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## A new clinical-ultrasound score to predict difficult videolaparocholecystectomies: A prospective study



Giuseppe Carbotta<sup>a,\*</sup>, Annunziata Panebianco<sup>a</sup>, Rita Laforgia<sup>a</sup>, Bianca Pascazio<sup>a</sup>, Giovanni Balducci<sup>a</sup>, Francesco Paolo Bianchi<sup>b</sup>, Silvio Tafuri<sup>b</sup>, Nicola Palasciano<sup>a</sup>

<sup>a</sup> General Surgery Unit “V. Bonomo”, Department of Emergency and Transplantation of Organs, University of Bari, P.zza G. Cesare 11, 70124, Bari, Italy

<sup>b</sup> Department of Biomedical Sciences and Human Oncology, University of Bari, P.zza G. Cesare 11, 70124, Bari, Italy

### ABSTRACT

**Background:** The gold standard treatment of symptomatic cholelithiasis is videolaparoscopic cholecystectomy (VLC). The aim of this study is to produce a predictive clinical ultrasound (US) score for difficult VLC to reduce the rate of conversion to open cholecystectomy surgery and intra and/or post-operative complications.

**Methods:** In this prospective study carried out in 2017 we enrolled 135 patients (pts) who underwent VLC in our General Surgery Unit. A specific pre-operative abdominal ultrasound scan was performed to assess gallbladder characteristics for each patient. All US and patients' characteristics were recorded in a standard form in order to obtain a preoperative score and were then added to the intra-operative variables.

**Results:** The analysis revealed a statistical significance between post-operative characteristics and parietal thickness, adhesions, stratifications and volume of gallstones. Comparing the degree of difficulty VLC assessed in the pre-operative stage to the intraoperative score, the sensitivity of the preoperative US scan test is 91.8% while the specificity is 76.7%.

**Conclusions:** The variables which proved statistically significant in predicting a difficult cholecystectomy were: age, parietal thickness > 3 mm, adhesions, stratifications, gallstones > 2 cm and fixed gallstones. We have definitively defined a predictive score for difficult VLC for which a VLC is to be considered potentially difficult whenever it presents a pre-operative score equal or greater than 4 (and a "easy" one with a pre-operative score less than 4). These findings may prove helpful in further reducing the conversion rate and the rate of intra- and/or post-operative complications.

### 1. Introduction

Cholelithiasis is a common pathology (10–15%) among adults [1]. The gold standard treatment of symptomatic cholelithiasis is videolaparoscopic cholecystectomy (VLC). This is one of the most frequently performed surgical procedures, but still represents a potential cause of serious post-operative complications. In literature, cholecystectomies are considered “difficult” when one, some or all the following characteristics are present: conversion from LC to open cholecystectomy, operating time (180 min), blood loss (300 ml) and efficacious haemostasis of the gallbladder bed, main bile duct injuries or of the cystic artery and the need to immediately summon another surgeon to the operating room [2]. Currently, the conversion rate is between 4.8 and 8% [3,4] while the incidence of peri- and post-operative VLC complications is about 5–15% [5,6]. The aim of this study is to produce a predictive clinical-ultrasound (US) score of difficult VLC by means of which the factors leading to conversion can be singled out and the rate of intra and/or post-operative complications can be further reduced. This will also permit the drawing up a specific information approval form to better program the timing of the surgical operation and the choice of

surgeon with sufficient laparoscopic experience to predict the difficulties of the surgical procedure.

### 2. Materials and methods

In this prospective study in 2017 we enrolled 135 patients (pts) who underwent VLC in our General Surgery Unit “V. Bonomo” of the Bari University Hospital. The inclusion criteria were asymptomatic cholelithiasis, symptomatic cholelithiasis, previous biliary colic, chronic cholecystitis, a recent episode of acute pancreatitis treated with a medical therapy and/or a recent episode of main bile duct lithiasis treated with ERCP. The exclusion criteria were acute cholecystitis, a suspected or histological diagnosis of gallbladder carcinoma and emergency surgical procedure within 48 h of the last episode of biliary colic. Each patient underwent a pre-operative abdominal ultrasound scan aimed at gallbladder characteristics' study and collection data. The diagnostic accuracy of ultrasound for the pathologies of the gallbladder is universally recognized as well as surgeons performed US in clinical practice. Therefore the study was focused on US examinations by our team of surgeons with excellent ultrasound training and responsible of

\* Corresponding author. General Surgery Unit “V. Bonomo”, Department of Emergency and Transplantation of Organs, University of Bari, Italy.

E-mail address: [pippocarbotta@gmail.com](mailto:pippocarbotta@gmail.com) (G. Carbotta).

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the US surgery of our Unit to perform US pre-op and the surgical procedures of the scanned patients. The advantages is to have more integrated decision making as surgeons and better pre-op planning. An Esaote My Lab 7 ultrasound scan was used with a 3500 Mhz convex probe. Written informed consent was obtained from all patients. The following parameters were recorded for each patient on a standardized form divided into patients' and US characteristics. The patients' characteristics were sex, age, body mass index (BMI), presence of chronic hepatopathy; comorbidity (diabetes, hypertension, PBCO...); previous upper or lower abdominal surgical procedures; a history of biliary colic; hospital admission (elective/emergency); previous episodes of pancreatitis and/or ASA score. US characteristics were: a specific measurement for gallbladder volume (three measurements in two consecutive projections of longitudinal and axial gallbladder diameter with a cut-off of 50 ml), gallbladder wall thickness (cut-off 3 mm), adhesions (to the duodenum, to the colon, to the stomach or to the omentum), stratifications (binary or triple layer stratus image), number of stones (cut-off 3) diameter of the largest stone (cut off < 2 cm), mobility of the stones, presence of pericholecystic fluid, intramural gas, power Doppler wall imaging and/or peritoneal effusion.

The laparoscopic procedure was performed by the team of expert surgeons (each with more than 50 procedures to their name). The French technique was employed, using three trocars (a 4th port was inserted only if needed). Drainage as well as the execution of an intra-operative cholangiography were not routinely used but only if required. The following intra-operative variables were considered: number of ports, type of cholecystectomy (considering as standard the retrograde vs. anterograde), adhesiolysis, wall fragility, aspiration of bile, spillage, intra-operative cholangiography, haemostasis of the gallbladder bed, laparotomy conversion, presence of drainage, operating time, anatomical anomalies, recognition of the elements of the hilus and/or post-operative complications. For each patient, the characteristics present on US were assessed in order to obtain a pre-operative score (from 0 to 12) which might prove predictive of a difficult VLC with a score of 0 representing an easy VLC through to 12 for a difficult one. Intra-operative parameters were also assessed in order to obtain a 2nd score (from 0 to 10). We therefore thus determined:

- The score for a difficult VLC assessed at the pre-operative stage was taken as greater than or equal to 4.
- The score for a difficult VLC assessed at the intra-operative stage, was taken as greater than or equal to 4 with an operating time longer than 100 min.

The patients', US and intra-operative characteristics, when added to pre- and intra-operative scores were inserted on a database created using Office Excel software and analyzed using Office Excel software and Stata SE 14. Continuous variables have been expressed as the mean value + or - standard deviation and range, while categorical variables have been expressed as proportions. The normality of continuous variables was evaluated whilst the normalization of the ones not normally distributed did not prove possible. The Wilcoxon test of the sum of the ranks (non-parametric) was used to compare the continuous variables between genders. The chi-squared test and the exact test of Fischer were used to compare categorical variables. Uni-varied linear regression was used to evaluate the association of intra-operative and pre-operative scores, by calculating the correlation coefficient with the IC 95% and the Student's t-test. Comparing the score for a difficult VLC, estimated during the pre-operative stage (difficult gallbladder/more difficult pre-operative), to the degree of real difficulty of the cholecystectomy (gold standard: difficult gallbladder/non-difficult post-operative), the sensitivity, the specificity together with the positive and negative predictive values were calculated with the indication of the relative IC 95% of the pre-operative US scan test. In order to estimate the association of the degree of the actual VLC difficulty encountered (difficult gallbladder/non-difficult post-operative) with all the above

**Table 1**  
Mean, standard deviation and range of variable age, per gender.

Gender	Mean	SD	Range
Femalepatients	50.5	16.4	20.0–83.0
Male patients	58.6	13.1	27.0–87.0
Total	54.1	15.7	20.0–87.0

mentioned parameters a uni-varied logistic regression was employed for each determinant by calculating the odds ratio (OR) with the IC 95% and the z-score test. A model of multi-varied logistic regression was devised by using the degree of real difficulty of the cholecystectomy as the outcome (difficult gallbladder/non-difficult post-operative) and, as the determinant, those variables which proved to be associated with the outcome in the uni-varied logistic analysis. The aOR (adjusted Odds Ratio) was calculated with the IC 95% and using the z-score test. For all the tests a value of  $P < 0,05$  was considered significant.

### 3. Results

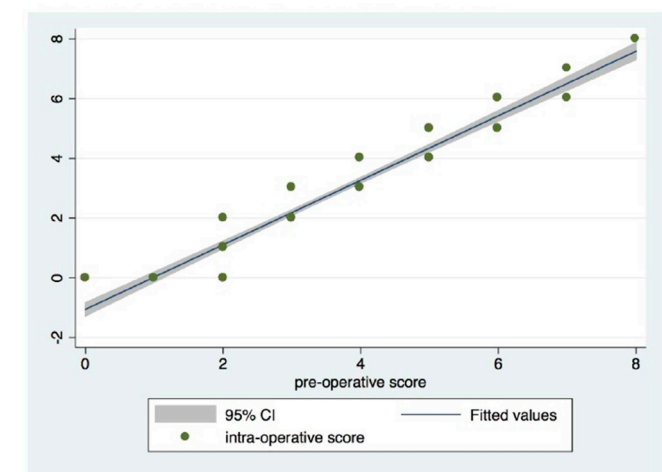
In this prospective study in 2017 we enrolled 135 patients (pts) who underwent VLC in our General Surgery Unit "V. Bonomo" of the Bari University Hospital. 60/135 (44.4%) male and 75/135 (55.6%) female. Their average age was  $54.1 \pm 15.7$  years (range = 20.0–87.0); there was a significant statistical difference in comparing the age variability per gender ( $z = 2.7$ ;  $p = 0.007$ , Table 1). The mean value of BMI was  $27.4 \pm 5.3$  (range 18.0–43.0). 124/135 patients (91.9%) suffered from biliary colic while 40/135 (29.6%) had had a previous abdominal surgical procedure, 30/40 (75.0%) of these being on the upper mesocolon, 5/40 (12.5%) on the lower mesocolon and 5/40 (12.5%) on an alternative site. 85/135 patients (60.7%) exhibited co-morbidity, their most frequent pathology being hypertension. ( $n = 45/135$ ) with multiple pathologies being found in 37 patients. Table 2 describes the US characteristics of the gallbladder identified during the pre-operative ultrasound scan. The mean value of the pre-operative score was  $3.5 \pm 1.6$  (range = 1.0–8.0), corresponding to 65/135 with a difficult gallbladder prognosis (48.2%) and 70/135 with a non-difficult one (51.8%). All pts underwent the surgical operation voluntarily. Class 2 ASA proved the most frequently attributed class ( $n = 70/135$ ; 51.9%). 8/135 patients (5.9%) received an anterograde cholecystectomy and 127/135 (94.1%) a retrograde one. Table 3 describes the VLC intra-operative parameters. The average number of medium percutaneous accesses (ports) was  $3.5 \pm 0.5$  (range = 3.0–4.0) while the average surgical operation time was  $70.7 \pm 28.5$  min (range 30.0–170.0) and the average value of the intra-operative score was  $2.7 \pm 1.8$  (range = 0.0–8.0), corresponding to 49/135 patients with "difficult gallbladder" (36.3%) and 86/135 non-difficult ones (63.7%). 3/135 patients (2.2%) presented complications after the surgical operation, 1/

**Table 2**  
Preoperative US characteristics.

Ultrasound Characteristics	Presence		Absence		Total n
	n	%	n	%	
Volume > 50 mL	98	73.1	36	26.9	135
Parietal thickness > 3 mm	79	58.5	56	41.5	135
Adhesions	94	69.6	41	30.4	135
Stratifications	27	20.0	108	80.0	135
Gallstones > 2 cm	39	28.9	96	71.1	135
Gallstones number $\geq 3$	70	51.9	65	48.1	135
Fixed Gallstones	48	35.8	86	64.2	135
Intramural Gas	1	0.7	134	99.3	135
Power Doppler wall imaging	4	3.0	131	97.0	135
Pericholecystic fluid	8	5.9	127	94.1	135
Peritoneal Effusion	1	0.7	134	99.3	135
Hepatopathy	2	1.5	133	98.5	135

**Table 3**  
Intra-operative variables.

Parameters	Presence		Absence		Total n
	n	%	n	%	
Anatomical anomalies	14	10.4	121	89.6	135
Aspiration of bile	30	22.2	105	77.8	135
Recognition of the elements of the hilus	4	3.0	131	97.0	135
Haemostasis of the gallbladder bed	59	44.0	75	56.0	134
Drainage	92	68.2	43	31.8	135
Adhesiolysis	87	64.4	48	35.6	135
Intra-operative cholangiography	4	3.0	131	97.0	135
Spillage	55	40.7	80	59.3	135
Wall fragility	13	9.6	122	90.4	135
Conversion	3	2.2	132	97.8	135



**Graph 1.** Correlation between intra-operative and pre-operative score.

3 of which (33.3%) were for residual lithiasis, 1/3 (33.3%) for a biliary fistula and 1/3 (33.4%) for sepsis. The univariate linear analysis revealed a statistically significant association of intra-operative and pre-operative scores (coef. = 1.08; CI 95% = 1.02–1.14;  $t = 36.7$ ;  $p = 0.000$ ;  $r = 0.91$ ; [Graph1](#)).

Comparing the preoperatively-assessed VLC degree of difficulty to the degree of difficulty of the cholecystectomy encountered ([Table 4](#)), one can note that the sensitivity of the preoperative US scan test is 91.8% (CI 95% = 80.4%–97.7%) while its specificity is 76.7% (CI 95% = 66.4%–85.2%), its positive predictive value is 69.2% (CI 95% = 56.6%–80.1%) and its negative predictive value is 94.3% (CI 95% = 86.0%–98.4%).

The uni-varied logistic analysis revealed a statistically significant association of difficult VLC with:

- Age (OR = 1.03, CI 95 = 1.01–1.06;  $z = 2.8$ ;  $p = 0.006$ )
- Parietal thickness > 3 mm (OR = 17.2; CI 95% = 5.7–52.2;  $z = 5.0$ ;  $p = 0.000$ )
- Adhesions (OR = 12.1; CI 95% = 3.5–42.1;  $z = 3.9$ ;  $p = 0.000$ )

**Table 4**  
Comparison between assessed VLC degree of difficulty in pre-operative US score and intraoperative score.

	Postoperative Difficult VLC	Postoperative Not Difficult VLC
Preoperative Difficult VLC	VP = 45	FP = 20
Preoperative Not Difficult VLC	FN = 4	VN = 66

**Table 5**  
Analysis of post-operative VLC variables in multi-varied logistic regression.

Variables	aOR	CI 95%	z	p
Age	1.03	0.99–1.06	1.4	0.157
Parietal thickness > 3 mm	15.4	3.9–60.2	3.9	0.000
Adhesions	15.4	3.0–78.8	3.3	0.001
Stratifications	4.3	1.2–15.1	2.3	0.022
Gallstone > 2 cm	9.3	2.4–36.4	3.2	0.001
Fixed Gallstone	1.7	0.6–5.3	1.0	0.328

- Stratifications (OR = 7.8; CI 95% = 3.0–20.3;  $z = 4.2$ ;  $p = 0.000$ )
- Gallstones > 2 cm (OR = 3.9; CI 95% = 1.8–8.4;  $z = 3.4$ ;  $p = 0.001$ )
- Fixed gallstones (OR = 2.8; CI 95% = 1.3–5.9,  $z = 2.8$ ;  $p = 0.006$ ).

The same was not observed for the other variables ( $p > 0.05$ ).

The model of multi-varied logistic analysis revealed a statistically significance of post-operative difficult gallbladder with the parietal thickness > 3 mm (aOR = 15.4;  $z = 3.9$ ;  $p = 0.000$ ) adhesions (aOR = 15.4;  $z = 3.3$ ;  $p = 0.001$ ); stratifications (aOR = 4.3;  $z = 2.3$ ;  $p = 0.022$ ), gallstones > 2 cm (aOR = 9.3;  $z = 3.2$ ;  $p = 0.001$ ); the remaining variables do not present any significance ( $p > 0.05$ ; [Table 5](#)).

#### 4. Discussion

Currently, worldwide, video-laparoscopic cholecystectomy represents the gold standard of treatment for gallbladder lithiasis, even in very complex cases. The possibility of a predictive score of the technical difficulties for VLC in the literature is still controversial, especially because the aim of studies is to single out the factors that are actually predictive of the necessity of conversion. Licciardello et al. reported a conversion rate of 8%, somewhat different from that generally reported in the literature (0–20%) and considered conversion as a necessary procedure to avoid the complications of laparoscopy and in order to cope with complex anatomical situations such as the difficult detection of the elements of Calot's triangle and the presence of a duodenal-gallbladder [7]. As other studies affirmed [8] that the use of US, aimed at the study of the gallbladder, represents an essential element to identify the predictive factors for a difficult VLC with the aim of enabling surgical teams to approach the operation with an as-far-as-possible tailored response which can only be assured if the anatomy of the patient is carefully investigated during the pre-operative stage. Our study considers very significant pre-operative US characteristics, comparing these to the intra-operative characteristics encountered. The results obtained reflect our objective of devising a universally applicable score predictive of a difficult VLC. In fact, from the statistical analysis carried out, the sensitivity of the preoperative US test was 91.8% and its specificity 76.7%, the positive predictive value being 69.2% and the negative one 94.3%. Therefore, the US approach to gallbladder pathologies proved accurate and effective as well as being in accordance with Pinto et al.'s results, even if it could be considered as an operator-dependent examination [9]. Furthermore, from the analysis of our findings there is statistical significance between the intra-operative score and the pre-operative one ( $p = 0.000$ ), particularly within the post-operative score with reference to the following parameters: parietal thickness > 3 mm ( $p = 0.000$ ), adhesions ( $p = 0.001$ ), stratifications ( $p = 0.022$ ), size of stone > 2 cm ( $p = 0.001$ ), fixed stones ( $p = 0.006$ ). These variables may represent situations likely to lead to a difficult VLC. In fact, an increase in wall thickness and stratifications intensify the rigidity of the organ, reducing the opportunities to approach the Calot's triangle and raising the risk of intra- and post-operative complications. This factor has also been identified and validated in other studies, especially in cases of acute cholecystitis [10]. Stone size > 2 cm implies difficulty, both in getting hold of the gallbladder

and in its extraction through the umbilical incision, as reported by Singh and Gabriel [11,12]. The increase in overall gallbladder volume, which, according to Vivek, combines with an increase in the difficulty of the cholecystectomy [13] did not represent a statistically significant risk in the present study. Considering the statistical significance between the preoperative and intra-operative scores, it is possible to define a single score whereby a VLC is to be considered potentially difficult, whenever it presents a pre-operative score greater than or equal to 4 (and a “non difficult” VLC with a pre-operative score of less than 4). The score obtained can allow us to predict the technical difficulty of the VLC to be undertaken. Should the score rise, a more complex technique, a longer surgical operation time may prove necessary with a higher possibility of conversion. Soltes et al. summarize Shrenk's study, published in 1998, by defining as “easy” a gallbladder with a score from 0 to 1 and “difficult” one as having a score from 4 upwards with a conversion rate of 100% [14,15]. These findings contrast with our own conversion rate of 2.2%. We should underline that conversion cannot be the end-point nor the only measurable factor in devising a predictive score. Nowadays expert surgeons tend to convert less frequently, even in cases of effective difficulty, obviously to the detriment of the operating time. For all of these reasons, in our opinion, the characteristics of the US scan test and an expert pre-operative evaluation using fixed parameters will best allow a surgical team to predict the potential technical difficulty of an imminent VLC. As this refers to the pre-operative characteristics, we have to examine the statistically significant difference between age and gender ( $p = 0.007$ ). In our sample the percentage of operations carried out upon males in comparison with females, increases with age. Almost all the patients presented a positive case history with an episode of biliary colic (91.9%) and 75% had undergone a surgical operation above the mesocolon. These two variables are relevant as they are relevant to the technical difficulty of a VLC for the possible presence of adhesions or alterations of the normal anatomy of the gallbladder and its elements. The most frequently encountered ASA class in our study was the 2nd (51.9%). An ASA score was associated with an increase in the risk of a difficult cholecystectomy, owing to the fact that the co-morbidities of patients oblige the surgeon to make use of lower endo-abdominal pressures during the VLC. No correlation between ASA and difficult cholecystectomy was found ( $p > 0.05$ ) in this study, in accordance with Sutter et al. [16]. In another study however, we did note an increase in operating time, in hospitalization time, in post-operative morbidity and of the percentage of conversion proportionate to the increase in the ASA score [17]. BMI also proved part of the pre-operative variables with the mean value of BMI being  $27.4 \pm 5.33$  (range = 18.0–43.0) and is therefore also associated with conditions of being overweight and Class 1 levels of obesity. Nachnani and Hussain report that BMI  $> 30$  values are associated to a considerable difficulty in performing Hasson's open technique and consequently in creating the pneumoperitoneum [18–20]. Some studies consider obesity a risk factor for post-operative breathing complications and of wound infection [21,22] while other studies do not report any difference in terms of outcome in this group of patients [23]. In our study we did not find any statistical significance between BMI and operative difficulty. The sample can be considered scant, but, actually, in our General Surgery Unit elective oncological and emergency surgical procedures are performed every year with a high number of patients, therefore VLC is a small part of all surgeries per year.

## 5. Conclusions

Our study has demonstrated that the US scan with a standardized report, carried out in the 48 h prior to the surgical procedure, provides a sensitivity of 91.8%. The variables which prove statistically significant in predicting a difficult cholecystectomy are: age, parietal thickness  $> 3$  mm, adhesions, stratifications, gallstones  $> 2$  cm and fixed gallstones. We have been able to define a predictive score for a difficult VLC which is to be considered potentially difficult whenever it presents

a pre-operative score greater or equal to 4 (and a “non difficult” one with a pre-operative score  $< 4$ ). These findings may prove helpful in further reducing the conversion rate and the frequency of intra- and/or post-operative complications. In this study the conversion rate was 2.2% (much lower than the average rates found in literature) but, from our point of view, this was not considered a predictive factor of an evidently difficult procedure. Nowadays experienced surgeons tend to convert less and less, even in cases of effective difficulty, obviously to the detriment of the operation time. Moreover, we have been able to draw up a more specific informative consent form to be signed by the patient, to better program the time of the surgical procedure and to choose the surgeon with the laparoscopic experience up to the difficulties likely to be encountered. This also grants great opportunities for training surgeons through optimal professional experiences. Our next step will be testing this scoring during emergency procedures, validated with a prospective multi-centered study (already planned and in the course of implementation).

## Ethical approval

All Authors declare that there is no need of any Ethical Approval for this kind of work.

## Sources of funding

All Authors state that there is any funding source for this work.

## Author contribution

Dr. Giuseppe Carbotta and Dr. Rita Laforgia wrote the main manuscript text; Dr. Annunziata Panebianco, Dr. Giovanni Balducci and Dr. Bianca Pascasio contributed in collections, database, all figures and tables. Dr. Silvio Tafuri and Dr. Francesco Paolo Bianchi prepared data analysis. Prof. Nicola Palasciano wrote the discussion, All authors reviewed the manuscript.

## Conflicts of interest

All Authors have nothing to declare in this category.

## Research registry number

researchregistry4208.

## Guarantor

Dr. Giuseppe Carbotta is the Guarantor.

## Provenance and peer review

Not commissioned, peer reviewed.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amsu.2018.09.015>.

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