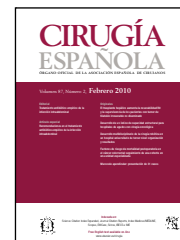


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Original article

Laparoscopic cholecystectomy performed as ambulatory major surgery in a regional hospital. Initial results of a series of 110 cases

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A B S T R A C T

Introduction: The aim of our study was to analyse the reliability of laparoscopic cholecystectomy (LC) in an Ambulatory Surgery unit, in order to encourage its use and achieve better management of health resources.

Material and method: Retrospective study of 110 patients operated on for LC between September 2004 and November 2008. The selection criteria were: absence of prior supramesocolic abdominal surgery, no previous admission for acute cholecystitis, absence of stones in the bile ducts and normal liver function tests, no intake of oral anticoagulants or antiplatelet agents and ASA I-II. All patients were operated using a previously established Major Ambulatory Surgery (MAS) protocol.

Results: The patients included 81 women and 29 men, with a mean age of 51.03 years (range 24–77), of which 57 had a medical and/or surgical history.

The overall morbidity was 6.36% with a mortality of 0%. The conversion rate was 0.9%. A total of 87 patients (79.1%) were discharged at 6 h after surgery, thus fulfilling the criteria of the MAS system. The mean overall hospital stay was 1.49 days (median 0). The reoperation rate was 1.81% and the rate of readmission after discharge was 0.9%.

Conclusions: The performance of outpatient laparoscopic cholecystectomy is feasible and safe. It should be integrated into the activities of Major Ambulatory Surgery, provided that patients are carefully selected and the surgeons performing it take a special interest.

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Colecistectomía laparoscópica en régimen de cirugía mayor ambulatoria en un hospital comarcal: resultados iniciales de una serie de 110 casos

R E S U M E N

Palabras clave:

Colecistectomía laparoscópica ambulatoria
Cirugía mayor ambulatoria
Colelitiasis

Introducción: El objetivo del estudio es analizar la fiabilidad de la colecistectomía laparoscópica (CL) realizada en el ámbito de cirugía mayor ambulatoria (CMA) para generalizar su uso y conseguir una mejor gestión de los recursos sanitarios.

Material y método: Estudio retrospectivo en el que se analizan 110 pacientes intervenidos de CL entre septiembre de 2004 y noviembre de 2008. Los criterios de selección fueron ausencia de cirugía abdominal supramesocólica previa, ausencia de ingresos previos por colecistitis aguda, ausencia de litiasis en la vía biliar principal y pruebas de función hepática normales, ausencia de ingesta de anticoagulantes orales o antiagregantes plaquetarios y clasificación I y II de la American Society of Anesthesiologists. Todos los pacientes fueron intervenidos bajo el protocolo de CMA previamente establecido.

Resultados: Se intervino a 81 mujeres y 29 varones, con una media de edad de 51,03 años (rango: 24-77). Cincuenta y siete pacientes presentaban antecedentes médicos o quirúrgicos.

La morbilidad general fue del 6,36% con una mortalidad del 0%. La tasa de conversión fue del 0,9%. Ochenta y siete pacientes (79,1%) fueron dados de alta a las 6 h de la intervención, cumpliendo así el régimen de CMA. La estancia hospitalaria global media fue de 1,49 días (mediana 0). La tasa de reintervenciones fue del 1,81% y la tasa de reingresos tras el alta fue del 0,9%.

Conclusiones: La realización de CL en CMA es factible y segura. Debería estar integrada en la actividad de las unidades de CMA, siempre que exista una correcta selección de los pacientes y un especial interés por parte de los cirujanos que la realicen.

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Introduction

Laparoscopic cholecystectomy (LC) has been accepted by the scientific community as the gold standard technique for the treatment of symptomatic cholelithiasis.¹⁻³ However, performing LC as major ambulatory surgery (MAS) is controversial for a number of reasons.⁴

In this study, we analysed the results from 4 years of implementing LC under a MAS regime with an early discharge at 6 hours after surgery. We wanted to answer the following question: is it possible to use LC routinely as MAS for better management of health resources? We will therefore analyse the impact of performing LC as MAS in terms of morbidity and mortality, and compare these with the national results for LC with a hospital stay. In addition, we will analyse the social and health problems that might lead to a change in the strategy previously developed for LC within a MAS regime, to improve patient selection.

Patients and methods

This is a retrospective study analysing 110 patients who underwent LC as MAS in our department between September 2004 and November 2008. The selection criteria were absence of supramesocolic abdominal surgery, absence of prior admissions for acute cholecystitis, no stones in the main bile

duct and liver function tests within normal limits, no intake of oral anticoagulants or antiplatelet agents and an American Society of Anesthesiologists status classification of I or II.

The surgeon who performed the surgery interviewed all patients in consultation, and provided them with all the information regarding admission on the day of the operation, the operation itself and the postoperative period. Particular attention was given to the topic of discharge 6 hours after the operation if patients met the previously established criteria. Patients who refused to accept the operation under these conditions were not included.

There were 81 women (73.6%) and 29 men (26.4%) with a mean age of 51 years (range 24-77, median 52). The personal history and clinical symptoms are listed in Table 1.

LC was performed in 100% of the operations with four entry points. The surgeon had carried out more than 50 similar procedures previously.

After regaining consciousness and being discharged from the unit, the patient was admitted to the MAS unit, where the previously established nursing care was given. In the following hours, the surgeon assessed the patient's clinical situation and authorised discharge from the hospital with a range of care instructions. We made a telephone call 6 h after discharge and a clinical visit was arranged for 7-10 days after surgery.

SPSS software version 14.0 was used for the statistical analysis, and a significance level of 5% established. In the

univariate analysis, quantitative variables were expressed by the measures of central tendency and dispersion (mean and standard deviation) and qualitative variables were expressed as absolute numbers and percentages. Confidence intervals of 95% were calculated for both types of variables. In the bivariate analysis, the comparison between qualitative variables was performed using the χ^2 test. In addition, the odds ratio was calculated between the exposure factor and the outcome variables, as well as the Student t-test to compare the means of the quantitative variables. The sample size of 110 patients allowed a 6% expected ratio to be estimated, with a precision of 4.4% at a confidence level of 95%.

Table 1 – Medical or surgical history and clinical presentation

	Number of patients	%
Medical history		
HTN	20	18.2
Obesity (BMI>25)	18	16.4
Respiratory disease	7	6.4
Previous ERCP	7	6.4
Cancer	3	2.7
Diabetes mellitus	2	1.8
TED	1	0.9
Surgical history		
Appendectomy	15	13.6
Hysterectomy	13	11.2
Caesarean	10	9.1
Diagnostic laparoscopy	2	1.8
Urologic surgery	1	0.9
Presentation		
Biliary colic	87	79.1
Dyspepsia	24	21.8
Acute pancreatitis	6	5.5
Previous episode of CBDL	6	5.5
Polyp/adenoma (incidental finding)	3	2.7

BMI indicates body mass index; CBDL: common bile duct ligation; ERCP: endoscopic retrograde cholangiopancreatography; HTN: hypertension; TED: thromboembolic disease.

Results

One hundred and five patients (95.5%) had no intraoperative complications described in the surgical protocol. In the remaining 5 (4.5%), there were 2 cases of organ damage (liver in both cases) and 3 cases of a bile duct rupture with a bile leak into the cavity. The conversion rate to laparotomy was 0.9%, corresponding to a single case, due to difficulty in identifying anatomical structures.

Anatomical pathology revealed gallstones in 94 patients (85%), chronic cholelithiasis-cholecystitis in 13 patients (12%), acute cholelithiasis-cholecystitis in 2 patients (2%) and polyp/adenoma in one patient (1%).

Eighty seven patients (79.1%) were discharged 6 hours after surgery, thus meeting MAS criteria. Reasons for admitting the remaining 23 (20.9%) included 9 cases of poorly controlled pain and vomiting, 3 cases of haemodynamic instability, 3 cases of non-specific dizziness, 2 cases for social reasons, 2 cases indicated by the surgeon, 2 cases of emphysema, 1 case of conversion to open surgery and 1 case due to urine retention. The morbidity rate was 6.36%, corresponding to the complications listed in Table 2. Two patients (1.8%) underwent reoperation for morbidity-related reasons, both

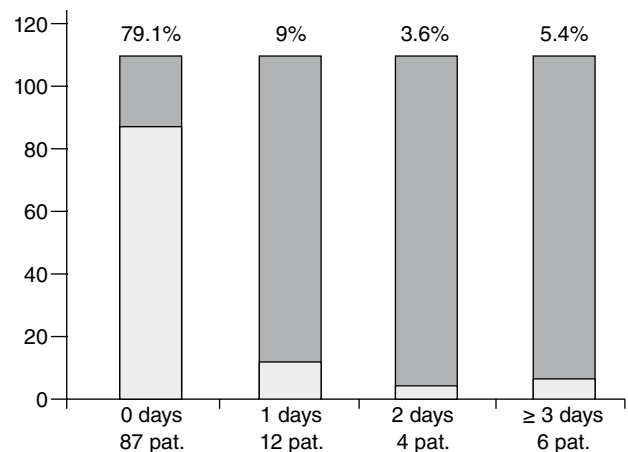


Figure – Hospital stay distribution. pat. indicates patients.

Table 2 – Reason for admission, morbidity and list of reoperations

Reason for admission	n	Morbidity	n	Reoperation	n
Poorly controlled pain/vomiting	9				
Haemodynamic instability	3	Haemoperitoneum	1	Gallbladder bed bleeding	1
Dizziness	3	Signs of anaemia	1		
Social	2	Bleeding trocar	1		
Surgical indication	2	Bile leak	1		
Subcutaneous emphysema	2	Extensive emphysema	1		
Reconversion	1	Hemoperitoneum	1	Gallbladder bed bleeding	1
Retention of urine	1	Urinary tract infection - retention	1		
	23 (20.9%)		7 (6.4%)		2 (1.8%)

Table 3 – List of statistically analysed parameters

Variable	n		OR (confidence interval)		Statistical significance	
	Morbidity	Admission	Morbidity	Admission	Morbidity	Admission
Sex (men vs women)	2/29 (6.9%)	6/29 (20.7%)	0.895 (0.184-4.363)	1.014 (0.443-2.323)	0.891	0.973
Age*					0.076	0.238
Clinical profile						
Colic	6/87 (6.9%)	18/87 (20.7%)	0.630 (0.080-4.979)	1.051 (0.437-2.528)	0.656	0.912
Cholecystitis	1/10 (10%)	3/10 (30%)	0.600 (0.080-4.499)	0.667 (0.239-1.857)	0.621	0.458
Dyspepsia	2/24 (8.3%)	7/24 (29.2%)	0.698 (0.144-3.374)	0.638 (0.297-1.370)	0.655	0.261
Personal history						
HTN	5/19 (26.3%)	8/19 (42.1%)	0.084 (0.017-0.399)	0.391 (0.194-0.789)	0.0001	0.012
CBDL	1/6 (16.7%)	1/6 (16.7%)	0.346 (0.049-2.434)	1.269 (0.204-7.891)	0.288	0.793
Respiratory disease	1/7 (14.3%)	1/7 (14.3%)	0.408 (0.057-2.935)	1.495 (0.235-9.528)	0.375	0.656
Obesity	2/20 (10%)	4/20 (20%)	0.556 (0.116-2.661)	1.056 (0.403-2.766)	0.461	0.912
Previous surgery	4/33 (12.1%)	11/33 (33.3%)	0.321 (0.076-1.357)	0.468 (0.230-0.950)	0.105	0.036

CBDL indicates common bile duct ligation; HTN, hypertension; OR, odds ratio.

*ANOVA test.

for haemoperitoneum. The readmission rate was 2.7%: all 3 readmitted patients had residual choledochal calculi.

The average overall stay of patients was 1.49 days (mode 0, median 0, range: 1-62), distributed as shown in Figure. There were 2 cases of extensive stays. One was 46 days for a 58-year old woman who underwent reoperation because of haemoperitoneum caused by poor liver bed haemostasis and postoperative respiratory failure which required her admission to the ICU. The stay of 62 days was the case of a 68 year old man with a bile leak originating from the cystic stump, which required percutaneous drainage, endoscopic retrograde cholangiopancreatography and postoperative papillotomy. In addition, during the postoperative period, there was an episode of chest pain consistent with non-Q wave acute myocardial infarction (no known history of heart disease) which further prolonged the hospital stay.

To improve patient selection and therefore our results, we studied whether there was a statistical correlation between preoperative variables, such as previous symptoms, a medical or surgical history, age and sex with the possibility of postoperative complications or re-admission. The results obtained are shown in Table 3. They show statistically significant differences between variables such as history of hypertension and the possibility of presenting an episode of illness and re-admission.

Discussion

The LC technique is considered to be the gold standard in the treatment of symptomatic cholelithiasis. The advantages to both patient and health system are very well established.^{1,5-7}

At the same time that the laparoscopic approach was becoming popular, we witnessed several changes in the health care management designed to provide better use of resources without negatively affecting health care and

patient outcomes. The creation of MAS units is pursuant to this objective, and many health care activities are carried out in these units.

However, implementation of LC as MAS is not present in all of Spain's national health service hospitals. Surgeons see an unnecessary "risk" to the patient's health because they know there may be complications after completing a LC.⁴ This is the main reason why LC as a MAS procedure (with discharge on the day of surgery) has not yet been firmly established in our hospitals. For example, in Britain only 11% of cholecystectomies are performed this way,² as in Finland.³ In Spain, in a multicentre study for the development of a clinical pathway for LC, only 3.8% of cases of LC were performed on an outpatient basis.⁷ More recently, a Spanish publication noted that 26.5% of patients with symptomatic cholelithiasis would be eligible for MAS⁴ even according to the strictest criteria.

Nevertheless, studies show that the LC as MAS is reliable and effective, with the same morbidity and mortality results and rates of conversion to open surgery as LC in hospitalised patients, as well as a similar degree of patient satisfaction and perceived quality.^{2,3,5,6,8,9} Previous studies have shown that the occurrence of major complications such as biliary fistula are usually diagnosed during surgery or after 48 hours, which would mean they would go equally unnoticed in LC procedures performed with admission.^{4,9,10}

Our results are comparable with those seen in the literature regarding LC,^{2,3,5-7,9} with a morbidity rate of 6.36% (6%-7%), a conversion rate of 0.9% (1.2% to 5%), reoperation in 1.8% (1%), hospital admissions of 20.9% (8%-40%), readmission of 2.7% (2%-4%), and mortality of 0%.

We must also note that many authors provide results related to outpatient treatment programs with an overnight stay.⁸ In our case, any patient not discharged 6 hours after surgery was admitted to hospital. This is the why the rate of exclusion of patients from the ambulatory regime

was somewhat higher than generally seen in the medical literature, as 52.2% (12 patients out of 23) required only an overnight stay. A recent meta-analysis showed the percentage of patients requiring unplanned prolonged hospitalization was the same (18%), regardless of whether the patient was treated on an ambulatory basis or given an overnight stay.⁹

Economically speaking, a recent study³ estimated that spending per patient under the MAS regime was €1836, while admitted patients cost €2712, meaning that MAS leads to health care savings of 32%; this is similar to data found in other studies.⁶

We believe it is important to compare these results with those on a national level and those from our own studies in hospitalised patients during the same period. This study is being carried out at the moment. With a larger sample size and greater statistical power, we could establish new selection criteria, thereby improving our results. Of course, we believe that the proper selection of patients, a personal interview and interaction between surgeon and patient are necessary to ensure the success of the managed care. Having demonstrated the benefits, we hope for an improvement in the legal framework, so that surgeons feel properly supported in implementing this mode of care, and can make it more generally available.

Conclusions

Performing LC as outpatient surgery is feasible, safe and efficient. We believe this process of care should be integrated into the activity of the MAS unit, provided there is proper patient selection, specific interest on the part of surgeons performing it and sufficient hospital resources.

Conflicts of interest

The authors affirm that they have no conflicts of interest.

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