orally, with no more than slight pain (evaluated on a 0-10 numerical oral scale NRS); without nausea or vomiting and who had had an uneventful surgical procedure lasting no longer than 90 minutes, were considered eligible for discharge. Patients were not forced to leave the hospital against their will or if they did not feel subjectively well.

Follow up

Follow-up consisted of a telephone interview on the first postoperative day conducted by the doctor on duty in the surgical ward (different from the operating surgeon) and patients were re-assessed at the outpatient clinic on postoperative day 7. On both occasions, patients were asked a series of questions concerning their satisfaction with the day surgery procedure and whether any problems had occurred during the postoperative period.

COSTS AND STATISTICAL ANALYSIS

Operating theatre and staff costs were assessed by the hospital accounts department and calculated according to the median operating time. Expenses for disposable instrumentation were also added in both day-cases and inpatient surgery.

The median cost of a day of stay in a surgical ward and in a day surgical ward was also assessed by the hospital's accounts department.

Results

During the two and half-year period, 43 patients underwent day surgery laparoscopic cholecystectomy. During

the same period, 125 patients underwent elective laparoscopic cholecystectomy as hospital inpatients (24 with a 1-night hospital stay) for gallstones, associated in 21 cases to other surgical procedures. Consequently, 34.4% (43/147) of patients were eligible and 21.5% (43/200) of the total number of LC considered in this series underwent day-case laparoscopic cholecystectomy. DSLC was performed on 28 females (65.1%) and 15 males (39.4%), with a mean age of 49 years (range 24-77). The ASA score was I in 12 cases (27.9%) and II in 31 (72.1%) and the mean body mass index was 26.8 (range 21-37). The indication for day-case surgery was symptomatic gallbladder stones in 42 cases (97.7%) and suspected adenomyoma in 1 case (2.3%).

Mean operation time (from skin incision to closure) was 48 minutes (range 20-85) and the mean duration of anaesthesia was 64 minutes (range 35-100).

Intraoperative cholangiography was never performed and no drain was placed in any case. No conversion to an open procedure was required.

6 patients (13.9%) were considered ineligible for same-day discharge and admitted to the inpatient ward for overnight observation. The reason for the unexpected admission was persisting nausea or vomiting in 4 cases (66.7%) and postoperative pain in 2 cases (33.3%). In all cases, patients were discharged the morning after admission in good general health. Only one patient was re-admitted ten days after a successful day surgery procedure for fever and abdominal pain in the right upper quadrant due to a biliary collection successfully treated by percutaneous drainage. The re-admission rate was 2.3%.

Fortyone patients (95.3%) were completely satisfied with the care they had received as outpatients; 2 patients (4.7%) were not fully satisfied because of the sense of anxiety experienced at home during the first night after discharge from the hospital.

The procedural cost to the hospital was 1463 euros for a day-case laparoscopic cholecystectomy compared with 2511 euros for an inpatient procedure (calculated on a two-night hospital stay). Thus, the reduction in cost for day case cholecystectomy was 41% (1048 euros).

TABLE I -Surgical treatment regimen

		GENERAL DATA	
Procedure Regimen		N° of Patients	
Emergency		32 (16%)	
Elective	168 (84%)	125 (74.4%) inpatient procedure	43 (25.6%) Day case procedure
Total		200	21 (16.8%) plus other procedure 104 (83.2%) sole cholecystectomy

Table II - Demographic data of the DSLC group (43 cases)

Demographic Data		
Male:female	15:28 (34.9%:65.1%)	
Median age	49 years (24-77)	
ASA score	I	12 (27.9%)
	II	31 (72.1%)
Median BMI	26.8 (21-37)	

Table III - Rate of unplanned admission and re-admission in the DSLC group (43 cases)

Outcomes	
Admission	6 (13.9%)
Re-admission	1 (2.3%)
Total	7 (16,27%)

Discussion

Worldwide, laparoscopic cholecystectomy is currently considered the gold standard treatment for symptomatic gallstone disease. Early positive outcomes and results of DSLC were described by Reddick and Olsen in 1990² and it is now widely accepted as a cost-effective and safe procedure for symptomatic gallstones^{3,4}.

Outpatient laparoscopic cholecystectomy facilities set up in the USA⁸ and many medical centres worldwide have performed day-case laparoscopic cholecystectomy in recent years^{6,8}. Although US studies report that DSLC accounts for 60-90% of the LC procedures performed in a number of centres and most patients were safely discharged from hospital after 6-8 hours of postoperative observation^{9,10}, the day-case procedure is not accepted in other areas, particularly in Europe.

In the UK, 11.3%^{3,4} and in Italy just 1.3% of elective laparoscopic cholecystectomies are performed as day-case procedures (Italian Ministry of Health data). Specifically, during 2010, of the 7232 LC performed in the Emilia-Romagna region, just 49 cases (0.67%) were day-case procedures (Emilia-Romagna Agency for Health report).

Despite the evidence available concerning the feasibility and safety of the day-case procedure, the Italian cultural background, both of patients and medical staff, is still inadequate for clear acceptance of the DSLC procedure. The provision of adequate staff education and training prior to wide-spread introduction of the DSLC procedure is essential to the success of this organisational model¹¹. In addition to medical staff training, correct preoperative counselling and information are essential to achieving patient satisfaction and same-day discharge from hospital.

Many authors have suggested that careful patient selection strongly influences the success rate of DSLC¹²⁻¹⁴. Use of standard selection criteria is considered mandatory for DSLC and strict compliance with these strategies seems to guarantee the success rate of the procedure¹⁵⁻¹⁷. These criteria include ASA (American Society of Anaesthesiologists – ASA) score inferior to III, clear understanding of the procedure, home within a short distance from the hospital and, in addition, surgical procedure performed in the morning¹⁸.

The ambulatory preoperative visit is of paramount importance to evaluating the clinical and social criteria for the selection of patients for DSLC¹. In our study, only patients belonging to ASA risk classes I and II, with a body mass index (BMI) less than 35 and a diagnosis of uncomplicated gallstone disease were considered eligible for DSLC. Besides, home within 1 hour of the hospital, availability of a responsible adult to take care of the patient after discharge until the following morning, availability of a telephone line and full comprehension of instructions and prescriptions (social criteria) were considered mandatory^{7,14-17,19}. In our series, all patients fulfilled the above criteria.

Information about the operation, expected postoperative course, possible complications and symptoms and the possibility of an unscheduled ordinary admission after surgery should be discussed thoroughly at the outpatient clinic. All information is given both verbally and in writing. Besides, in our experience, patients tend to feel more secure if examined by an experienced surgeon, ideally those who will be present in the operating theatre, as already described by other authors^{14,20}. This also reduces errors in patient selection that may lead to unplanned admissions^{14,21}.

The success or failure rate of the day-case procedure is reflected in the number of admissions (considered as admission to the inpatient ward for overnight observation) and re-admission after discharge. Very different rates of admission (range 14.3% - 39%) and re-admission (range 1.9% - 8%) are reported in literature^{3,22-24}. In our series, the admission rate of 13.9% and the re-admission rate of 2.3% compare favourably those reported by other centres^{3,25-28}. The reason for unplanned overnight observation was persisting nausea or vomiting in 4 cases (66.7%) and postoperative pain in 2 more cases (33.3%), therefore an effective protocol for postoperative pain control, nausea and vomiting has to be considered an essential factor in a day-case cholecystectomy service³. Postoperative vomiting and pain are considered a major concern in outpatient laparoscopic surgery in several randomised studies, and there is still no consensus on the anaesthetic protocol and postoperative antiemetic and analgesic administration^{19,29-32}. Port site infiltration with local anaesthetic (ropivacaine) seems to provide efficacious postoperative pain control when combined with an efficacious medication protocol³³⁻³⁵. Finally, if we consider the sole case of re-admission for

a biliary collection, even an inpatient procedure and management would not have prevented this complication, since it appeared several days after discharge.

Patient satisfaction was complete in 95.3% of cases and just 2 patients (4.7% of cases) rated their experience as poor, stating that, if asked, they would not retrospectively choose the outpatient approach. The main concern of these patients involved the sense of anxiety experienced at home during the first night after discharge from the hospital and is connected to their participation in a study that involves leaving the hospital on the day of the surgical procedure, which is not currently routine practice³⁶. The good patient satisfaction rate is closely related to correct preoperative counselling and information and education of both staff and the patients¹¹

In our series, the reduction in hospital costs for day-case laparoscopic cholecystectomy amounted to approximately 41%. According to Emilia-Romagna Agency for Health data, during 2010, of the 7232 LC performed in the Emilia-Romagna region, just 49 cases (0.67%) were day-case. In this study, 21.5% of all LC were performed as day cases with a reduction in hospital costs of 1041 euros for each case. If 21.5% of all LS in Emilia-Romagna were performed using the outpatient model, the annual cost savings would be approximately 1,565,606 euros ($[0.215 \times 7223] - 0.67 \times 1041$). The main difference in costs concerns the duration of hospital stays and the difference in cost for a one-day stay in an inpatient ward compared to an outpatient ward, whereas operating theatre costs are considered identical for day-case and inpatient procedures. Besides, although in Emilia-Romagna, the refund given to the hospital by the Regional Health Agency is 3324 euros for each case of laparoscopic cholecystectomy as inpatients and 2660 euros for day cases, the gain is about 813 euros for inpatients ($3324-2511=813$) and 1197 euros for day cases ($2660-1463=1197$): 384 euros in favour of DSLC.

Nevertheless, the most important social and economic saving consists in keeping hospital beds free for complex cases, through a more rational use of resources.

Conclusions

Laparoscopic cholecystectomy can be performed safely in an outpatient setting if there is careful selection and education of patients and the surgical and anaesthesiology team is well-trained. Besides, good results can be achieved by considering inclusion criteria that evaluate not only the clinical but also the socio-economical characteristics of the patients. For admissions to be kept to a minimum, postoperative pain and nausea management has to be carefully planned, as do the discharge criteria evaluated.

At the very least, for selected patients, day-case laparoscopic cholecystectomy is feasible and safe and can lead to reductions in hospital costs.

Riassunto

La colecistectomia videolaparoscopica è attualmente il trattamento elettivo per i Pazienti affetti da litiasi della colecisti e ha ampiamente sostituito il tradizionale trattamento laparotomico. La colecistectomia videolaparoscopica in Day-Surgery è una pratica ben consolidata negli Stati Uniti dove rappresenta il regime di ricovero adottato in una elevata percentuale di pazienti. I primi risultati positivi della colecistectomia videolaparoscopica in Day-Surgery sono stati descritti da Reddick nel 1990 e oggi viene considerata una pratica sicura per il trattamento della colelitiasi sintomatica. Molti autori hanno suggerito come un'attenta selezione dei pazienti in base a criteri rigorosi (età, ASA) contribuisca ad aumentare il successo di tale trattamento. Inoltre lo sviluppo e la diffusione del modello di "Day Surgery" consentono un rapido turn-over dei letti e una riduzione dei costi con evidenti vantaggi per il sistema sanitario; infatti le procedure ambulatoriali o in regime di Day-Surgery possono rappresentare una delle opzioni per diminuire l'uso delle risorse ospedaliere e per risparmiare sui costi.

Dall'analisi dei costi risulta che la colecistectomia videolaparoscopica ha un costo pari a 1463 euro se eseguita in regime di day surgery e un costo pari a 2511 euro in regime ordinario con un ricovero complessivo di 2 notti; possiamo quindi affermare che la colecistectomia videolaparoscopica rappresenta un vantaggio non solo per il paziente, ma che comporta anche una riduzione dei costi. Dai risultati ottenuti, sebbene la casistica presa in esame sia numericamente limitata, si evince che la colecistectomia laparoscopica possa essere considerata una procedura eseguibile anche in day surgery, in modo sicuro e mantenendo un'elevata qualità delle cure offerte. E' però necessaria un'attenta selezione dei pazienti così come un'adeguata informazione ed educazione dello staff sanitario e del paziente stesso.

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