



## Predictive factors and importance of Critical View of Safety in difficult elective laparoscopic cholecystectomy

Haldun KAR\*<sup>id</sup>, Arif ATAY<sup>id</sup>

Department of General Surgery, Izmir Katip Celebi University Ataturk Training and Research Hospital, Izmir, Turkey

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### Abstract

Knowing the surgical anatomy and related variations, revealing the factors that indicate difficult cholecystectomy, knowing and applying various safe surgical cholecystectomy techniques and guidelines recommended to prevent injuries can prevent complications. This study, it is aimed to evaluate the preoperative factors that will predict difficult elective cholecystectomy. We retrospectively analyzed the data of patients treated for cholelithiasis by an experienced hepatobiliary surgeon or under his supervision between March 2018 and March 2020. Clinical, laboratory, and imaging data obtained from patients' files were evaluated. According to the Modified Nassar Scale (MNS), 140 (79.5%) patients were considered grade 1-2 (easy) and 36 (20.5%) grade 3-5 (difficult) patients within the framework of intraoperative findings. Critical View of Safety was successfully performed in 170 (96.6%) of the patients. Converting laparoscopic cholecystectomy to open was performed in two (1.1%) patients who had an MNS of 4 and 5. The most common comorbidity was hypertension.

Male gender, previous cholecystitis and ERCP, and increased gall bladder wall thickness from preoperative USG findings are independent risk factors for difficult cholecystectomy in patients scheduled for laparoscopic cholecystectomy. In addition, it should be kept in mind that LC can be difficult in patients with hypertension and coronary artery disease.

**Keywords:** Modified Nassar Scale, laparoscopic cholecystectomy, diagnosis, prediction, treatment

### 1. Introduction

Laparoscopic cholecystectomy (LC), which is the gold standard in the treatment of gallstones disease, is globally the most frequently performed surgical procedure (1,2). In line with the increasing number of laparoscopic cholecystectomies, there has been an increase in bile duct injuries. The risk of LC-related biliary injury is 0.1-1.5%. This rate is 0.1-0.2% in open cholecystectomy (3). The leading predisposing factors that cause bile duct injuries are anatomical variations, disease-related pathology, and inappropriate surgical techniques. Bile duct and vasculobiliary injuries are associated with high morbidity, mortality, and reduced quality of life. It has serious medicolegal effects as well (4,5).

Knowing the surgical anatomy and related variations, revealing the factors that indicate difficult cholecystectomy, knowing and applying various safe surgical cholecystectomy techniques and guidelines recommended to prevent injuries can prevent complications (2).

The most widely accepted and recommended method is the Critical View of Safety (CVS) technique, which was described by Strasberg in 1995 (1,3). Preoperative prediction of difficult cholecystectomy in patients who will be planned for laparoscopic cholecystectomy, informing the patient and their relatives about possible complications, and the surgeon's preparation of an operation plan in advance is vital to reduce

the rate of mortality and morbidity (1,6).

The first aim of our study is to define the preoperative factors that will predict difficult elective cholecystectomy, and the second aim is to present our clinical results in cases where we applied the Critical View of Safety.

### 2. Materials and methods

The study was designed and carried out in accordance with the Declaration of Helsinki and was conducted with the approval of the Our Clinical Research Ethics Committee (20.01.2022 / 0013). All patients signed a written informed consent form.

The files of 176 patients who underwent laparoscopic cholecystectomy by an experienced hepatopancreaticobiliary (HPB) surgeon or under his supervision between March 2018 and March 2020 were reviewed retrospectively.

Our 1100-bed hospital with an average of 1350 cholecystectomies per year is also a regional HPB center. After examining the surgical notes, the patients were divided into two groups as easy (non-difficult) and difficult laparoscopic cholecystectomies using the Modified Nassar Scale (MNS) (3) (Table 1). Those with a MNS of 3 to 5 were considered difficult laparoscopic cholecystectomy (Group B).

In both groups, demographic data (age, gender, body mass

\*Correspondence: haldunkar@hotmail.com

index), ASA grade, previous acute cholecystitis, pancreatitis, and endoscopic retrograde cholangiopancreatography (ERCP) history, co-morbidities, history of anticoagulant and anti-aggregant use, previous abdominal operation, preoperative ultrasonography findings and inflammation criteria (leukocyte, neutrophil-to lymphocyte (NLR), and neutrophil-to platelet ratio) were examined. Intraoperative findings, perioperative complications, operation time, transition information, and hospital stay were noted. The morbidity and mortality that developed during the 30-day follow-up of all patients were recorded.

During the operation, all patients were given 1 g cephalosporin antibiotic prophylaxis.

**Table 1.** Operative difficulty grading: Modified Nassar Scale

Grade	Description
<b>I</b>	Gallbladder—foppy, non-adherent
	Cysticpedicle—thin and clear
	Adhesions—simple up to the neck/Hartmann’s pouch
<b>II</b>	Gallbladder—mucocele, packed with Stones
	Cysticpedicle—fat laden
	Adhesions—simple up to the body
<b>III</b>	Gallbladder—deep fossa, acute cholecystitis, contracted, fibrosis, Hartmann’s adherent to CBD, impaction
	Cysticpedicle—abnormal anatomy or cystic duct—short, dilated or obscured
	Adhesions—dense up to fundus; involving hepatic flexure or duodenum
<b>IV</b>	Gallbladder—completely obscured, empyema, gangrene, mass
	Cystic pedicle—impossible to clarify Adhesions—dense, fibrosis, wrapping the gallbladder, duodenum or hepatic flexure difficult to separate
<b>V</b>	Mirizzi Syndrome type 2 or higher, cholecysto-cutaneous, cholecysto-duodenal or cholecysto-colic fistula

**2.1. Surgical procedures**

Laparoscopic cholecystectomy was performed using the four-port technique. A Veress needle was inserted (in 7 patients open access was performed with the Hasson technique) and the abdominal cavity was insufflated with the maximum insufflation pressure being 12mm Hg. All patients underwent cholecystectomy. Nasogastric tubes were placed in all patients. Simultaneous umbilical hernia repair was performed in 11 patients. Hepatocystic triangle dissection was performed with CVS (7,8) method in all patients. The hepatocystic triangle was cleared of fat and fibrous tissue, the peritoneum over the infundibulum was opened from the medial and lateral aspect, and the lower 1/3 of the gallbladder was separated from the liver bed and the cystic plate was exposed. Only two tubular structures were observed to enter the gallbladder. Intraoperative cholangiography was not performed in any of the patients.

**2.2. Statistical analysis**

Data were evaluated in the statistical package program IBM SPSS Statistics 25.0 (IBM Corp., Armonk, New York, USA). The conformity of the data of continuous variables to the normal distribution was evaluated with the Shapiro Wilk test and Q-Q charts. Descriptive statistics were given as frequency (n), percent (%), median (M), 25th percentile (C1), and 75th percentile (C3). Mann-Whitney U test, Fisher exact test, and Fisher Freeman Halton test were used for comparisons between groups. Risk factors (multivariate logistic regression) for difficult cholecystectomy were investigated by logistic regression analysis. p<0.05 was considered statistically significant.

**Table 2.** Univariate analysis for risk factors of difficult and easy cholecystectomy group

Variable	Modified Nassar Scale		P
	1-2 n=140, n (%)	3-5 n=36, n (%)	
	Group A		Group B
<b>Age (years)</b>			0,750
>50	62 (44.29%)	10 (27.78%)	
<=50	78 (55.71%)	26 (72.22%)	
<b>Gender</b>			<b>0.017</b>
Female	106 (75.71%)	20 (55.56%)	
Male	34 (24.29%)	16 (44.44%)	
<b>Body mass index</b>			0.946
<20	3 (3.06%)	1 (4%)	
20-24	22 (22.45%)	6 (24%)	
25-30	48 (48.98%)	11 (44%)	
>30	25 (25.51%)	7 (28%)	
<b>Previous acute cholecystitis</b>			<b>&lt;0.001</b>
No	131 (93.57%)	20 (55.56%)	
Yes	9 (6.43%)	16 (44.44%)	
<b>Previous ERCP</b>			<b>&lt;0.001</b>
No	134 (95.71%)	26 (72.22%)	
Yes	6 (4.29%)	10 (27.78%)	
<b>Previous acute pancreatitis</b>			0.212
No	128 (91.43%)	30 (83.33%)	
Yes	12 (8.57%)	6 (16.67%)	
<b>Diabetes mellitus</b>			0.092
No	115 (82.14%)	25 (69.44%)	
Yes	25 (17.86%)	11 (30.56%)	
<b>Hypertension</b>			<b>0.017</b>
No	89 (63.57%)	15 (41.67%)	
Yes	51 (36.43%)	21 (58.33%)	
<b>Coronary artery disease</b>			<b>0.029</b>
No	129 (92.14%)	28 (77.78%)	
Yes	11 (7.86%)	8 (22.22%)	
<b>Pulmonary pathology</b>			0.186
No	138 (98.57%)	34 (94.44%)	
Yes	2 (1.43%)	2 (5.56%)	
<b>Chronic kidney disease</b>			0.499
No	138 (98.57%)	35 (97.22%)	
Yes	2 (1.43%)	1 (2.78%)	
<b>Used anticoagulants</b>			0.271
No	137 (97.86%)	34 (94.44%)	
Yes	3 (2.14%)	2 (5.56%)	

<b>Used antiaggregant</b>			0.231
No	126 (90.65%)	30 (83.33%)	
Yes	13 (9.35%)	6 (16.67%)	
<b>ASA score</b>			1.000
1-2	130 (92.86%)	34 (94.44%)	
3-4	10 (7.14%)	2 (5.56%)	
<b>Previous abdominal operation</b>			<b>0.036</b>
No	96 (68.57%)	31 (86.11%)	
Yes	44 (31.43%)	5 (13.89%)	
<b>Drain</b>			<b>0.006</b>
No	32 (22.86%)	1 (2.78%)	
Yes	108 (77.14%)	35 (97.22%)	
<b>Hepatosteatoz</b>			0.710
Grade 1≤	68 (68.69%)	16 (72.73%)	
Grade>1	31 (31.31%)	6 (27.27%)	
<b>Gallbladder wall thickness</b>			<b>&lt;0.001</b>
<4mm	131 (93.57%)	21 (58.33%)	
≥ 4mm	9 (6.43%)	15 (41.67%)	
<b>Common bile duct diameter</b>			<b>0.007</b>
<6 mm	129 (92.14%)	27 (75%)	
>6mm	11 (7.86%)	9 (25%)	
<b>Contracted gallbladder</b>			<b>0.049</b>
No	134 (95.71%)	31 (86.11%)	
Yes	6 (4.29%)	5 (13.89%)	
<b>White blood cell count</b>	7.32 (6.11;8.72)	7.43 (6.1;8.87)	0.885
<b>C-Reactive Protein</b>	0.14 (0.05;0.40)	0.27 (0.03;0.9)	0.278
<b>Neutrophil-to-lymphocyte ratio</b>	1.88 (1.47;2.37)	1.87 (1.62;2.3)	0.549
<b>Platelet-to-lymphocyte ratio</b>	122.3 (92;157)	125 (94.1;175)	0.520
<b>Postoperative pathology</b>			<b>&lt;0.001</b>
Others	2 (1.43%)	10 (27.78%)	
Chronic cholecystitis	138 (98.57%)	26 (72.22%)	
<b>Operation time</b>	65 (54;80)	86.50 (72;107)	<b>&lt;0.001</b>
<b>Length of hospital stay</b>	1 (1;1)	2 (1;3)	<b>&lt;0.001</b>

### 3. Results

Of 176 patients who underwent elective laparoscopic cholecystectomy, 126 (71.59%) were female and 50 (28.41%) were male, with a mean age of 52.9 (19-84) years. 174 (98.86%) patients were operated on with the diagnosis of symptomatic gallstone disease and 2 (1.14%) patients with a preliminary diagnosis of gallbladder polyps. There was a history of cholecystitis in 25 (14.2%) patients, pancreatitis in 18 (10.2%) patients, and ERCP in 16 (9.1%) patients. The most common comorbidity was hypertension (HT) (Table 2). Of the patients, 19 (10.7%) were receiving anti-aggregant and 5 (2.8%) anticoagulant treatment, and 49 had a history of previous surgery (Table 2). The rate of previous surgery was significantly higher in Group A patients (p=0.036). Converting laparoscopic cholecystectomy to open was performed in two (1.1%) patients who had a MNS of 4 and 5. In our study, no intraoperative bile duct injury and/or major artery injury occurred. Pathology results were consistent with 164 (93.2%)

chronic cholecystitis, 6 (3.4%) ulceroflegmanous cholecystitis, 3 (1.7%) chronic cholecystitis with acute attack, 2 (1.1%) biliary polyps, 1 (0.6%) xanthogranulomatous cholecystitis (Table 2).

Complications developed in 3 patients during the postoperative period. Two patients had superficial surgical site infection in the subxiphoid incision. One patient was reoperated for postoperative bleeding. In the operation, hematoma drainage was performed and no active bleeding focus was observed. This patient had a history of heart valve replacement and aortic aneurysm stenting and anticoagulant use. No mortality was observed in our series.

According to the MNS, 140 (79.5%) patients were considered grade 1-2 (non-difficult) and 36 (20.5%) grade 3-5 (difficult) patients within the framework of intraoperative findings. CVS was successfully performed in 170 (96.6%) of the patients.

In the univariate analyzes, a statistically significant difference was found between difficult and easy cholecystectomy group gender, previous cholecystitis and ERCP history, HT, atherosclerotic coronary heart disease, previous operation history, the wall thickness of the bladder, the diameter of the common bile duct, and contracted gall bladder variables on ultrasound (Table 2).

There was a statistically significant difference between the difficult and easy cholecystectomy group and the mean operative time and hospital stay, drain use, and pathology results (Table 2).

In the multivariate analysis, ERCP, HT, and a wall thickness greater than 4 mm were seen as independent risk factors for difficult cholecystectomy. When the pathology is considered as a variable, this is seen as a protective factor. The presence of ERCP increases the probability of difficult cholecystectomy 20,947 times, the wall thickness of the bladder > 4mm increases 6.482 times, and the presence of HT increases 3.206 times (Table 3).

### 4. Discussion

To date, different parameters and criteria have been used to define difficult laparoscopic cholecystectomy. Initially, the conversion from laparoscopy to open and long operation times were defined as difficult laparoscopic cholecystectomy criteria. With the scoring systems developed in recent years, the LC difficulty level has been standardized (1,9). The MNS, which we used in our study, is an easily applicable intraoperative difficulty score, and it was defined by Nassar et al. in 1996 and its reliability has been demonstrated in studies (10-12).

Despite advances in LC techniques, biliary tract injuries continue to be an important problem today. In a recent study, Strasberg described a safe 3-step cholecystectomy method to prevent bile duct injuries (5). Here CVS is a threshold point. Today, the CVS technique is accepted as the most effective

method for reducing morbidity and mortality associated with laparoscopic cholecystectomy. The European Association of Endoscopic Surgery and the Society of American Gastrointestinal and Endoscopic Surgeons recommend the CVS as the most effective approach to preventing bile duct injury (13-15). In the study of Sgaramella et al., it was shown that CVS plays a protective role in the prevention of intraoperative complications in multivariate analysis (2). Kaya et al. applied the CVS method in their 120 LC series, which none of the patients had biliary tract injury (14). Similarly, in their systematic review on the prevention of biliary tract injuries in laparoscopic cholecystectomy, Graaf et al found the incidence of biliary tract injury to be 0.03%, the median success rate 95.8%, and the median coverage rate 0.95% in CVS (13). In our study, our CVS success rate was 96.6% and our conversion rate to open was 1.1%, while no biliary tract injury was observed in any patient.

In some studies, advancing patient age has been defined as a predictor for difficult cholecystectomy, as it may cause an increase in the number of cholecystitis attacks (1,11). In our study, as the patient's age was taken as a cut-off 50, it was not found to be a risk factor for difficult elective LC.

It has been suggested that the reason why difficult cholecystectomy is more common in men is the fact that men can tolerate the symptoms caused by gallstones more than women, and that, as a result, they apply to a physician late with a more advanced disease picture (1,6,11). Similarly, in our study, the male gender was found to be a risk factor for difficult elective LC.

Contrary to studies in the literature reporting that obesity is a risk factor for difficult cholecystectomy, Sgaramella et al. reported that obesity reduces complications such as biliary tract injury and bleeding during LC (2). In our study, no statistically significant difference was found between body mass index and difficult elective cholecystectomy.

Recurrent cholecystitis attacks prevent dissection with increased inflammation in the hepatocystic triangle and cause difficult cholecystectomies. Studies are showing the effect of pancreatitis attacks and ERCP on the difficulty of cholecystectomy with a similar mechanism (6,9,16). A stronger association was found in a recent study modifying Randhawa's model of prior biliary inflammation and procedure (1). In our study, history of acute cholecystitis and ERCP were defined as significant predictors for difficult elective LC. However, no statistically significant correlation was found with pancreatitis.

In our study, the presence of hypertension and coronary artery disease were found to be independent risk factors for difficult elective LC. Although leukocyte activation and infiltration have been found in many tissues in cases of arterial hypertension, the mechanisms causing this remain unclear (17). In the study of Sgaramella et al., the presence of more

than one co-morbid disease was found to be associated with poor prognosis and intraoperative complications (2). It should be kept in mind that cholecystectomy may be difficult in patients with hypertension and coronary artery disease who are scheduled for LC.

ASA grade is a globally recognized grade. It is well validated as a marker of patients preoperative health status. Contradictory studies are reporting the effect of ASA grade on difficult LC (6,11). In this study, no statistically significant relationship was detected.

A good preoperative ultrasonography is very valuable in predicting difficult elective LC. In particular, gallbladder wall thickness > 4 mm, signs of the contracted bladder, and bile duct diameter greater than 6 mm have been described in the literature as important predictive factors in difficult LC and the need for conversion to open surgery (1,6). In our study, all three findings were found to be significant risk factors in the univariate analysis.

There is literature studying NLR as a predictive factor in predicting complicated and uncomplicated cholecystitis. In these studies, NLR was found to be associated with the severity of acute cholecystitis (18-19). In our study, we studied NLR as a predictive factor in predicting difficult cholecystectomy in patients who will undergo elective LC. As a result, no significant difference was found between difficult and easy elective LC.

Studies are reporting that acute inflammation increases the difficulty of cholecystectomy and surgical complications (1,6). According to the final pathology results in our study, 99% were patients who had acute-chronic cholecystitis. However, cholecystitis other than chronic cholecystitis was observed significantly more frequently in Group B patients. When the pathology is considered as a variable, this is seen as a protective factor.

In the study of Sgaramella et al., the conversion rate (CR) averaged 4.9% (2). In the study of Bhandari et al., the average CR was found to be 8.9% (6). We think that our rate of conversion to open surgery is lower than the literature since all surgeries were performed by a single surgeon who was experienced in hepatobiliary surgery and performs advanced laparoscopic surgery. Especially in patients with risk factors for difficult cholecystectomy, surgery should be planned by making necessary preliminary preparations.

With the development of laparoscopic surgery, an acceleration in the time to return to work after cholecystectomies, a lower need for analgesics in the postoperative period, and a shorter hospital stay have been reported (2). In our study, the duration of operation and hospital stay were found to be longer in group B patients in accordance with the literature.

Many factors have been defined in studies to predict difficult LC preoperatively. Male gender, previous



cholecystitis and ERCP, and increased gall bladder wall thickness from preoperative ultrasonography findings are independent risk factors for difficult cholecystectomy in patients scheduled for elective LC. In addition, it should be kept in mind that LC can be difficult in patients with hypertension and coronary artery disease, except for biliary inflammation and interventions. Knowing these risk factors can assist surgeons in selecting suitable patients for elective laparoscopic cholecystectomy, preoperative preparation, and postoperative patient follow-up.

### Conflict of interest

The authors declared no conflict of interest.

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### Authors' contributions

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