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



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ABSTRACT

Background: The gold standard treatment of symptomatic cholelithiasis is vi-

deolaparoscopic 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 gall-stones. 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

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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, laparotomic conversion, presence of drainage, operating time, anatomical anomalies, recognition of the elements of the hilus and/or postoperative 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 1Mean, standard deviation and rage 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 + / -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 + / -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+/ -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 intraoperative parameters. The average number of medium percutaneous accesses (ports) was 3.5 + / -0.5 (range = 3.0-4.0) while the average surgical operation time was 70.7 + / -28.5 min (range 30.0-170.0) and the average value of the intra-operative score was 2.7 + / -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 Chracteristics	Presence		Absenc	Absence	
	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≥ 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

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