

**ORIGINAL ARTICLE** 

# Factors associated with difficult laparoscopic cholecystectomy in adults at a high-complexity hospital in Trujillo, Peru

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#### Keywords:

cholecystectomy; laparoscopic; difficult; complicated; adults; surgery; conversion (Source: MeSH - NLM).

#### **ABSTRACT**

**Objective.** To determine the factors associated with difficult laparoscopic cholecystectomy in adults at a high-complexity hospital in Trujillo, Peru. **Methods.** Observational, cross-sectional, and analytical study. Simple random sampling was conducted. Patients under 18 years of age, those classified as ASA IV or V, and individuals with liver cirrhosis, gallbladder cancer, biliary tract cancer, pancreatic cancer, or incomplete medical records were excluded. The dependent variable was difficult laparoscopic cholecystectomy. Descriptive and inferential statistics were used, and Poisson regression was applied to estimate crude and adjusted prevalence ratios in bivariate and multivariate analyses. **Results.** Among the 150 patients included, the median duration of illness was 10 days (IQR: 2–90), and total cholecystectomy, the median surgical time was 60 minutes (IQR: 30–150), and conversion occurred in 6.7% of cases (n = 5). In the adjusted analysis, surgical time was statistically significant (aPR: 1.03; 95% CI: 1.01–1.04). **Conclusions.** Surgical time is an intraoperative factor associated with difficult laparoscopic cholecystectomy.

## Factores asociados a la colecistectomía laparoscópica difícil en adultos del Hospital de Alta Complejidad de Trujillo, Perú

Palabras clave: colecistectomía; laparoscópica; difícil; complicada; adultos; cirugía; conversión (Fuente: DeCS - BIREME).

#### RESUMEN

**Objetivos**. Determinar los factores asociados a la colecistectomía laparoscópica difícil en adultos del Hospital de Alta Complejidad de Trujillo en Perú. **Métodos**. Estudio observacional, transversal y analítico. Se realizó un muestreo aleatorio simple excluyéndose a menores de 18 años, pacientes con ASA IV o V, cirrosis hepática, cáncer (Ca) vesicular, Ca de vías biliares y Ca de páncreas, así como aquellos que presentaban datos incompletos en las historias clínicas. La variable dependiente fue la colecistectomía laparoscópica difícil. Se utilizó la estadística descriptiva e inferencial y la regresión de Poisson para calcular razones de prevalencia cruda y ajustada en el análisis bivariado y multivariado. **Resultados**. De los 150 pacientes incluidos, el promedio del tiempo de enfermedad fue de 10 días (RI: 2–90), y en el 98,7 % de los casos (n = 148) se realizó la colecistectomía total. Con relación a la colecistectomía laparoscópica difícil, el tiempo de cirugía tuvo una mediana de 60 minutos (RI: 30-150) y la conversión se dio en el 6,7 % (n = 5) de los casos. En el análisis ajustado se encontró significancia estadística al tiempo de cirugía (RPa: 1,03; IC95 %: 1,01-1,04). **Conclusiones.** El tiempo de cirugía es un factor intraoperatorio asociado a la colecistectomía laparoscópica difícil.

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Inflammation of the gallbladder, also known as acute cholecystitis (AC), is a disease that affects approximately 5% to 10% of all patients and nearly 20 million people in the United States, with almost 200,000 new cases diagnosed annually in the country. In approximately 90% of cases, the primary cause of acute cholecystitis is obstruction of the cystic duct (or gallbladder neck) by gallstones <sup>(1)</sup>.

In Latin America, from 2018 to 2022, the prevalence of AC due to gallstone disease ranges from 5% to 15%, with higher rates in countries such as Bolivia (15.7%) and Mexico (10%-15%) <sup>(2)</sup>. In Peru, there are no population-based studies to determine the frequency of acute cholecystitis; however, a study by Téllez Yáñez et al. <sup>(3)</sup>, conducted at the Hospital de Vitarte in Lima (Peru) in 2018, reported a prevalence of 17.1%, with an average age of 43.4 years and 81.1% of cases being female.

Surgical removal of the gallbladder is required for treatment. Currently, two surgical techniques are most frequently performed in General Surgery Departments: the conventional cholecystectomy, performed since 1882 via an abdominal incision, and laparoscopic cholecystectomy, which in some populations is the first-line therapy within the first three days after diagnosis <sup>(1,4)</sup>.

Despite the relative frequency of this surgical procedure, a clinical scenario referred to as difficult laparoscopic cholecystectomy (DLC) has been recognized, for which there is still no consensus definition. However, studies such as that by Álvarez et al. define it as follows <sup>(5)</sup>: "The surgical removal of the gallbladder when there are certain associated conditions of the organ itself, neighboring organs, or the patient, that prevent an easy, rapid, and comfortable dissection of the gallbladder, resulting in a prolonged surgical time and increased risk of complications for the patient."

To classify DLC, several scales have been developed. One of them is the Presurgical Score for Difficult Laparoscopic Cholecystectomy (SPRECLAD, by its Spanish acronym), which assigns points to various parameters to predict the difficulty: easy (<5 points), difficult (6–10 points), and very difficult (11–15 points) <sup>(6)</sup>. For this scale, the study by Ellis et al. <sup>(7)</sup> reported a positive predictive value (PPV) of 63%, a negative predictive value (NPV) of 100%, and a strong cutoff point of 8 points with an area under the curve (AUC) of 0.99. Similarly, Menacho et al. <sup>(8)</sup> reported an optimal AUC of 0.79 for the same scale.

Internationally, different studies have identified factors related to DLC. For example, in China, Chen et al. <sup>(9)</sup> in 2022 concluded that a body mass index (BMI) greater than 25 kg/m<sup>2</sup>, leukocyte count over 10 x 10<sup>9</sup>/L, gallstones in the gallbladder neck, more than four episodes of acute cholecystitis within the last two months, wall thickness greater than 0.5 cm, and stone diameters over 2 cm were independently associated factors. In Indonesia, Wibowo et al. <sup>(10)</sup> in 2022 designed a study to validate a preoperative score for predicting DLC between 2015 and 2022, in which they found that prior hospitalization for acute cholecystitis, elevated BMI, abdominal scar, palpable gallbladder, and leukocytosis were associated factors.

In Spain, Manuel-Vasquez et al. <sup>(11)</sup> in 2021 proposed the development of a consensus definition for difficult cholecystectomy through a Delphi-type study, selecting specific characteristics and ultimately reporting intraoperative criteria in 96.7% of cases. In Nepal, Bhandari et al. <sup>(12)</sup> in 2021 reported the following associated factors with DLC: male sex, past history of acute cholecystitis, gallbladder wall thickness > 4 mm, fibrotic gallbladder, and adhesion to Calot's triangle. Lastly, in the United Kingdom, Stanisic et al. <sup>(13)</sup> in 2020 conducted a study using logistic regression, concluding with five associated factors for DLC: gallbladder fibrosis, leukocytosis, pain duration of at least four hours, and diabetes mellitus.

At the national level, in Cusco, Fuentes et al. <sup>(14,15)</sup> in 2020 found risk factors for DLC such as: age over 55 years, male gender, non-elective surgery, hypertension, leukocytosis, gallbladder wall thickness > 4 mm, and gallbladder hydrops.

In summary, although difficult laparoscopic cholecystectomy is not highly frequent, it constitutes a condition that—when identified—implies risks and potential complications, generating costs and morbidity/mortality that could be preventable. Identifying associated factors such as disease duration, type of surgery, type of cholecystectomy, surgical time, and conversion may allow the surgeon to perform a thorough analysis of the patient's profile and determine whether the case qualifies as a difficult laparoscopic cholecystectomy. The objective of this study was to determine the factors associated with difficult laparoscopic cholecystectomy in adults at the Hospital de Alta Complejidad Virgen de la Puerta, Trujillo, Peru.

## METHODS

#### Study type and area

An observational, cross-sectional analytical study was conducted at the Hospital de Alta Complejidad Virgen de la Puerta of Trujillo, located in the department of La Libertad (Peru), from 2019 to 2022.

#### **Population and sample**

The population size was calculated using the formula for two proportions, based on data from the study by Bhandari et al. (12), which considered male sex as a variable, and reported that 6.25% of the non-exposed group were positive (16/256), with a non-exposed to exposed ratio of 1. These data were incorporated into the proportion difference formula for cross-sectional analytical studies (16,17), resulting in a sample size of 150 patients, equally divided into the "difficult" and "non-difficult" categories (50% each). Simple random sampling without replacement was used. Inclusion criteria included being 18 years of age or older, having a confirmed diagnosis of acute cholecystitis via pathology, and having undergone laparoscopic cholecystectomy. Exclusion criteria included patients who died within 30 days post-operation, those whose cholecystectomy required additional intraoperative procedures, incomplete data entries, and those with ASA classification IV or V, liver cirrhosis, gallbladder cancer, biliary tract cancer, or pancreatic cancer.

#### Variables and data collection instrument

The dependent variable was difficult laparoscopic cholecystectomy, defined using the SPRECLAD scale, where a score of  $\geq 6$  and < 10 was classified as difficult, and a score of 1 to 5 as non-difficult <sup>(6,7)</sup>. Independent variables were divided into preoperative (duration of illness) and intraoperative (type of surgery, type of cholecystectomy, surgery duration, and conversion).

#### Data collection techniques and procedures

Patient medical records were reviewed until the sample size was completed. The SPRECLAD scale was applied to classify cases as either "difficult" or "non-difficult" according to their score. The collected data were recorded in a data collection form alongside additional study variables, and a two-stage data cleaning process was conducted: in the first stage, inconsistencies were identified and removed; in the second, selection criteria were applied to generate a

final cleaned database ready for analysis. Data were initially processed using Microsoft Excel, following the variable operationalization coding chart, and then imported into Stata version 18 for statistical analysis.

#### **Data analysis**

Descriptive and inferential statistics were used for data analysis. For qualitative variables, absolute and relative frequencies were used, and associations were evaluated using the Chi-square test. For quantitative variables, the Mann-Whitney U test was applied. In the inferential analysis, statistical significance was set at p < 0.05. To quantify associations, Poisson regression was used to calculate the crude prevalence ratio (PR) for the bivariate analysis, and the adjusted PR for the multivariate analysis. All analyses were performed using Stata version 18.

#### **Ethical considerations**

This study complied with the ethical principles for research involving human subjects as stated in the CIOMS Declaration <sup>(18)</sup>, and followed the Peruvian Ministry of Health's guidelines for human research <sup>(19)</sup>. Additionally, the study received approval from the Ethics Committee of the Hospital de Alta Complejidad Virgen de la Puerta, Trujillo, La Libertad, Peru.

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Regarding the SPRECLAD criteria: 60% (n = 90) were 50 years old or younger, 76% (n = 114) were female, 37.33% (n = 56) had a BMI between 25 and less than 27.5 kg/m<sup>2</sup>, 36% (n = 54) had a history of hospitalization, 67.33% (n = 101) had no abdominal scars from previous surgeries, 78% (n = 117) had a palpable gallbladder, 77.33% (n = 116) had a gallbladder wall thickness greater than 4 mm, 45.8% (n = 77) had pericholecystic fluid, and 46% (n = 69) had an impacted gallstone (see Table 1).

In relation to difficult laparoscopic cholecystectomy, due to the non-normal distribution of the duration of illness, the median was used, with a value of 10 days (IQR: 3–30). The type of surgery was emergency in 89.3% (n = 67), total cholecystectomy was performed in 100% (n = 75), the surgery duration had a median of 60 minutes (IQR: 30–150), and conversion occurred in 6.7% (n = 5) of cases. Statistically significant differences were observed between the variables and the occurrence of difficult laparoscopic cholecystectomy. The Mann-Whitney U test revealed significance for duration of illness (p = 0.008) and **Table 1.** SPRECLAD criteria in adults undergoing laparoscopic

 cholecystectomy at the Hospital de Alta Complejidad Virgen de la Puerta, Trujillo, La Libertad, Peru

	n = 150			
	Freq.	%		
Age				
>50 years	60	40.0		
< 50 years	90	60.0		
Sex				
Male	36	24.0		
Female	114	76.0		
Body Mass Index	25 ±	25 ± 3.18		
< 25 Kg/m2	48	32		
25-< 27.5 Kg/m2	56	37.33		
>= 27.5 kg/m2	46	30.67		
History of hospitalization				
Yes	54	36.0		
No	96	64.0		
Abdominal scar				
No	101	67.3		
Infraumbilical	49	32.7		
Palpable gallbladder				
Yes	117	78.0		
No	33	22.0		
Gallbladder wall thickness	5.07 :	5.07 ± 1.4		
<= 4mm	34	22.7		
> 4mm	116	77.3		
Pericholecystic fluid				
Yes	77	45.8		
No	91	54.2		
Impacted gallstone				
Yes	69	46.0		
No	81	54.0		

surgery time (p = 0.001), while the Chi-square test showed significant associations for type of surgery (p = 0.031) and conversion (p = 0.023) (see Table 2). **Table 2.** Factors associated with difficult laparoscopic cholecystectomy in adults operated at the Hospital de Alta Complejidad Virgen de la Puerta, Trujillo, La Libertad, Peru (2019–2022)

	Difficult Laparoscopic Cholecystectomy							
	Ye	es	N	n velve				
	Freq.	%	Freq.	%	<i>p</i> -value			
Duration of illness	10 IQR: 3-30		15 IQR: 2-90		0.008			
Type of surgery					0.031			
Emergency	67	89.3	57	76.0				
Elective	8	10.6	18	24.0				
Type of cholecystect		0.155						
Total	75	100	73	97.3				
Subtotal	0	0.0	2	2.7				
Surgery time	60 min. RI:30-150		40 min. RI:20-75		0.001			
Conversion					0.023			
Yes	5	6.7	0	0				
No	70	93.3	75	100				

A crude analysis was conducted, revealing a significant association for surgery time (Crude PR: 1.02, Cl: 1.01–1.03). Subsequently, an adjusted analysis using Poisson regression found statistical significance in surgery time as well (Adjusted PR: 1.03, 95% Cl: 1.01–1.04) (see Table 3).

#### DISCUSSION

According to Álvarez et al., DLC is defined as <sup>(5)</sup> "the surgical removal of the gallbladder under associated conditions that do not allow an easy, quick, and comfortable dissection, which results in prolonged surgical time and increased risk of complications for the patient." For its classification, the SPRECLAD scale is used, which categorizes DLC as easy ( $\leq$ 5 points), difficult (6–10 points), and very difficult (11–15 points) <sup>(6,7)</sup>.

 Table 3. Factors associated with difficult laparoscopic cholecystectomy in adults operated at the Hospital de Alta Complejidad Virgen de la Puerta, Trujillo, La Libertad, Peru (2019–2022)

Characteristics -	Crude analysis			Adjusted analysis			
	cPR	95 % CI	p-value	aPR	95 % CI	p-value	
Duration of illness	0.97	0.94-1	0.029	0.98	0.95-1	0.082	
Type of surgery (EMG vs Elective)	1.76	0.84-3.7	0.132	1.21	0.57-2.58	0.619	
Surgery time	1.02	1.01-1.03	0.001	1.03	1.01-1.04	0.001	
Conversion (Yes vs No)	2.07	0.84-5.13	0.116	0.3	0.07-1.16	0.081	

When evaluating the factors associated with difficult laparoscopic cholecystectomy in this study, surgical time was found to have a significant association, where an increase in surgical time was associated with an increased probability of DLC (Adjusted PR: 1.03; 95% CI: 1.01-1.04). Upon reviewing the literature related to DLC, no previous studies have directly reported an association between surgical duration and DLC. However, Álvarez et al. <sup>(5)</sup> reported that other non-patient-related factors can extend surgical time and lead to iatrogenic complications, particularly when adequate abdominal distension is not achieved. It is important to note that this finding should be interpreted with caution, as this is a cross-sectional study, and the temporality between classification of the case and duration of surgery cannot be firmly established. Nevertheless, it is reasonable to consider that the characteristics of complicated cases inherently increase surgical time.

In our study, no association was found between conversion and DLC (Adjusted PR: 0.3; 95% CI: 0.07-1.16), with a conversion rate of 6.67% (n = 5). By contrast, Manuel-Vásquez et al. (11) reported a much higher conversion rate to laparotomy (87.1%) in association with DLC. A contrary relationship was expected, since conversion typically occurs when the complexity of the surgical scenario prevents continuation of the laparoscopic method, requiring the conventional open approach for greater safety. This discrepancy should be interpreted cautiously and may be explained by an insufficient sample size to adequately evaluate this parameter: as shown in Table 2, only 5 patients with DLC required conversion, while 70 did not, and there was no comparable control group with conversion but without DLC.

No significant associations were found for emergency vs. elective surgery (Adjusted PR: 1.21; 95% CI: 0.57–2.58), disease duration (Adjusted PR: 0.98; 95% CI: 0.95–1), or type of cholecystectomy (Crude PR = 1; Adjusted PR = 1). However, Fuentes et al. <sup>(15)</sup> reported that non-elective surgery was associated with increased risk (PR: 2.68; 95% CI: 1.42–5.08), while Di Buono et al. <sup>(20)</sup> found an association with disease duration (OR: 1.8; 95% CI: 1.04–3.13). Although a significant difference was observed using Chi-square analysis for type of surgery (p = 0.031), this may be due to limitations in sample size and variable distribution, thus reducing statistical power.

This study adopted the SPRECLAD score, as it is an optimal predictive tool for DLC. Supporting this, Menacho et al. <sup>(8)</sup> reported an AUROC of 0.793, endorsing its validity. Furthermore, to confirm its effectiveness, it was compared with the findings of Randhawa et al. <sup>(21)</sup>, who reported an AUROC of 0.82. It is worth highlighting that both investigations were thoroughly analyzed and validated for use.

However, this finding can also be interpreted to emphasize that: emergency admission due to an acute condition, duration of illness in patients with cholecystitis, and the type of cholecystectomy performed are not determining factors for whether a laparoscopic surgery will be difficult. While these conditions may influence the decision to proceed with laparoscopic removal, they do not necessarily imply a complex procedure. This highlights the need to refocus attention on the inherent characteristics of the gallbladder itself as the key elements that define whether an intervention is difficult or not.

The sample size in this study was limited by access and resource constraints. To mitigate this impact, simple random sampling without replacement was applied, ensuring adequate population representativeness. Future research should consider expanding the exploration to different settings, which could further enrich the findings and reveal potential variations.

#### Conclusions

Among patients who underwent difficult laparoscopic cholecystectomy at the Hospital de Alta Complejidad Virgen de la Puerta of Trujillo, La Libertad, Peru between 2019 and 2022, surgical time was the factor most strongly associated with procedural difficulty. No significant association was found with disease duration, type of surgery, type of cholecystectomy, or conversion.

It is recommended to enhance surgical training, particularly through simulation-based learning and high-complexity scenarios, with particular emphasis on optimizing operative time. Additionally, it is advised to conduct comparative studies evaluating the SPRECLAD scale against other models such as Wibowo or Nassar, to assess their clinical effectiveness.

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