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A Prospective Cohort Analysis of the Prevalence and Predictive Factors of Delayed Discharge After Laparoscopic Cholecystectomy in Italy: The DeDiLaCo Study

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Background: The concept of early discharge ≤24 hours after Laparoscopic Cholecystectomy (LC) is still doubted in Italy. This prospective multicentre study aims to analyze the prevalence of patients undergoing elective LC who experienced a delayed discharge >24 hours in an extensive Italian national database and identify potential limiting factors of early discharge after LC.

Methods: This is a prospective observational multicentre study performed from January 1, 2021 to December 31, 2021 by 90 Italian surgical units.

Results: A total of 4664 patients were included in the study. Clinical reasons were found only for 850 patients (37.7%) discharged >24 hours after LC. After excluding patients with nonclinical reasons for delayed discharge >24 hours, 2 groups based on the length of hospitalization were created: the Early group (≤24 h; 2414 patients, 73.9%) and the Delayed group (>24 h; 850 patients, 26.1%). At the multivariate analysis, ASA III class ($P<0.0001$), Charlson's Comorbidity Index ($P=0.001$), history of choledocholithiasis ($P=0.03$), presence of peritoneal adhesions ($P<0.0001$), operative time >60 min ($P<0.0001$), drain placement ($P<0.0001$), pain ($P=0.001$), postoperative vomiting ($P=0.001$) and complications ($P<0.0001$) were independent predictors of delayed discharge >24 hours.

Conclusions: The majority of delayed discharges >24 hours after LC in our study were unrelated to the surgery itself. ASA class >II, advanced comorbidity, the presence of peritoneal adhesions, prolonged operative time, and placement of abdominal drainage were intraoperative variables independently associated with failure of early discharge.

Key Words: Laparoscopic cholecystectomy, Early Discharge, Delayed discharge, Outcomes, Predictive factors, Multicentre study

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Laparoscopic Cholecystectomy (LC) is the gold standard for treating benign gallbladder diseases, such as symptomatic gallstones and acute cholecystitis.[1,2] It is now well-established that the safety and feasibility profile of early discharge ≤24 hours after LC is similar to that of the procedure performed on patients with a conventional hospital stay in terms of complications and hospital readmission, with an excellent level of perceived quality by the patients and substantial reduction in health care costs.[3–8] Different factors contribute to successful early discharge ≤24 hours after LC, ranging from good anesthetic practice and surgical technique to careful selection of patients and timing of surgery.[9] Nevertheless, the incidence of delayed discharge >24 hours still ranges from 4.6% to 37% in different series, and the reasons for this include psychosocial issues, postoperative nausea and pain, placement of abdominal drainage, postoperative complications, conversion to open surgery, and residual choledocholithiasis.[7,10,11] Moreover, many studies have shown that the advanced age of the patient, prolonged operating time, presence of abdominal adhesions, and complexity of surgical dissection can affect the early discharge rate and, as such, should be taken into account when selecting patients for elective LC.

The concept of early discharge ≤24 hours after LC is still doubted in many countries, including Italy. The lack of implementation of early discharge after LC in our country is likely to be multifactorial and influenced by organizational and cultural reasons. Among the main factors affecting the application of an early discharge pathway, the fear of medico-legal issues in case of complications and peculiar reimbursement systems might play an important role.

Within this context, a large multicentre study investigating the reasons for delayed discharge >24 hours of LC in our country might enhance the selection process and outcomes of patients undergoing LC. This study aims to

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The study meets and conforms to the standards outlined in the principles of the Declaration of Helsinki of 1975 (as revised in 2008). It is reported under the ethical standards of the responsible committee on human experimentation. The study protocol was approved by the Ethics Committee of the Azienda Tutela Salute (ATS) Sardegna on October 20, 2020 with protocol number 271/2020/CE. All the investigators conducted the study according to the rules of the ethics committee regarding the retrospective collection of data.
Part of this study was presented at the 16th Italian Forum on Risk Management (Sessions: Officina delle Idee and Poster Gallery). Arezzo, Italy, November 30, 2020 to December 3, 2021.
This study has been endorsed by the Italian Association of Hospital Surgeons (ACOI—Associazione Chirurghi Ospedalieri Italiani). The members of the DeDiLaCo Collaborative Group must be considered co-authors of the present article.
The authors declare no conflicts of interest.
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analyze the prevalence of patients undergoing elective LC who experienced a delayed discharge >24 hours in an extensive Italian national database and identify potential limiting factors of early discharge after LC. Results from these analyses can be used to select patients who can be safely discharged on the same day or within 24 hours from the operation and help enhance organizational pathways for early discharge after LC.

METHODS

The Delayed Discharge after day-surgery Laparoscopic Cholecystectomy prospective Observational multicentre study is presented according to the STrengthening the Reporting of OBservational Studies in Epidemiology (STROBE) criteria[12] and conducted in line with the study protocol that was included in the "iFAIR program",[13] a project finalized to the dissemination of FAIR (Findability, Accessibility, Interoperability, and Reuse of digital assets) best practices among the clinical researches in Sardinia (Italy). The study protocol was approved by the Ethics Committee of the Azienda per la Tutela della Salute (ATS) Sardegna on October 20, 2020 with protocol number 271/2020/CE.

On November 1, 2020, the link with the invitation to participate in the study was circulated by an open recruitment call to interested investigators in the field of LC through the ACOI (Associazione dei Chirurghi Ospedalieri Italiani) website. The local leads from 122 Italian surgical units registered their interest in participating in the study through an electronic form (SurveyMonkey©).

After study approval at each center was obtained following local policies, individual patient data (anonymized demographic and clinical data) were entered into the database. Monthly reminders were sent until December 2021, when the database was closed for the primary analyses and left open only for follow-up data until February 2022. Patient data were encoded and collected in an encrypted electronic database (SurveyMonkey©).

Primary and Secondary Outcomes

The primary outcome measure was the rate of patients discharged >24 hours from LC. The secondary outcome measures were intraoperative and postoperative complications, drain insertion, open surgery conversion, operative time, postoperative pain and nausea, and hospital readmission.

Inclusion Criteria

From a clinical perspective, study inclusion criteria were: age ≥18 years, indications for LC including symptomatic cholelithiasis confirmed by ultrasound scan, computed tomography, or magnetic resonance; polypoid gallbladder lesions; gallbladder adenoma polyps; dyskinesia; chronic cholecystitis; previous episodes of acute biliary cholecystitis or biliary pancreatitis; history of choledocholithiasis and Association of American Anesthesiologists (ASA) score. In addition, patients who had a previous hospitalization for complicated biliary disease were discharged from the hospital and returned to the clinic for definitive management and were also eligible for enrollment.

Regarding the postdischarge organizational pathway, the presence of a responsible adult to look after the patient at home for 24 hours postprocedure had to be ensured. Moreover, the availability of immediate telephone contact with the patient after the discharge was mandatory to be included in the study, as well as the possibility of reaching the hospital within 1 hour in case of need.

Exclusion criteria were: body mass index (BMI) >40 Kg/m^2; acute cholecystitis; acute pancreatitis; concomitant choledocholithiasis; obstructive jaundice; pregnancy or breastfeeding; the patient's lack of compliance or inability to provide informed consent; absolute contraindications to laparoscopy (including septic shock, cirrhosis with portal hypertension, severe coagulopathy, and presence of biliary-enteric fistula); and history of an adverse drug reaction to analgesic medications included in the analgesic protocols (ketorolac, paracetamol, ketoprofen).

Patients deemed eligible were asked to fill in the Italian version of the questionnaire "Patient Activation Measure 13" (PAM13-I) to measure patient involvement in the treatment pathway.[14–16]

Patient Data

The following patient data were extracted and analyzed: demographic data (age, gender, BMI), Apfel score for postoperative nausea and vomiting, PAM 13-I, ASA score, comorbidity [diagnosis of diabetes, Charlson Comorbidity Index, (CCI)], preoperative diagnosis, administration of antibiotic prophylaxis, presence of peritoneal adhesions, anomalies of the vascular and biliary anatomy, operative time, conversion to open surgery, drain insertion and hemostatic agents, intraoperative complications, Numerical

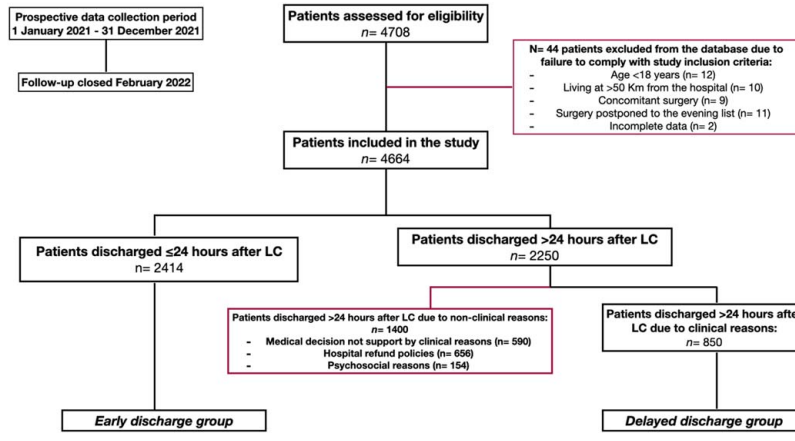

FIGURE 1. DeDiLaCo study flow diagram.

TABLE 1. General Cohort Characteristics

Characteristics	General cohort (n = 4664)
Median (IQR) age, y	56 (46–67)
Age classes, n (%)	—
< 30 years	—
30–50 years	1448 (31.1)
51–70 years	2138 (45.8)
> 70 years	845 (18.1)
Females, n (%)	2706 (58.0)
BMI, n (%)	—
< 30 kg/m^2	3768 (80.8)
30–40 kg/m^2	896 (19.2)
Delayed discharge > 24 h, n (%)	2250 (48.2)
Reasons for delayed patient discharge following day surgery, n (%)	—
Postoperative blood tests derangement	265 (11.8)
Postoperative abscess	9 (0.4)
Postoperative cholangitis	3 (0.1)
Residual choledocholithiasis	6 (0.3)
Conversion to open	64 (2.8)
Medical decisions not supported by clinical reasons	590 (26.2)
Uncontrolled postoperative pain	203 (9.0)
Refund/economic factors	656 (29.2)
Postoperative fever (> 38°C)	50 (2.2)
Surgical site infection	8 (0.4)
Biliary leak	23 (1.0)
Psychosocial reasons	154 (6.8)
Intraoperative/postoperative bleeding	55 (2.4)
Other (specified)	164 (7.3)
Preoperative diagnosis, n (%)	—
Adenomyomatosis	81 (1.7)
Chronic cholecystitis	446 (9.6)
Symptomatic cholelithiasis	3302 (70.8)
Biliary dyskinesia	6 (0.1)
Gallbladder polyp	116 (2.5)
History of acute biliary cholecystitis	334 (7.2)
History of choledocholithiasis	171 (3.7)
History of acute biliary pancreatitis	208 (4.5)
Apfel score, n (%)	—
0	864 (18.5)
1	2066 (44.3)
2	1596 (34.2)
3	134 (2.9)
4	4 (0.1)
ASA score, n (%)	—
I	1356 (29.1)
II	2633 (56.5)
III	675 (14.5)
Median (IQR) Charlson's Comorbidity Index (CCI) score	1 (0–3)
Diabetes, n (%)	447 (9.6)
Antibiotic prophylaxis, n (%)	3445 (73.9)
Peritoneal adhesions, n (%)	2150 (46.1)
Anatomic variants of the biliary tract, n (%)	143 (3.1)
Anatomic variants of the vascular anatomy, n (%)	144 (3.1)
Median (IQR) operating time, minutes	60 (45-80)
Operating time, n (%)	—
< 60'	2097 (45.0)
60'–120'	2295 (49.2)
> 120'	272 (5.8)
Conversion to open surgery, n (%)	100 (2.1)
Reasons for conversion to open surgery, n (%)	—
Adhesions	55 (58.5)
Anatomical variants	12 (12.8)
Bleeding	10 (10.6)
Other	17 (12.1)
Placement of abdominal drainage, n (%)	2573 (55.2)
Placement of hemostatic agents, n (%)	381 (8.2)
Intraoperative complications, n (%)	—
Anesthesiology	7 (0.2)
Bleeding	98 (2.1)
Biliary leak	38 (0.8)
Hollow viscus perforation	12 (0.3)
Other (specified)	95 (2.0)
None	4414 (94.6)
Median (IQR) Numerical Rating Scale (NRS) pain score	2 (1–3)
Postoperative nausea, n (%)	483 (10.4)
Postoperative vomiting, n (%)	168 (3.6)
Postoperative fever > 38°C, n (%)	85 (1.8)
Complications according to Clavien Dindo, n (%)	—
Class I	616 (13.2)
Class II	72 (1.5)
Class IIIa	26 (0.6)
Class IIIb	26 (0.6)
Class Iva	5 (0.1)
Class IVb	1 (0.0)
Class V	5 (0.1)
None	3913 (83.9)
Surgical site infection, n (%)	—
None	4480 (96.0)
Organ space	9 (0.2)
Deep	19 (0.4)
Superficial	156 (3.3)
Unplanned access to a health care acute setting early after the discharge, n (%)	—
None	4232 (90.7)
Self-managed	169 (3.6)
Managed by GP (General Practitioner)	33 (0.7)
Managed in the surgical unit	230 (4.9)
Hospital readmission, n (%)	54 (1.2)

Rating Scale (NRS) for pain at discharge, nausea, vomiting, fever, discharge ≤24 hours from LC, reasons for delayed discharge >24 hours, complications according to Clavien-Dindo,[17] Surgical Site Infection (SSI),[18] unscheduled access to health care facilities within 7 days of surgery, and unplanned hospital readmission (patient readmitted to the ward after initial discharge from the hospital). The presence and severity of the adhesions involving the gallbladder, the occurrence of any intraoperative complications, and the use of drains were documented in the theater notes.

Data Handling and Extraction

In April 2022, a member of the steering committee (N. C.) downloaded the full data set and shared it with the other members for data analysis and discussion. The local leaders provided quality assurance mentorship at every participating site. Centers were asked to validate that all eligible patients had been entered during the study period and to achieve complete data field entry before final submission.

Ethical Considerations

This study was performed in accordance with the principles of the Declaration of Helsinki and Good Epidemiological Practices.[19] All participating centers had institutional review board approval or equivalent after the coordinating center's approval of the study protocol. All

TABLE 2. Reasons for Delayed Patients Discharge > 24 Hours After Laparoscopic Cholecystectomy, n (%)

	N (%)
Clinical reasons	850 patients (37.7%)
Postoperative blood tests derangement	265 (11.8)
Postoperative fever (> 38°C)	50 (2.2)
Postoperative abscess	9 (0.4)
Postoperative cholangitis	3 (0.1)
Residual choledocholithiasis	6 (0.3)
Conversion to open surgery	64 (2.8)
Uncontrolled postoperative pain	203 (9.0)
Surgical Site Infection	8 (0.4)
Biliary leak	23 (1.0)
Intraoperative/Postoperative bleeding	55 (2.4)
Other (specified)	164 (7.3)
Nonclinical, organizational, or behavioral reasons	1400 patients (62.3%)
Medical decision not supported by clinical elements	590 (26.2)
Refund/economic factors	656 (29.2)
Psychosocial reasons	154 (6.8)

study participants provided written informed consent before study enrolment and patient consent was securely stored.

Statistical Analysis

Demographic and clinical characteristics of the patients were reported as absolute numbers and percentages, or as median and IQR (or mean ± SD). The Shapiro-Wilk test was used to assess the normality of quantitative data. Specifically, quantitative variables were summarized with medians and 25° to 75° percentiles in non-normally distributed data or with mean and SD in normal distribution. Pearson χ^2 or Fisher exact tests were used to assess differences between qualitative variables. Student t or Mann-Whitney tests, depending on the distribution, were used to assess differences between quantitative variables. Multivariate logistic regression analysis was performed to identify independent risk factors associated with failed discharge ≤ 24 hours after LC. All significant variables in the simple regression model were included in the multiple logistic regression analysis. Discrimination was assessed with the area under the receiver operating characteristic curve, while calibration was assessed by the Hosmer-Lemeshow (HL) goodness of fit test. A 2-tailed p-value <0.05 was considered statistically significant. Data analyses were carried out with STATA 13.1 (StatsCorp, TX).

RESULTS

From January 1, 2021 to December 31, 2021, 4708 patients were scheduled to undergo elective LC at the 122 surgical units that registered their interest in participating in the study. Of these, 44 patients were excluded from the database due to failure to comply with the inclusion criteria (Fig. 1).

Demographic data and general characteristics of patients included in the total cohort of the Delayed Discharge after day-surgery Laparoscopic Cholecystectomy data set are detailed in Table 1.

Of the finally included 4664 patients, 2250 (48.2%) were discharged > 24 hours after LC. The reasons for delayed discharge > 24 hours were divided into 2 groups. Clinical reasons were found for 850 patients (37.7%), while psychosocial, organizational, or behavioral reasons were reported as causes of delayed discharge > 24 hours for 1400 patients (62.3%), as shown in Table 2.

After excluding patients with no clinical reasons for delayed discharge > 24 hours, 2 groups based on length of hospitalization were created: the Early group with a length of hospitalization ≤ 24 hours (2414 patients, 73.9%) and the Delayed group with hospitalization > 24 hours (850 patients, 26.1%).

TABLE 3. Comparison of Baseline Sociodemographic, Epidemiological and Clinical Variables Between the 2 Study Groups: *Early* Group With a Length Of Hospitalization ≤ 24 hours (2414 patients, 73.9%) and the *Delayed* Group With Hospitalization > 24 hours (850 patients, 26.1%). Psychosocial, Organizational, and Behavioral Reasons Were Excluded

	Discharge ≤ 24 hours		
Characteristics	**No (n = 850)**	**Yes (n = 2414)**	***P***
Median (IQR) age, y	60 (49–72)	54 (44–65)	< 0.0001
Age classes, n (%)			
< 30 years	30 (3.5)	144 (6.0)	< 0.0001
30–50 years	202 (23.8)	828 (34.3)	
51–70 years	373 (43.9)	1106 (45.8)	
> 70 years	245 (28.8)	336 (13.9)	
Females, n (%)	413 (48.6)	1451 (60.1)	< 0.0001
BMI, n (%)	—	—	
< 30 kg/m^2	654 (76.9)	1962 (81.3)	0.01
30-40 kg/m^2	196 (23.1)	452 (18.7)	—
Reasons for delayed patient discharge > 24 hours, n (%)	—	—	—
Adenomyomatosis	6 (0.7)	50 (2.1)	0.01
Chronic cholecystitis	119 (14.0)	158 (6.6)	< 0.0001
Symptomatic cholelithiasis	486 (57.2)	1843 (76.3)	< 0.0001
Biliary dyskinesia	1 (0.1)	3 (0.1)	1.00
Gallbladder polyp	21 (2.5)	72 (3.0)	0.44
History of acute biliary cholecystitis	99 (11.7)	141 (5.8)	< 0.0001
History of choledocholithiasis	55 (6.5)	58 (2.4)	< 0.0001
History of acute biliary pancreatitis	63 (7.4)	89 (3.7)	< 0.0001
Apfel score, n (%)	—	—	< 0.0001
0	192 (22.6)	410 (17.0)	—
1	384 (45.2)	1065 (44.1)	—
2	246 (28.9)	873 (36.2)	—
3	27 (3.2)	65 (2.7)	—
4	1 (0.1)	1 (0.0)	—
ASA score, n (%)	—	—	< 0.0001
I	162 (19.1)	796 (33.0)	—
II	476 (56.0)	1361 (56.4)	—
III	212 (24.9)	257 (10.6)	—
Median (IQR) Charlson's Comorbidity Index (CCI) score	2 (1-4)	1 (0-2)	< 0.0001
Diabetes, n (%)	160 (18.8)	164 (6.8)	< 0.0001
Antibiotic prophylaxis, n (%)	722 (84.9)	1711 (70.9)	< 0.0001
Peritoneal adhesions, n (%)	561 (66.0)	956 (39.6)	< 0.0001
Anatomic variants of the biliary tract, n (%)	67 (7.9)	37 (1.5)	< 0.0001
Anatomic variants of the vascular anatomy, n (%)	40 (4.7)	52 (2.1)	< 0.0001

TABLE 4. Differences in Intraoperative Outcomes Between the 2 Study Groups: *Early* group With A Length Of Hospitalization ≤24 hours (2414 patients, 73.9%) and the *Delayed* Group With Hospitalization >24 hours (850 patients, 26.1%). Psychosocial, Organizational, And Behavioral Reasons Were Excluded

	Discharge ≤24 h		
Characteristics	**No (n = 850)**	**Yes (n = 2414)**	***P***
Median (IQR) operating time, minutes	73 (55–110)	55 (42–70)	<0.0001
Operating time, n (%)	—	—	<0.0001
<60′	256 (30.1)	1645 (55.7)	—
60′–120′	450 (52.9)	1025 (42.5)	—
>120′	144 (16.9)	44 (1.8)	—
Conversion to open surgery, n (%)	86 (10.1)	7 (0.3)	<0.0001
Postoperative Nausea, n (%)	632 (74.4)	1102 (45.6)	<0.0001
Postoperative Vomiting, n (%)	162 (19.1)	100 (4.1)	<0.0001
Intraoperative complications, n (%)	132 (15.5)	58 (2.4)	<0.0001
Intraoperative complications, n (%)	—	—	—
Anesthesiology	5 (0.6)	2 (0.1)	<0.0001
Bleeding	55 (6.5)	18 (0.8)	—
Biliary leak	21 (2.5)	10 (0.4)	—
Hollow viscus perforation	10 (1.2)	1 (0.0)	—
Other (specified)	41 (4.8)	27 (1.1)	—
None	718 (84.5)	2356 (97.6)	—

Comparison Between the 2 Study Groups: Demographic Characteristics, Intraoperative and Postoperative Outcomes

Differences in demographic variables between the 2 groups are reported in Table 3.

The comparative analysis of baseline characteristics showed statistically significant differences between patients in the Early group and those in the Delayed group in terms of median age in years ($P<0.0001$), female gender ($P<0.0001$), BMI ≥30 Kg/m^2 ($P=0.01$), chronic cholecystitis ($P<0.0001$), previous episodes of acute cholecystitis ($P<0.0001$), history of choledocholithiasis ($P<0.0001$), previous episodes of acute biliary pancreatitis ($P<0.0001$), ASA class III patients ($P<0.0001$), higher CCI score ($P<0.0001$), Apfel score III ($P<0.0001$), median PAM score ($P<0.0001$), diagnosis of diabetes ($P<0.0001$), peritoneal adhesions ($P<0.0001$), anatomic variants of the biliary tract ($P<0.0001$), and anatomic variants of the vascular anatomy ($P<0.0001$).

The analysis of intraoperative outcomes in the 2 study groups is reported in Table 4. Patients in the Early group had shorter median operating time compared with patients in the Delayed group ($P<0.0001$), lower rate of conversion to open cholecystectomy ($P<0.0001$), less placement of intra-abdominal drainage ($P<0.0001$) and hemostatic agents ($P<0.0001$), and a lower rate of intraoperative complications ($P<0.0001$). Specifically, patients discharged ≤24 hours reported a statistically significant ($P<0.0001$) lower rate of intraoperative bleeding, biliary leak, accidental perforation of hollow viscus, and complications related to anesthesia.

The analysis of postoperative outcomes in the 2 study groups (Table 5) showed statistically significant differences in favor of the group of patients who were discharged ≤24 hours concerning median NRS pain score ($P<0.0001$), postoperative nausea and vomiting ($P<0.0001$), fever ($P<0.0001$), postoperative complications ($P<0.0001$), SSI ($P<0.0001$), unscheduled access to health care facilities within 7 days of surgery ($P<0.0001$), and hospital readmission ($P=0.003$).

Comparison Between the 2 Study Groups: Univariate and Multivariate Analyses

Univariate and multivariate analyses are reported in Table 6. Of all the factors analyzed in the univariate analysis, age >51 years, male gender, BMI >30 Kg/m^2, Apfel score I-II, ASA score II-III, CCI, diagnosis of diabetes, chronic cholecystitis, interval cholecystectomy after acute cholecystitis, history of choledocholithiasis or acute biliary pancreatitis, presence of adhesions, vascular or biliary anatomy variants, operative time >60 min, placement of

TABLE 5. Differences in Postoperative Outcomes Between the2 Study Groups: Early Group With a Length Of Hospitalization ≤24 hours (2414 patients, 73.9%) and the Delayed Group With Hospitalization >24 hours (850 patients, 26.1%). Psychosocial, Organizational, And Behavioral Reasons Were Excluded

	Discharge ≤24 hours		
Characteristics	**No (n = 850)**	**Yes (n = 2414)**	***p***
Median (IQR) Numerical Rating Scale (NRS) pain score	2 (1–3)	1 (1–2)	<0.0001
Postoperative nausea, n (%)	209 (24.6)	174 (7.2)	<0.0001
Postoperative vomiting, n (%)	102 (12.0)	38 (1.6)	<0.0001
Postoperative fever >38° C, n (%)	72 (8.5)	3 (0.1)	<0.0001
Postoperative complications, n (%)	492 (57.9)	100 (4.1)	<0.0001
Complications according to Clavien Dindo, n (%)	—	—	—
Class I	375 (44.1)	92 (3.8)	<0.0001
Class II	62 (7.3)	5 (0.2)	<0.0001
Class IIIa	20 (2.3)	2 (0.1)	<0.0001
Class IIIb	24 (2.8)	1 (0.0)	<0.0001
Class Iva	5 (0.6)	0 (0.0)	0.001
Class IVb	1 (0.1)	0 (0.0)	0.26
Class V	5 (0.6)	0 (0.0)	0.001
None	358 (42.1)	2314 (95.9)	<0.0001
Surgical site infection, n (%)	79 (9.3)	64 (2.6)	<0.0001
Unplanned access to a health care acute setting early after the discharge, n (%)	—	—	—
None	738 (86.8)	2185 (90.5)	<0.0001
Self-managed	27 (3.2)	124 (5.1)	—
Managed by GP (General Practitioner)	10 (1.2)	12 (0.5)	—
Managed in the surgical unit	75 (8.8)	93 (3.9)	—
Hospital readmission, n (%)	19 (2.2)	21 (0.9)	0.003

TABLE 6. Logistic Regression Analysis to Assess the Relationship Between Sociodemographic, Epidemiological, and Clinical Variables and Failed Discharge After Surgery. Outcome: Delayed Discharge > 24 hours

	Univariate analysis		Multivariate analysis	
Characteristics	**OR (95% CI)**	**p**	**OR (95% CI)**	**p**
Age classes, n (%)	—	—	—	—
< 30 years	Ref.	Ref.	Ref.	Ref.
30–50 years	1.17 (0.77–1.79)	0.46	0.90 (0.53–1.53)	0.70
51–70 years	1.62 (1.07–2.44)	0.02	0.69 (0.40–1.20)	0.19
> 70 years	3.50 (2.28–5.36)	< 0.0001	0.68 (0.36–1.29)	0.24
Females, n (%)	0.63 (0.56–0.73)	< 0.0001	0.92 (0.69–1.23)	0.58
BMI 30- 40 kg/m^2	1.30 (1.08–1.57)	0.01	0.89 (0.67–1.16)	0.38
Apfel score, n (%)	—	—	—	—
0	Ref.	Ref.	Ref.	Ref.
1	0.77 (0.63–0.95)	0.01	0.77 (0.56–1.04)	0.09
2	0.60 (0.48–0.75)	< 0.0001	0.74 (0.50–1.10)	0.14
3	0.89 (0.55–1.43)	0.63	0.73 (0.35–1.55)	0.42
4	2.14 (0.13–34.32)	0.59	0.59 (0.00–4185.04)	0.91
ASA score, n (%)	—	—	—	—
I	Ref.	Ref.	Ref.	Ref.
II	1.72 (1.41–2.10)	< 0.0001	1.32 (1.00–1.76)	0.05
III	4.05 (3.16–5.20)	< 0.0001	2.40 (1.62–3.57)	< 0.0001
Diabetes, n (%)	3.18 (2.52–4.02)	< 0.0001	1.39 (0.97–2.00)	0.07
Median (IQR) Charlson's Comorbidity Index (CCI) score	1.35 (1.29–1.41)	< 0.0001	1.14 (1.04–1.26)	0.001
Adenomyomatosis	Ref.	Ref.	Ref.	Ref.
Chronic cholecystitis	6.21 (2.58–14.96)	< 0.0001	2.32 (0.77–6.95)	0.13
Preoperative diagnosis, n (%)	—	—	—	—
Symptomatic cholelithiasis	2.20 (0.94–5.16)	0.07	1.89 (0.66–5.39)	0.24
Gallbladder polyp	2.43 (0.92–6.45)	0.08	2.14 (0.63–7.31)	0.22
History of acute biliary cholecystitis	5.85 (2.41–14.18)	< 0.0001	2.99 (1.00–8.96)	0.05
History of choledocholithiasis	7.90 (3.14–19.90)	< 0.0001	3.63 (1.14–11.58)	0.03
History of acute biliary pancreatitis	5.90 (2.38–14.60)	< 0.0001	2.88 (0.93–8.95)	0.07
Peritoneal adhesions	2.96 (2.51–3.49)	< 0.0001	1.51 (1.20–1.90)	< 0.0001
Anatomic variants of the biliary tract, n (%)	5.50 (3.65–8.28)	< 0.0001	1.70 (0.93–3.10)	0.09
Anatomic variants of the vascular anatomy, n (%)	2.24 (1.47–3.41)	< 0.0001	0.81 (0.42–1.57)	0.54
Operating time	—	—	—	—
< 60′	Ref.	Ref.	Ref.	Ref.
60′–120′	2.31 (1.94–2.74)	< 0.0001	1.53 (1.21–1.92)	< 0.0001
> 120′	17.19 (11.96–24.72)	< 0.0001	5.82 (3.65–9.29)	< 0.0001
Placement of abdominal drainage, n (%)	3.45 (2.90–4.11)	< 0.0001	2.22 (1.75–2.82)	< 0.0001
Median (IQR) Numerical Rating Scale (NRS) pain score	1.34 (1.27–1.41)	< 0.0001	1.14 (1.06–1.22)	0.001
Postoperative nausea, n (%)	4.20 (3.37–5.23)	< 0.0001	0.91 (0.62–1.33)	0.63
Postoperative vomiting, n (%)	8.53 (5.82–12.49)	< 0.0001	2.66 (1.46–4.85)	0.001
Complications according to Clavien Dindo, n (%)	31.80 (24.96–40.51)	< 0.0001	24.36 (18.40–32.24)	< 0.0001

abdominal drainage, NRS pain score, nausea, vomiting, and postoperative complications were associated with delayed discharge > 24 hours after LC.

However, at the binary logistic regression model, only ASA III score ($P < 0.0001$), CCI ($P = 0.001$), history of choledocholithiasis (P = 0.03), the presence of peritoneal adhesions ($P < 0.0001$), operative time 60 to 120 min ($P < 0.0001$) and > 120 min ($P < 0.0001$), drain insertion ($P < 0.0001$), NRS pain score ($P = 0.001$), postoperative vomiting ($P = 0.001$) and postoperative complications ($P < 0.0001$) were independent predictors of delayed discharge > 24 hours (AUC 0.87, 95% CI 0.85–0.88, Hosmer-Lemeshow test $P = 0.96$; Fig. 2).

DISCUSSION

Our experience supports the conclusion that early discharge ≤24 hours can be safely performed after elective LC.[7,9,20–22] Early discharge strategies after LC are currently practiced in many countries with different penetration rates. In the UK, day-case LC took a long time to become part of the standard practice, but now it is considered routine.[10] The British Association of Day Case Surgery recommends that at least 60% of LCs be performed as day cases[23] for optimal patient outcomes and cost-effectiveness. Increasing the number of elective LCs performed as day-case at 75% was also a key target in the NHS plan issued by the Department of Health in 2015.[24] Following the recommendations, reports from the UK showed that 70% to 85% of patients undergoing LC are discharged home on the day of surgery.[25–27] Equivalent results have been achieved in the USA after implementing same-day discharge protocols for LC.[28] In Italy, since its definition, the National Result Plan has established postoperative hospitalization fewer than 3 days after LC as an indicator of the performance of the surgical units. This goal, reached in 2016 in 72.71% of cases, is based on the literature analysis that documented the postoperative hospitalization after LC being generally between 3 and 5 days.

However, this goal appears anachronistic and not stimulating for achieving new objectives currently achieved in the rest of the world. Undoubtedly, the admission of LC patients overnight increases the pressure on acute hospital beds, with significant economic implications.[21,22,29] Pathways

that include early discharge ≤24 hours after LC are still underused in our country, as demonstrated in the present study, where 47.8% of patients were discharged >24 hours from surgery. Therefore, not only is day-case LC underimplemented, but strategies according to which patients come on the day of their operation and are discharged the following morning are not common. Among the 2250 patients admitted to the hospital for >24 hours after LC, 1400 (62.2%) were admitted without any clinical reason, but only because of organizational reasons, health care refunding policies that favor hospitalization for at least 48 hours (29.2%), personal medical behaviors (26.2%), and psychosocial issues (6.8%). Psychosocial reasons accounted for a large percentage of reasons for delayed discharge also in the study by Cao et al.[6]

As not every patient is suitable to be discharged early, the correct selection of patients for day-case or overnight stay LC is important in terms of patient scheduling, counselling, and allocation of hospital resources. Factors that have been shown to contribute to the failure of early discharge plans in other studies included advanced age, duration of surgery, gallbladder wall thickness, diagnosis of acute cholecystitis, biliary pancreatitis, and advanced comorbidity.[8,28] The results of our study confirm that ASA score >II and advanced comorbidity contribute to delayed discharge. Furthermore, the presence of peritoneal adhesions, prolonged operative time, and drain insertion were intraoperative variables independently associated with failure of early discharge.

PostOperative Nausea and Vomiting (PONV) were associated with prolonged hospitalization. Our results were in keeping with Tebala et al.[30] Their multivariate analysis found that uncomplicated symptomatic gallstones and no history of choledocholithiasis were independently associated with discharge ≤24 hours from the operation. Some of the cited factors, such as ASA score, comorbidities, and history of complicated biliary disease, cannot be altered.

However, knowing these predictive factors of longer hospitalization can allow better patient selection.

Educational and technical strategies can be implemented for other factors, such as abdominal drain, pain, and PONV.[31] The development of PONV in patients undergoing laparoscopic surgery has been found to correlate with the duration of anesthesia[32] and the total amount of carbon dioxide insufflated.[33] The creation of pneumoperitoneum constitutes the first step of every laparoscopic procedure and should be given due consideration. As demonstrated by Ortenzi et al[34] in a recent systematic review and meta-analysis of randomized trials, lowering the pneumoperitoneum pressure has a positive impact on postoperative pain in elective LC. The high rate of drain insertion (55.2%) is another aspect of our study that should be necessarily audited, as meta-analyses of randomized trials have demonstrated lower morbidity, lower SSI, and reduced pain if drains are not used after LC, with no difference in the rates of intra-abdominal collections and length of hospital stay.[35]

It has been suggested that patients candidates for early discharge after LC should be younger than 65 years[7] and with BMI <35 Kg/m^2.[7,36] In our study, although age >70 years was a predictor of delayed discharge in the univariate analysis, no relation between age and delayed discharge was demonstrated in the logistic regression analysis. Gregori et al[37] showed that obesity is not a contributory variable for postoperative complications and prolonged hospital admission. In keeping with Gregori et al, Bowling et al[38] reported that the overall complication rate was equivalent between different BMI groups, and the majority of patients with BMI >30 Kg/m^2 can be planned and successfully complete LC with early discharge ≤24 hours. Even though a limited number of patients were obese in our cohort, we have shown that increased BMI was not associated with worse outcomes after day-case LC.

Furthermore, in our study, male gender is associated in the univariate analysis with delayed discharge after LC but not in the multivariate analysis. Also, a prospective study conducted by El-Sharkawy et al[39] identified male gender as

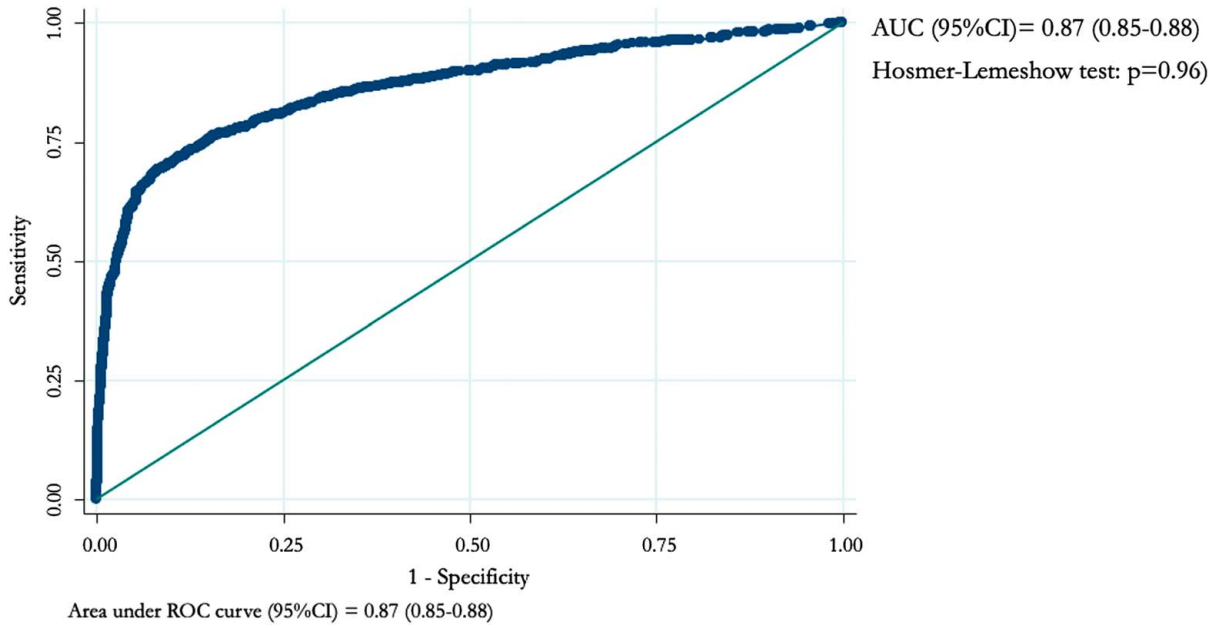

FIGURE 2. The area under the ROC curve. Analysis of the predictive model of delayed discharge >24 hours after LC. [Area Under ROC curve(AUC), 0.87, 95% CI 0.85–0.88, Hosmer-Lemeshow test $P=0.96$].

a factor that impacts the likelihood of same-day discharge following LC.

The main obstacle to developing day-case LC in Italy remains the opinion of many surgeons that at least 24 to 48 hours is necessary to avoid delays in identifying immediate postoperative complications. However, major surgical complications, such as bleeding, biliary leak, and hollow viscus perforation, are usually detected at the time of surgery or immediately after surgery,[40] whereas delayed complications become symptomatic more than 48 hours after LC.[37,41] Therefore, standard hospital admission of 24 to 48 hours does not improve safety and may be avoided in motivated, fit patients within an organized environment.[20,42]

Readmission rate following early discharge ≤ 24 hours after LC is the actual discussion point on whether LC in a short-stay or even same-day surgery pathway is safe and feasible. In our study, the hospital readmission rate was lower than in previous studies (1.2%), and low was the percentage of patients (10.5%) who accessed hospital facilities immediately after discharge. This rate compares favorably with those reported by other authors.[7,9,10,20,30,43] Interestingly, we found no difference in readmission when patients were discharged home ≤ 24 or > 24 hours. As shown in the univariate analysis, however, patients who had been discharged > 24 hours had an almost double hospital readmission rate compared with those discharged ≤ 24 hours (2.2% vs. 0.9%), thus demonstrating that longer hospital stay does not decrease the chance of unplanned postoperative hospital visits.

The present study has some relevant limitations. We did not administer questionnaires to evaluate the patient's quality of life and, more generally, to assess the quality of the recovery plan. Moreover, patient satisfaction was nonquantified through the use of standardized instruments. Protocols for early discharge ≤ 24 hours after LC usually apply to a selected group of patients using rigid exclusion criteria, thus resulting in an overall high rate of same-day surgery. Conversely, no limitation to the enrolment was established, but the presence of acute biliary inflammatory disease, ASA score > III, and BMI > 40 Kg/m^2. This probably resulted in a higher rate of delayed discharge > 24 hours than previously reported. Another limiting factor is that in most of the centers that participated, there are no established organizational pathways for day-case LC. This was made evident by the high number of patients who were discharged > 24 hours for nonclinical reasons. The study by Akoh et al[10] reported that an essential requirement for a successful day-case LC is the surgeon's experience, probably because the duration of the operation is a relevant factor in determining whether the patient can be discharged ≤ 24 hours from surgery. Unfortunately, our study did not evaluate the experience of the operating/supervising surgeon.

CONCLUSIONS

Clinical reality differs from the results of randomized studies by a complex series of nonobjectionable real-world data influencing treatment plans. It is of utmost importance to consider that the vast majority of delayed discharges > 24 hours in our study were unrelated to the surgery itself and can be prevented with both hospital logistic re-organization and a readjustment of the trust refund policies. If, on the one hand, it is necessary to act with a reform of the reimbursement systems and education of patients and health professionals on the benefits and feasibility of early discharge after LC, on the other, better patient selection, stringent preoperative assessment, operation scheduling, and reduction of unnecessary drain insertion can contribute in decreasing the length of hospitalization. The results of this study show that discharge ≤ 24 hours represents a valid treatment option for patients requiring LC, but this can only be achieved in Italy through the creation of an adequate performance indicator for surgeons and hospital managers and educating patients before and after surgery with appropriate discharge instructions. Strategies that aim to increase the rate of day-case LC without overnight admission will put Italy in step with the times and have significant positive financial implications for the health care system.

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