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# Feasibility of Routine Ambulatory Laparoscopic Cholecystectomy in Brazil

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## ABSTRACT

**Background and Objectives:** In several developed countries, most laparoscopic cholecystectomies (LCs) are performed as an ambulatory operation (ALC) with a high rate of success. In Latin America, the experience with this procedure is still limited. Our objective is to evaluate the feasibility to implement ALC in a Brazilian teaching hospital.

**Methods:** Data obtained from electronic medical records and study protocols of all patients who underwent an LC between January 2011 and March 2018 were evaluated. All patients with chronic or acute cholecystitis were initially considered for an ALC.

**Results:** Of a total of 1645 patients who underwent LC, 1577 (95.9%) were discharged on the same day of the operation. The main reasons for hospital admission after ALC were patient refusal to be discharged (n = 23; 1.4%), nausea and vomiting (n = 15; 0.9%), and complicated acute cholecystitis. No patient was excluded from consideration for ALC based only on age, history of previous upper abdominal operation, and presence of comorbidity. Patient age ranged from 12 to 100 years, with a mean of  $50.23 \pm 15.35$  years. Intraoperative and postoperative complication rates were 0.4% and 5.5%, respectively. Most perioperative complications were because of technical surgical difficulties and complications common to most abdominal operations (surgical site, pulmonary, urinary, and venous complications). Thirteen (0.8%) patients were readmitted to the hospital because of abdominal pain and fever (n = 4), pneumonia (n = 3), deep venous thrombosis (n = 3), or urinary retention (n = 3).

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Informed consent: Dr. Coelho declares that written informed consent was obtained from the patient/s for publication of this study/report and any accompanying images.

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**Conclusions:** ALC may be performed in Brazil with low rates of morbidity, mortality, and hospital readmission. Its implementation should be stimulated in Latin America.

**Key Words:** Ambulatory surgery, Laparoscopic cholecystectomy, Cholelithiasis.

## INTRODUCTION

Laparoscopic cholecystectomy (LC) is one of the most common surgical procedures worldwide.<sup>1,2</sup> Minimal trauma, rapid recovery, low rate of postoperative complications, and improvements in anesthetic techniques have contributed to progressively reduce postoperative hospital stays.<sup>3–5</sup> LC has been performed as an ambulatory procedure in several countries with high rates of success and acceptance.<sup>6–10</sup> Ambulatory or outpatient LC (ALC) reduces health care costs and relieves pressure on the need for hospital beds.<sup>11–12</sup> In addition, patient satisfaction is high. In recent years, LC has gained popularity and is widely accepted.<sup>13–15</sup>

Presently, most LCs are performed in ambulatory settings in the United States and some European countries.<sup>9</sup> In Latin America, ALC is slowly gaining acceptance from patients and the scientific community.<sup>16–19</sup> Brazilian experience is limited to a few publications with small number of patients.<sup>20</sup> To the best of our knowledge this is the largest series of ALC in a Latin country. The objective of our study is to evaluate the feasibility of a large series of patients who underwent ALC in a Brazilian teaching hospital.

#### **METHODS**

All consecutive patients who were admitted to our surgical unit at the Hospital Nossa Senhora das Graças, Curitiba, Brazil, for LC January 1, 2011, to March 31, 2018, were considered for this retrospective study. Data were obtained from electronic medical records and study protocols of all patients who underwent either elective or emergency cholecystectomy for chronic and/or acute cholecystitis. Patients who underwent cholecystectomy for neoplasia were excluded from the study. Critically ill pa-

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tients with acute cholecystitis with high risk for cholecystectomy underwent percutaneous transparietohepatic cholecystostomy and also were excluded from the study. Patients who underwent additional surgical procedures, except umbilical hernia repair and liver biopsy, were excluded from the study.

Indications for cholecystectomy were history or presence of biliary colic, jaundice, cholangitis, or biliary pancreatitis. All operations were performed or supervised by the same surgeon. Surgical residents participated in all procedures.

As a protocol of our surgical unit, all patients with chronic or acute cholecystitis, including those who underwent a previous abdominal operation, were initially considered for ALC. In cases of conversion to open cholecystectomy, the indications were recorded. Patients with the presence or a history of acute pancreatitis, jaundice, and dilation of the common bile duct on ultrasonography underwent magnetic resonance cholangiography. If common bile duct stones were identified, retrograde cholangiopancreatography and endoscopic stone extraction were performed.

As recommended by the International Association for Ambulatory Surgery, ALC, also known as same-day or outpatient LC, is defined as a surgical procedure performed in a patient who is admitted and discharged on the same workday.<sup>21</sup> When the patient was admitted to the hospital for >24 hours or required an overnight hospital stay, the procedure was called inpatient LC.

All patients underwent complete clinical evaluation and all necessary diagnostic examinations before the operation. Preadmission anesthesia and nursing consultations were performed 1 to 7 days before the surgical procedure. Complete verbal and written information on the procedure and postoperative follow-up was given to the patients before the operation. A signed informed consent form for the operation was also obtained from all the patients. All patients were required to have a responsible adult available to accompany them home and stay with them for  $\geq 24$  hours.

All patients were admitted to the hospital 1 to 3 hours before the procedure. The operation was performed under general anesthesia. Thromboembolism prophylaxis with enoxaparin sodium 40 mg was administered subcutaneously at the anesthesia induction in patients  $\geq 40$ years old, patients with obesity, or patients with a history of previous thromboembolism. Antibiotic prophylaxis was given to patients with complicated acute cholecystitis or gallbladder perforation with bile and/or stone spillage into the abdominal cavity.

After routine temporary nasogastric tube insertion, the abdominal cavity was insufflated with  $CO_2$  at an intraabdominal pressure of  $\leq 14$  mm Hg. Four trocars (2 of 5 mm and 2 of 10 mm) were carefully inserted into the abdominal cavity. Operative cholangiography was performed only in selected cases—dilation of common bile duct, difficulty of identification of biliary tree anatomy, and suspicion of biliary tree lesion. Immediately before wound closure at the end of the operation, all layers of the 4 surgical incisions were infiltrated with local anesthetic (bupivacaine 0.5%).

Thirty-five patients underwent additional procedures: umbilical hernia repair (n = 23) and liver biopsy (n = 12). In the presence of umbilical hernia, the umbilicus trocar was inserted into the hernia ring after its complete dissection. At the end of the cholecystectomy, the hernia ring was closed with separate stitches after gallbladder removal.

The patients received a single intraoperative dose of intravenous parocoxib sodium 40 mg, tramadol hydrochloride 100 mg, and dipyrone 2 g for analgesia during the induction of anesthesia. A single dose of ondansetron 4 mg was also administered intravenously before completion of the procedure to prevent postoperative nausea and vomiting (PONV).

After the operation, patients remained in the recovery room for 60 to 90 minutes with intravenous analgesia medications administered as needed. Then, they remained under observation in a hospital room for 5 to 9 hours. The patients were encouraged to ambulate and to ingest a liquid diet as tolerated as soon as possible.

The patients were discharged from the hospital after reevaluation by the surgical team. Criteria for hospital discharge included stable vital signs, adequate level of consciousness, ability to ambulate, spontaneous diuresis, low abdominal pain, and acceptance of an oral diet. Analgesic prescriptions (acetaminophen and codeine) and discharge instructions, including to call the surgical team or to go to the emergency department if necessary, were given to the patients at hospital discharge. Ambulatory appointment was scheduled on the seventh postoperative day and at 1 and 3 months after surgery. Follow-up was extended as needed in the presence of complications.

The study was approved by the Ethical Committee of the Federal University of Parana, Curitiba, Brazil. The following data were obtained and analyzed: age, sex, clinical and diagnostic test findings, American Society of Anesthe-

Table 1.Reasons for Hospital Admission After AmbulatoryLaparoscopic Cholecystectomy				
Reason	n	%		
Patient refusal to be discharged	23	1.4		
Nausea and vomiting	15	0.9		
Complicated acute cholecystitis	15	0.9		
Conversion to open surgery	5	0.3		
Urinary retention	5	0.3		
Intestinal perforation	2	0.1		
Others	3	0.2		
Total	68	4.1		

siologists (ASA) Score, operative findings and complications, operative conversion, type of operation, postoperative complications and mortality, hospital stay duration, and hospital readmission. Values were expressed as mean  $\pm$  standard deviation (SD). Statistical analysis was performed using the IBM SPSS Statistics version 23.0 program (IBM Inc., Armonk, NY). The  $\chi^2$  test was used to determine the difference between the expected frequencies and the observed frequencies of 2 groups. Results with a value of  $p \leq .05$  (5%) were considered as statistically significant.

## RESULTS

Of a total of 1645 patients who underwent LC, 1577 (95.9%) were discharged on the same day of the operation. Sixty-eight (4.1%) patients stayed in the hospital for >24 hours or required an overnight stay (inpatient LC).

The reasons for hospital admission after ALC are displayed in **Table 1**. The main reasons were patient refusal to be discharged (n = 23; 1.4%), PONV (n = 15; 0.9%), and complicated acute cholecystitis (n = 15; 0.9%), such as gallbladder empyema or gangrenous acute cholecystitis. Conversion to open cholecystectomy was required in 5 patients (0.3%) in whom the anatomy of the biliary tract was not adequately identified because of intense gallbladder fibrosis and adherence to adjacent structures. Most patients admitted to the hospital (n = 47; 2,9%) were discharged on the second postoperative day.

#### **Demographic and Clinical Characteristics**

**Table 2** shows the demographic and clinical characteristics of the patients. Patient age ranged from 12 to 100 years, with a mean  $\pm$  SD of 50.23  $\pm$  15.35 years. There

Table 2.Demographic and Clinical Characteristics of Patients WhoUnderwent Ambulatory Laparoscopic Cholecystectomy			
Characteristic	n	%	
Number	1645		
Age (years)			
Mean $\pm$ SD	$50.23 \pm 15.35$		
Range	12-100		
Sex			
Female	1,105	67.2	
Male	540	32.8	
Clinical presentation			
Biliary colic	1,645	100	
Fever	9	0.5	
Jaundice	13	0.8	
Prior abdominal surgery	366	22.2	
ASA Score			
Ι	770	46.8	
II	849	51.6	
III	25	1.5	
IV	1	0.1	

ASA = American Society of Anesthesiologists.

were 1105 female patients (67.2%) and 540 male patients (32.8%). The female:male ratio was 2:1.

Preoperative ASA Score distribution of the patients is also shown in **Table 2**. Almost all patients had score I (normal healthy patients) or score II (patients with mild systemic disease). Twenty-five patients (1.6%) had score III (patient with severe systemic disease that is not life-threatening), and only 1 patient (0.06%) had score IV (patient with severe systemic disease that is a constant threat to life).

**Table 3** displays intraoperative and postoperative data. Operative times range from 25 to 360 minutes, with a mean  $\pm$  SD of 67.8  $\pm$  27.2 minutes. A total of 168 (10.2%) patients had acute cholecystitis. Intraoperative complications occurred in 6 (0.4%) patients: bronchospasm at extubation (n = 2), intestinal perforation (n = 2), hepatic laceration (n = 1), and lesion of the right hepatic artery (n = 1).

Postoperative complications are shown in **Table 4**. The most common complications were associated with the wound at the umbilicus, namely infection, hematoma, and incisional hernia.

Table 3.Intraoperative and Postoperative Data			
Data	Ν	%	
Operative time (min)			
Mean ± SD	$67.8 \pm 27.2$		
Range	25-360		
Acute cholecystitis	168	10.2	
Intraoperative complications	6	0.4	
Postoperative complications	90	5.5	
Mortality	3	0.2	

Table 4.   Postoperative Complications*			
Complication	Ν	%	
Surgical site infection	13	0.79	
Pulmonary atelectasis	11	0.69	
Incisional hernia	10	0.61	
Venous thrombosis	9	0.55	
Urinary retention	8	0.49	
Subcutaneous hematoma	8	0.49	
Subhepatic abscess	4	0.24	
Cardiac arrhythmia	4	0.24	
Urinary infection	3	0.18	
Pneumonia	3	0.18	
Biliary fistula	2	0.12	
Skin burning	1	0.06	
Others	14	0.85	
Total	90	5.47	
*Some patients had >1 complica	tion.		

Four patients presented with fever, abdominal pain, and loss of appetite. After identification of subhepatic abscess with the use of tomography, the patients were successfully treated with broad-spectrum intravenous antibiotics (n = 2) and ultrasound-guided percutaneous drainage and parenteral antibiotics (n = 2). Biliary fistula was diagnosed in 2 patients who presented with subhepatic fluid collection. Both patients were effectively treated conservatively with ultrasound-guided percutaneous tube drainage.

Three patients died (0.2%); the causes of death were pneumonia, myocardial infarction, and *Pseudomonas* sepsis.

A total of 484 (29.7%) patients were  $\geq 60$  years old. The mean  $\pm$  SD age in the younger group was 42.55  $\pm$  10.78 (range, 12–59) years, and that in the older group was 68.65  $\pm$  7.03 (range, 60–100) years. There was no difference in the rate of intraoperative complications between the younger group (n = 4; 0.3%) and the older group (n = 2; 0.4%) (*P*.999). Postoperative complication rate was lower in the younger group (n = 55; 4.7%) than in the older group (n = 35; 7.2%) (*P* = .042).

Body mass index (BMI) was not recorded in 134 patients. Of the remaining 1511 patients, 1238 (81.9%) had a BMI < 30 kg/m<sup>2</sup> (nonobese patients), and 273 (18.1%) had a BMI of  $\geq$ 30 kg/m<sup>2</sup> (obese patients). The mean  $\pm$  SD BMI was 23.6  $\pm$  2,2 (range, 20.1 to 29.9) kg/m<sup>2</sup> in the nonobese group and 34.8  $\pm$  3.5 (range, 30 to 44.3) kg/m<sup>2</sup> in the obese group. There was no difference in intraoperative and postoperative complication rates between the 2 groups (P = 1.0 and P = .34, respectively).

#### Return to the Hospital

A total of 32 (2.0%) patients went to the emergency department for consultation before the scheduled postoperative ambulatory appointment. The most common complaints were abdominal pain and wound hematoma or bleeding. Most patients were simply reassured. Thirteen (0.8%) patients were readmitted to the hospital because of abdominal pain and fever (n = 4), pneumonia (n = 3), deep venous thrombosis (n = 3), or urinary retention (n = 3).

## DISCUSSION

Our study confirms the safety of ALC with low morbidity and mortality in patients with either chronic or acute cholecystitis in a teaching hospital in Brazil. Careful selection of patients is pivotal to avoid postoperative complications. Patients with risk for complications or who require special assistance should be excluded from the ALC protocol.

Some authors have suggested that the presence of some preoperative criteria, such as older age, ASA grade >3 or 4, length of operation, acute cholecystitis, and previous abdominal operation, would be indications for patient exclusion from ACL protocol to avoid complications.<sup>7,14,21,22</sup> However, in the largest retrospective study on the outcomes of LC in the elderly, Rao et al.<sup>24</sup> demonstrated that ALC is safe in patients older than 65 years. The complication and mortality rates in the elderly were low and similar in the ambulatory and nonambulatory groups. The authors have concluded that older age alone should

not be considered an exclusion factor for ALC. Many other investigators have failed to show correlation between other perioperative or demographic criteria, such as diabetes, obesity, and previous abdominal operation, and need to hospital admission for overnight observation.<sup>7,13,14</sup>

In our study, no patient was excluded from consideration for ALC based solely on age, history of previous upper abdominal operation, and presence of comorbidity. Although preoperative risk factors increase the possibility of overnight hospital admission, their presence alone should not determine whether the patient should be excluded from the ALC protocol. Occurrence of perioperative complications and inadequate postoperative recovery should be the main factors to determine the necessity for hospital admission.

In a recent literature review, Bueno Lledó<sup>7</sup> reported that the rate of unexpected hospitalization in patients who initially underwent ALC ranges between 6% and 25%. In our study, only 4.1% of our patients were admitted to the hospital after ALC. Despite careful preparation of our patients, the major cause of hospital admission after ALC in the immediate postoperative period was patient refusal to be discharged from the hospital. The patients felt insecure and referred that they were afraid to have pain or complications at home. Other authors have also shown that patient refusal to go home is a major cause for overnight hospital admission after planned ALC.<sup>7</sup>

PONV is a very common and distressing symptom, with an incidence of 10% to 50% after LC performed under general anesthesia.<sup>22,23</sup> PONV may be responsible for delay in hospital discharge or readmission.<sup>23</sup> In our study, PONV was a frequent cause of hospital admission after ALC in the immediate postoperative period. Therefore, it is very important that an adequate anesthetic regimen be implemented to prevent PONV. Selective 5-hydroxytryptamine<sub>3</sub> receptor antagonists, such as ondansentrom and palonosetron, are effective in reducing PONV and should be incorporated into the perioperative plan.<sup>23</sup>

Other important causes of hospital admission after ALC in our study were the diagnosis of complicated acute cholecystitis at surgery, need for conversion to open cholecystectomy, and occurrence of perioperative complications such as urinary retention and perforation of the gastrointestinal tract. These factors are associated with slower postoperative recovery, prolonged hospital stay, and greater possibility of other complications. Therefore, it is important to identify these factors to exclude patients with these conditions from the ALC protocol.<sup>14</sup> These patients should be admitted to the hospital for further observation.

Several authors have demonstrated that ALC has similar complication and hospital readmission rates as those observed after LC with overnight hospital observation.14,22 There are no differences regarding patient satisfaction, pain level, PONV, quality of life, anxiety, well-being, and other postoperative symptoms.<sup>22</sup> In our study, the perioperative complications were not related to early hospital discharge. They were mainly the result of technical surgical difficulties (scleroatrophic gallbladder and visceral adhesion) and complications common to most abdominal operations (surgical site, pulmonary, urinary, and venous complications).25 As reported by other authors, some of our complications were not diagnosed in the early postoperative period.<sup>10,22,24</sup> However, it is unclear if a prolonged hospital stay would have prevented the occurrence of these complications or changed the clinical course of these patients.

Our results are similar to those of other studies performed in Latin America.<sup>16–18,20</sup> The percentage of patients who needed hospital admission for >24 hours after LC varied from 1.9% to 11%. Operative complications varied from 0.6% to 2%. Conversion to open cholecystectomy was reported from 0% to 2.2%. As in our study, the most common cause of conversion to open cholecystectomy in these reports was the difficulty in adequately identifying the anatomy of the biliary tract. There was no mortality in these studies.<sup>16–18,20</sup> This is possibly because of small number of patients in some of these studies and because no data were reported on follow-up after hospital discharge.

Outpatient surgery requires careful planning and preparation to reach patients' satisfaction and avoid complications.<sup>26,28</sup> Preoperative workup is extremely important to increase patients' confidence and cooperation. At our hospital, all our patients have received complete verbal and written orientation on hospital admission, operation and postoperative recovery, and follow-up before the operation. It was emphasized to the patient and the family that a member of the surgical team would be permanently available for contact by phone or in the emergency department of the hospital.

ALC reduces hospital costs significantly with no change in the rate of perioperative complication and patient satisfaction, which is of enormous importance for developing countries with their scarcity of funds.<sup>11,14,22</sup> However, there are several limitations to the implementation of ALC in developing countries, mainly the shortage of appropriate hospital infrastructure. Another major limitation is the surgeons' concern to be involved in medical malpractice litigation because of a possible postoperative complication.

The major strengths of our study are the large sample size and few exclusion factors. The major limitation of our study is the retrospective evaluation of the data of our patients. This is minimized because all surgical procedures were coordinated and supervised by only one surgeon and the data were retrieved from electronic medical records and study protocols.

## CONCLUSIONS

Routine ALC may be implemented in Brazil with few exclusion factors. Because of the safety of ALC with its low rate of morbidity, mortality, and hospital readmission, its use should be encouraged.

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