Validity and accuracy of scoring system of Randhawa and pujahari for prediction of difficult laparoscopic choleystectomy in Egyptian population

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ABSTRACT

Introduction: *Laparoscopic cholecystectomy is the procedure of choice for treating symptomatic gallstone disease and it is a procedure from the most commonly performed procedures by surgeons. Sometimes, it is challenging and takes much more time even sometimes has to be turned into an open surgery due to some difficulties faced while undergoing the procedure.* ***Purpose:*** *Evaluation of the validity and accuracy of Randhawa and Pujahari preoperative grading scoring system in prediction of difficult laparoscopic cholecystectomy in Egyptian population.* ***Methods and materials:*** *This is a prospective observational study that has been conducted in general surgery department, Kasr Al Ainy hospitals, including fifty patients undergoing elective laparoscopic cholecystectomy for symptomatic gallstones disease from November 2018 to March 2019. Scoring system of Randhawa and Pujahari had been given for each patient the day before the operation on the bases of history, clinical examination and radiological finding.* ***Results:*** *Prediction came true in 95% of easy cases and 77.8% of difficult cases, with no cases with score above 10. The scoring system is clinically and statistically valid test for predicting outcome in laparoscopic cholecystectomy with sensitivity 77.78 % and specificity 95.12 % with area under ROC = 0.962.* ***Conclusion:*** *This study shows that Ranhawa and Pujahari scoring system is reliable and could be used in Egyptian patients undergoing elective laparoscopic cholecystectomy.*

INTRODUCTION

Cholecystectomy is the basic and standard treatment for symptomatic calcular cholecystitis. Laparoscopic cholecystectomy has become superior to conventional open cholecystectomy and has become the best management for gallstone disease. Sometimes, it is difficult and shows intraoperative challenges.{1}

Recently, laparoscopic cholecystectomy has been preferred to open surgery in elective cases. Open procedure used to be preferred in the past because of the technical challenges and the high complication rates related to laparoscopic procedure. However, several studies have shown that LC is safe and recommended it as a type of cholecystectomy. {2}

Initially the scoring system developed for laparoscopic cholecystectomy was based on the previously recorded videos. There was need for development of scoring system to inform the high-risk groups prior to the operation so that they can make the required arrangements before surgery. It is useful for the surgeons also, in a way that time and schedule of the surgery can be managed appropriately.{3}

Risk stratification of patients is important to be assessed preoperatively for better planning of surgery. Therefore, scoring systems have been developed to be used for prediction of operative challenges and/or complications e.g. RSCLO score, Randhawa & Pujahari score and ultrasound scoring system.{3,4,5}

PATIENTS AND METHODS

This is an observational prospective study that has been conducted in general surgery department, Kasr Al Ainy hospitals, including fifty patients undergoing elective laparoscopic cholecystectomy for symptomatic gallstones disease from November 2018 to March 2019 fulfilling inclusion and exclusion criteria.

All the surgeries have been performed by an expert surgeon (Consultant) by conventional method using CO2 pneumoperitoneum, using classic standard two “five millimeter” ports and

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two "ten millimeter" ports. Time has been recorded from the first port insertion until the last incision closure.

Randhawa and Pujahari scoring system has been given for each patient the day before the operation based on history, clinical examination and radiological finding without informing the surgeon.

Laboratory parameters including ALP, AST, ALT, total and direct bilirubin were recorded to test whether they could be used to expect LC difficulty or not.

Table 1: Scoring system of Randhawa and Pujahari:{4}

Scoring items	Minimum score	Maximum score	Total
By History:			
Age	< 50 years (0)	>50 years (1)	1
Sex	Female (0)	Male (1)	1
History of hospitalization for acute cholecystitis	No (0)	Yes (4)	4
By Clinical examination:			
BMI	<25 (0)	25-27.5 (1) >27.5 (2)	2
Abdominal scar	No (0)	Infra-umbilical (1)	2
		Supra-umbilical (2)	1
Palpable Gall bladder	No (0)	Yes (1)	
By Sonography :			
Wall thickness	Thin (0)	Thick >4mm (2)	2
Pericholecystic collection	No (0)	Yes (1)	1
Impacted stone	No (0)	Yes (1)	1

The patients were divided into grades of risks based on the total score:
0-5 = No risk **6-10** = Moderate risk **11-15** = High risk
All intra-operative events like duration of surgery, bile or stone spillage, injury to custic duct or artery and conversion to open has been noted and surgery will be labeled as easy, difficult or very difficult.

Table 2: Scale for categorization of patients { 4}

Parameters	Easy	Difficult	Very difficult
Time taken during surgery	< 60 minutes	60 to 120 minutes	>120 minutes
Bile or stone spillage	No	Yes	------
Injury to cystic duct or artery	No	Yes	------
Conversion to open surgery	No	No	Yes

Hypothesis:

We hypothesized that Ranhawa and Pujahari grading system for preoperative prediction of difficulty of LC is valid and can be used for assessment of difficulty of LC in Egyptian population.

Method of sampling:

Systematic stratified randomization.

Inclusion criteria

The subjects were considered appropriate candidates for this study if they were:

1. Willing to give consent, were older than 18 years old.
2. Patients of both genders (male and female)
3. Having symptomatic gallstone disease.
4. Patients are generally fit for anesthesia and surgery.

Exclusion criteria:

1. All patients with conversion from laparoscopic to open procedure because of equipment failure.
2. All patient undergoing laparoscopic cholecystectomy performed with other laparoscopic intervention in same setting.
3. Patients presented with current acute attack of cholecystitis.
4. Patients presented with CBD stones.

Institutional review board approval:

All procedures and research regimens are IBR approved

Possible Risk

No attributed risks were related to the study.

Primary outcome

1. To measure incidence of cases converted to open cholecystectomy due to difficult laparoscopic procedure.
2. To decrease intraoperative biliary or vascular injury.

Secondary outcome

1. To measure incidence of complicated cases without conversion to open cholecystectomy.

Limitations of study:

1. Number of patients involved in the study.

Ethical committee approval:

"All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards"

Statistical methods:

IBM computer using statistical program for social science version 21 "SPSS" did analysis of data as follows:

- **Description** of quantitative variables as mean, SD, Median and iqr.
- **Description** of qualitative variables as number and percentage.
- **Chi-square** test was used to compare qualitative variables between groups.
- **Fisher exact** test was used when one expected cell or more are less than 5.
- **Unpaired t-test** was used to compare quantitative variables, in parametric data (SD<30% mean).
- **Mann Whitney** test was used instead of unpaired t-test in non-parametric data (SD>30%mean).
- **ROC curve (**receiver operator characteristic curve) was used to find out the best cut off point and validity of certain variable.

RESULTS

This Prospective observational study has been carried on 50 patients undergoing elective laparoscopic cholecystectomy for symptomatic gallstones disease from November 2018 to March 2019 in department of general surgery, Kasr Al Ainy hospitals.

- **Demographic data**

Gender distribution and relation to difficulty of surgery: There were 8(16%) males and 42(84%) females. In addition, we found that Age is not significant risk factor for difficult LC.

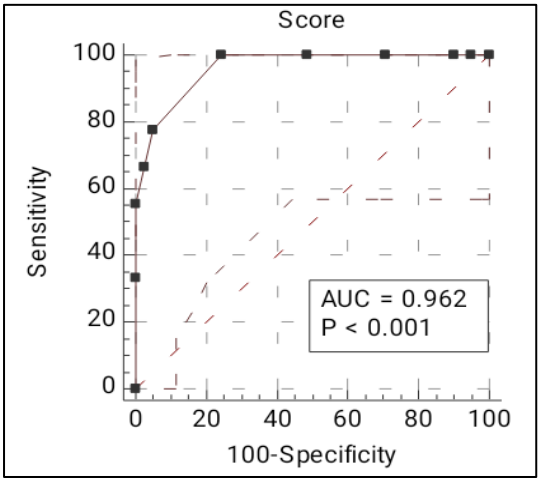
Age distribution and relation to difficulty of surgery: The age of the patients ranged from 19 to 73 years old, with a mean of 39.2 years. We found that males are not statistically significant risk factor for difficult LC.

- **Body mass index and relation to difficulty of surgery:** BMI ranged from 22 to 49 kg/m2 with a mean of 30.9. Moreover, we found that 55.6% of difficult cases were with BMI more than 27.5 kg/m2. BMI is not statistically significant risk factor for LC.
- **According to past history of patients:** 88.9% of difficult cases gave history of previous hospitalization for acute attack and / or complicated GB stone disease (Obstructive jaundice, biliary pancreatitis or ERCP). 85.4% of easy cases did not give any history of hospitalization for acute attack and or complicated GB stone disease. History of hospitalization parameter is statistically significant.
- **Relation between previous lower abdominal open surgery and difficulty of the operation:** Fourteen cases out of the 50 cases underwent previous lower abdominal surgery. Only one case was difficult. Previous lower abdominal surgery is insignificant risk factor for difficult LC.
- **Relation between GB wall thickening and difficulty of the operation :** 88.9% of difficult cases had GB wall thickening in preoperative abdominal ultrasound. GB wall thickening in ultrasound is statistically significant risk factor for difficult LC.
- **Relation between pericholecystic collection and difficulty of surgery:** All easy cases had no pericholecystic collection in preoperative abdominal ultrasound. On the other hand, two out of nine difficult cases had Pericholecystic collection on preoperative ultrasound with P value 0.029. Its presence was noted to be statistically significant risk for difficult LC.
- **Relation between impacted stone and difficulty of the operation:** Out of 41 easy cases, no recorded cases were found to have

impacted stones at Hartmann's pouch by ultrasound. On the other hand, only one case out of 8 difficult cases was found to have impacted stone. Impacted stone is not significant risk factor for difficult LC.

- **Relation between elevated alkaline phosphatase level and difficulty of the LC:** Elevated ALP is statistically significant factor for difficult LC with P value 0.008. (Normal range 70 -100 U/L)
- **ROC curve analysis for evaluation of the preoperative score in prediction of difficult operation: (Table 3)**

Area under the curve (AUC)	**0.962**
95% Confidence interval b	**0.866 to 0.966**
Significance level P (Area=0.5)	**<0.0001**
Associated criterion (Cut-Off Value)	**≤ 5**
Sensitivity	**77.78**
Specificity	**95.12**
Positive Predictive Value	**77.8**
Negative Predictive Value	**95.1**



At score ≤ 4, it has sensitivity 100% and specificity 75.61% with positive predictive value is 47.4% and negative predictive value equals 100%.

At score ≤ 5, it has sensitivity 77.78 % and specificity 95.12 % with positive predictive value is 77.8 % and negative predictive value is 95.1%.

- **Grading system prediction for easy and difficult cases:** Prediction came true in 95% of **easy** cases and 77.8% of **difficult** cases. 95.1% of easy cases presented with preoperative score less than cut-off point. 77.8% of difficult cases presented with preoperative score more than cut-off point. It shows P value <0.001.

DISCUSSION

Laparoscopic cholecystectomy has been established as the standard procedure for treating symptomatic calcular gallbladder disease and one of the most commonly performed operations by general surgeons. Sometimes, it is challenging and takes much more time even has to be turned into an open surgery due to some challenges faced while undergoing the procedure. {4}

This study included fifty patients of both genders and of the age group older than 18 years undergoing elective laparoscopic cholecystectomy for symptomatic gallstones disease.

In this study, the mean age of the population was 39.2 years and SD ±12.1 ranging from 19 to 73 years old. It finds that that age is not significant risk factor for difficult LC with P value 0.385.

Randhawa et al study included 228 patients with the age ranging between 9 and 71 years old with mean age 44.37 years (SD ±12.45), most of cases were in the age group of 30–50 years (54.4%). They as well as Khetan and Yeola found that age is not significant predictor for difficult LC with P value 0. 937{ 4, 6}. On the other hand, Yang et al in a meta-analysis demonstrated that age above 65 years is found to be associated with a twofold increase in conversion rate from LC to open surgery.{7}

The present study shows that male gender is not statistically significant risk factor for difficult LC with P value 0.144.

Randhawa et al study showed the same sex results with P value 0.144{4}. On the other hand, Sippy et al study in 2015 found that males have more prominent adhesions between the GB and surrounding structures, internal organs and omentum, have a higher laparoscopic to open conversion rate and require a much more operation time.{8}

The population of the present study has a BMI ranging between 22 and 49 with a mean of 30.9 and SD 5.9. Only 55.6% of difficult cases were with BMI more than 27.5 kg/m2. BMI is not statistically significant risk factor for LC with P

value 0.442. Also Randhawa et al study showed similar BMI results with P value 0.227{4}. Compared to the non-obese patients, class I and class II–III obese patients have a two- and threefold increase in the risk of CTO respectively.{12}

The present study shows eight of the nine difficult cases gave history of hospital admission for an attack of acute cholecystitis with or without obstructive jaundice, ERCP or biliary pancreatitis. It is found that history of hospitalization for acute attack is statistically risk factor for difficult LC with P value <0.001.

Randhawa et al study showed that 14 cases of 18 difficult cases gave history of hospitalization and found hospitalization parameter is statistically risk factor for difficult LC with P value <0.001.{4}

The present study finds that GB wall thickening in ultrasound is statistically significant risk factor for difficult LC, 88.9% of difficult cases had GB wall thickening in preoperative abdominal ultrasound with P value is 0.007.

Randhawa et al study showed that US-thick-walled GB was of statistical significance in predicting difficult LC with P value 0.038, it scored five of eight cases with thickened GB wall were difficult{4}. Also In 2007, Lipman et al study found that thickened gallbladder wall on ultrasound of the upper abdomen is associated with conversion to open surgery{10}. Another study performed in 2015 by Goonawardena et al showed doubling of the risk of conversion to open surgery with every millimetre increase in gallbladder wall thickness. Patients with GB wall thickness >5 mm on transabdominal US have higher risk of conversion to open than those with GB wall thickness 3–5 mm by 16 times.{11}

The present study shows that pericholecystic collection on preoperative ultrasound is not statistically significant risk for difficult LC with P value 0.029.

Randhawa et al study found that pericholecystic collection on ultrasound is not significant risk factor for difficult LC with P value 0.999{4}. On the other hand, in 2017, Siddiqui et al study found that there was no any statistical significance between difficulty during LC and the presence of pericholecystic collection, multiple stones or enlarged liver.{5}

The present study shows that previous lower abdominal surgery is not statistically significant risk factor for difficult LC with P value 0.414.

Randhawa et al study found that previous upper and lower abdominal surgery is insignificant predictor for difficult LC (p 0.882).{4} On the other hand, In 2012 Paajanen et al study found that the risk for CTO for patients with the past history of upper abdominal surgery 20 times higher than for those without previous surgery above the umbilicus.{12}

The present study did not score any case with palpable GB or with previous history of upper abdominal surgery.

However, Randhawa et al study found that clinically palpable gallbladder is a predictor of difficult cholecystectomy with P value 0.022.{4}

The present study scored only one case with impacted stone and it was difficult.

Randhawa et al study found that impacted stone is not statistically significant risk factor for difficult LC. {14}

In 2017, Siddiqui et al study found that patients with an impacted stone had higher incidence of operative difficulty and the association between the two was statistically significant.{5}

Similar to the results of the original study by Randhawa and Pujahar that was showing sensitivity 75.00% and specificity 90.24% at score ≤ 5, The present study shows that at score ≤ 5, it has sensitivity 77.78 % and specificity 95.12 % with positive predictive value 77.8 % and negative predictive value 95.1%{4}. Also In 2015, Agrawal et al study found that the proposed grading system is reliable and valid with a sensitivity of 76.47% and specificity of 100%{13}. In 2017, Khetan et al study found that the scoring system had a positive prediction value for easy prediction of 81.9% and for difficult prediction of 75%.{6}

CONCLUSION

This study shows that Ranhawa and Pujahari scoring system is reliable and could be used in Egyptian patients undergoing elective laparoscopic cholecystectomy. This scoring system can help each of patients, surgeons and trainers. It helps to inform the high-risk groups prior to the operation so that they can make the required arrangements before surgery. It is useful for the surgeons also, in a way that time and schedule of the surgery can be managed

appropriately. It could be involved in training process for residents and junior staff. It helps also in prediction of high possibility for conversion from LC to open surgery.

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