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Original Research Article

Nassar operative grade and ultrasonography prediction for difficult laparoscopic cholecystectomy

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ABSTRACT

Background: 'Gold standard' for symptomatic cholelithiasis is laparoscopic cholecystectomy (LC) with advantages of minimal access surgery, early return to activity with cosmetic scar. However, this may not always hold-true in all cases. Conversion to open procedure in challenging circumstances would be in better interest of the patient even after the learning curve of the surgeon has surpassed several years.
Methods: Forty patients undergoing symptomatic gall stone disease without any acute episode in past six weeks were investigated. All cases were evaluated with clinical examinations, biochemical parameters and preoperative ultrasonography done a day prior for prediction of difficult LC. All cases correlated with preoperative USG parameters and Nassar per operative grade (1-4 and 5) and analyzed for prediction to open method in difficult challenging situations. Complications associated with in 30 day of surgical interventions were also recorded.
Results: Difficult cholecystectomy was anticipated with USG parameters in 20 cases, and Nassar operative grading of difficulty (Grade-3, 4 and 5) predicted in 13 cases; the latter was correlated with conversion to open methods. $p<0.05$ in USG parameters and Nassar grading of operative difficulty was considered significant. There were no complications nor any surgical interventions required during 30 days interval.
Conclusions: Per operative Nassar grading and prior USG parameters for prediction of likelihood of difficult cholecystectomy helps in guiding surgeon in challenging situation to safely proceed to complete cholecystectomy procedure either by laparoscope or open method in the better interest of the patient.

Keywords: Gall bladder, LC, Negative predictive value, Positive predictive value, Confidence interval, Liver function test, USG

INTRODUCTION

Advancement of laparoscopic surgery ever since its inception has been very exhaustive and challenging.[1] All patients posted for laparoscopic cholecystectomy; it may not be feasible to proceed with completion all the time. The successful completion of laparoscopic procedure depends on patient's factor, technical skills of surgeon(s) and instruments, gallbladder anatomy and anomalies, fibrosis, adhesions and fistula with surrounding organs. Many studies have been done to predict the difficult cholecystectomy cases prior to surgery including co-morbid conditions. Contextually USG done a day prior to procedure regarding GB status have been extensively studied. The actual insight about the operating difficulty on initial assessment of GB status; cystic pedicle; surrounding adhesions have been overlooked and not possible with USG prediction alone. Nassar grade of operative difficulty (grade 1- 4 and 5) with parameters of GB, cystic pedicle and associated adhesions contribute to completion of the procedure is a simple grading tool to assist surgeons in tricky situations. Nonetheless,

conversions depend upon safe judgment of the operating team in the best interest of the patient.[2] Hence the prospective observational study was undertaken with the objective of correlating USG and Nassar operative grading for prediction of difficult cholecystectomy and actual conversion to open cholecystectomy.

METHODS

Sample size calculation

The study of Griffiths, et al observed that odds ratio of Nassar grade 3, 4 and 5 for predicting conversion to open was 12.26 and 115.6 respectively.[3] Taking these values as reference, the minimum required sample size with 90% power of study and 5% level of significance is 36 patients. To reduce margin of error, total sample size taken is 40.

Formula used is: $n \geq (4*(Z_\alpha+Z_\beta)^2)/(\log(OR))^2$

Where Z_α is value of Z at two-sided alpha error of 5% and Z_β is value of Z at power of 90%, OR is odds ratio.

Calculations

Calculation of Nassar grade 3:

$n \geq [4*(1.96+1.28)^2)/(\log(12.26)]^2=35.44=36$, cases (approx.)

Calculation of Nassar grade 4 and 5:

$n \geq [4*(1.96+1.28)^2)/(\log(115.6)]^2=9.87=10$, cases (approx.)

Keeping the unknown status of the conversion rate including morbidity and mortality in this observational prospective surgical complexity study and for sake of ethical issues total 40 cases were included in study group.

Present study is a prospective observational study conducted after ethical clearance by hospital. Single consultant Surgeon with 25 years of experience in laparoscopic surgery was undertaken from Jan 2018 to Jan 2020. Forty cases of symptomatic gall stones posted for laparoscopic cholecystectomy with age above 18 years, cases with acute cholecystitis episode in last 8 weeks, pancreatitis, deranged LFT, increased TLC counts, increase serum amylase and lipase, CBD stenting and ERCP intervention were excluded along with co-morbidities of diabetes and hypertension, chronic COPD, tuberculosis and past upper abdominal surgery. Laboratory and USG parameters evaluated a day prior to surgery included patient's age, sex, BMI, LFT, and serum amylase and lipase. USG parameters for predictions included GB wall thickness (<4 mm or >4 mm), presence or absent of pericholecystic edema, calot's anatomy, CBD diameter (up-to 6 mm/more than 6 mm), GB anatomy (contracted, normal, fibrosis,) GB dilated (stones, mucocele, empyema), GB calculus (single, multiple, densely packed), presence of biliary sludge, any abnormal anatomy of hepatobiliary system.

Difficult LC on USG were correlated with intra-operative Nassar difficulty grading scale (1-4 and 5) for completion of LC. Per operatively Nassar operating grading of difficulty (grade 1-4 and 5) done after port placement; aspiration of GB (yes/no); GB difficult to hold (packed stones/fibrosis/contracted); Calot's anatomy with ease of dissection, Mirrizi's type, clips application; GB bed dissection time (easy/difficult/bleeding); Spillage of (stones/bile); Extraction of GB (stones, sludge spillage); Saline wash of GB bed (required/peritoneal cavity); Drain (*in situ*/no drain); Completion time; Technical instrument failure; Conversions to open; Complications (bleeding, related to surgery) and surgical intervention undertaken in next 30 days .

Nassar grades of operative difficulty (Grade 1-4 and 5): Based on GB anatomy, cystic pedicle, adhesions with surroundings, no of stones, fistulas with surrounding structures and Mirrizi's anatomy

Grade 1

Gall bladder-Floppy, non-adherent. Cystic pedicle-Thin and clear. Adhesions-Simple up to the neck/Hartmann's pouch.

Grade 2

Gall bladder-Mucocele, Packed with stones. Cystic pedicle-Fat laden. Adhesions-Simple up to body.

Grade 3

Gall bladder-Deep fossa, acute cholecystitis, contracted, fibrosis, Hartmann adherent to CBD, impaction. Cystic pedicle-Abnormal anatomy or cystic duct-short dilated or obscured. Adhesions-Dense up to fundus; Involving hepatic flexure or duodenum.

Grade 4

Gall bladder-completely obscured, Empyema, Gangrene, Mass. Cystic pedicle- Impossible to clarify. Adhesions-Dense fibrosis, wrapping the gall bladder (GB), Duodenum or hepatic flexure difficult to separate.

Grade 5

Mirrizi's type 2/higher, cholecysto-cutaneous, cholecysto-duodenal, or cholecysto-colic fistula.

This difficulty scale was modified in 1996 in reference cohort to include a grade 5 (which was defined as presence of either Mirrizi's type 2 or higher, cholecysto-cutaneous, cholecysto-duodenal, or cholecysto-colic fistula were combined with grade 4 for the analysis. This

grading the operative findings of the individual cases with overall summary of worst factor of operative findings in GB conditions, cystic pedicle and adhesions Outcomes were-Conversion to open, Duration of surgery, Complications and re-intervention.

Statistical analysis

Categorical variables were done in the form of number and percentage (%), presentation of the continuous variables was done as mean±SD and median values. The data normality was checked by using Kolmogorov-Smirnov test. Data was not nominal, nonparametric tests used. Statistical tests in association of the variables quantitative were analyzed using Mann-Whitney test (for two groups) and qualitative variables analyzed using Fisher's extract test. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated predicting difficult cholecystectomy by USG. Data entered in Microsoft excel spreadsheet and analysis done with using SPSS software version 21.0. and p value of less than 0.05 was considered as significant.

RESULTS

The age range was from 22-65 years and mean age was 41years. 70% were females. 17.50% had normal BMI while 45% were overweight and 37.50% were obese.

Table 1: Distribution of socio-demographic characteristics of study subjects.

Socio-demographic characteristics	Frequency	Percentage (%)
Age (years)		
Mean±SD	41.35±12.4	
Median (25^{th}-75^{th} percentile)	38.5 (32-49.75)	
Range	22-65	
Gender		
Female	28	70
Male	12	30
Body mass index (kg/m²)		
<25 (Normal BMI)	7	17.50
25-29.99 (Overweight)	18	45
≥30 (Obese)	15	37.50
Mean±SD	27.98±3.17	
Median (25^{th}-75^{th} percentile)	29 (25-30)	
Range	24-35	

GB wall thickness more than 4mm predictive of difficult cholecystectomy was seen in 37.50% of cases while GB packed with stones was seen in 22.50% cases. Single calculus was seen in 17.50% cases. CBD diameter more than 6mm was seen in 12.50% cases. Thick fibrosed contracted GB predictive of difficult cholecystectomy was seen in 25% of cases. Pericholecystic edema suggestive of inflammatory reaction was seen in 5 cases accounting for 12.50% cases. Biliary sludge was seen in 15% of cases. Prediction by USG parameters suggesting difficult cholecystectomy was seen in 50% of cases.

Table 2: Distribution of operative findings of study subjects.

Operative findings	Frequency	Percentage (%)
Aspiration of gall bladder		
No	31	77.50
Yes	9	22.50
Gall bladder difficult to hold		
No	30	75
Yes	10	25
Gall bladder difficult to hold (adhesions/packed with stones)		
Difficult (packed stones)	10	25
Difficult (contracted GB)	7	17.50
Normal	23	57.50
Calot's dissection		
Frozen/adhesions	13	32.50
Not frozen (not difficult)	27	67.50
Extra time GB (bed dissection)		
No	25	62.50
Yes	15	37.50
Spillage of stones		
No	37	92.50
Yes	3	7.50
Conversion to open		
Conversion (lap to open)	7	17.50
No (Lap cholecystectomy)	33	82.50
Nassar grade (operative difficulty)		
I	22	55
II	5	12.50
III	6	15
IV	7	17.50
Wash/drain		
No wash	31	77.50
Drain placed	6	15
Wash and drain placed	3	7.50
Time taken for GB bed dissection (minutes)		
Mean±SD	22.52±8.22	
Median (25^{th} -75^{th} percentile)	20 (15-30)	
Range	11-40	

After USG predictions for difficult cholecystectomy; port placements and Nassar grading of operative difficulty (GRADE 1-4 and 5) was assessed and correlation done accordingly. Grade 1 (55%), grade 2 (12.50%), grade 3 (15%) and grade 4 and 5 (17.50%).

Table 3: Operative findings and correlation of USG prediction for difficult cholecystectomy.

Operative findings	Not predicted, (n=20) (%)	Predicted, (n=20) (%)	Total, (%)	P value	Test performed
Aspiration of gall bladder					
No	16 (80)	15 (75)	31 (77.50)	1	Fisher exact test
Yes	4 (20)	5 (25)	9 (22.50)		
Gall bladder difficult to hold					
No	19 (95)	11 (55)	30 (75)	0.008	Fisher exact test
Yes	1 (5)	9 (45)	10 (25)		
Gall bladder difficult to hold because of adhesions/full of stones					
Difficult packed stones	7 (35)	3 (15)	10 (25)	0.009	Fisher exact test
Difficult (contracted/ fibrosis) GB	0 (0)	7 (35)	7 (17.50)		
Normal	13 (65)	10 (50)	23 (57.50)		
Calots dissection					
Frozen calots/adhesions	2 (10)	11 (55)	13 (32.50)	0.006	Fisher exact test
Not frozen	18 (90)	9 (45)	27 (67.50)		
Extra time taken for GB bed dissection					
No	17 (85)	8 (40)	25 (62.50)	0.008	Fisher exact test
Yes	3 (15)	12 (60)	15 (37.50)		
Spillage of stones					
No	18 (90)	19 (95)	37 (92.50)	1	Fisher exact test
Yes	2 (10)	1 (5)	3 (7.50)		
Conversion to open					
Conversion	0 (0)	7 (35)	7 (17.50)	0.008	Fisher exact test
Not (Lap cholecystectomy)	20 (100)	13 (65)	33 (82.50)		
Nassar criteria on laparoscopic GB status					
I	14 (70)	8 (40)	22 (55)	0.0002	Fisher exact test
II	5 (25)	0 (0)	5 (12.50)		
III	1 (5)	5 (25)	6 (15)		
IV	0 (0)	7 (35)	7 (17.50)		
Wash/drain					
No wash	18 (90)	13 (65)	31 (77.50)	0.02	Fisher exact test
Drain	0 (0)	6 (30)	6 (15)		
Wash and drain	2 (10)	1 (5)	3 (7.50)		
Time taken for GB bed dissection (minutes)					
Median (25^{th}-75^{th} percentile)	17 (13-21.25)	30 (20-30)	20 (15-30)	0.005	Mann Whitney test; 97.5

Table 4: Operative findings correlation with conversions (Open procedure).

Operative findings	Conversion, (n=7) (%)	Lap cholecystectomy, (n=33) (%)	Total, (%)	P value	Test performed
Aspiration of gall bladder					
No	3 (42.86)	28 (84.85)	31 (77.50)	0.034	Fisher exact test
Yes	4 (57.14)	5 (15.15)	9 (22.50)		
Gall bladder difficult to hold					
No	1 (14.29)	29 (87.88)	30 (75)	0.0003	Fisher exact test
Yes	6 (85.71)	4 (12.12)	10 (25)		
Gall bladder difficult to hold because of adhesions/full of stones					
Difficult (packed stones)	1 (14.29)	9 (27.27)	10 (25)	0.017	Fisher exact test
Difficult (contracted/ fibrosed GB)	4 (57.14)	3 (9.09)	7 (17.50)		
Normal	2 (28.57)	21 (63.64)	23 (57.50)		
Calot's dissection (adhesions)					
Frozen calot's	6 (85.71)	7 (21.21)	13 (32.50)	0.003	Fisher exact test
Not difficult	1 (14.29)	26 (78.79)	27 (67.50)		

Continued.

Operative findings	Conversion, (n=7) (%)	Lap cholecystectomy, (n=33) (%)	Total, (%)	P value	Test performed
Extra time taken for GB bed dissection					
No	1 (14.29)	24 (72.73)	25 (62.50)	0.007	Fisher exact test
Yes	6 (85.71)	9 (27.27)	15 (37.50)		
Spillage of stones					
No	6 (85.71)	31 (93.94)	37 (92.50)	0.448	Fisher exact test
Yes	1 (14.29)	2 (6.06)	3 (7.50)		
Nassar criteria on laparoscopic GB status					
I	0 (0)	22 (66.67)	22 (55)	<0.0001	Fisher exact test
II	0 (0)	5 (15.15)	5 (12.50)		
III	0 (0)	6 (18.18)	6 (15)		
IV	7 (100)	0 (0)	7 (17.50)		
Wash/drain					
No wash	1 (14.29)	30 (90.91)	31 (77.50)	<0.0001	Fisher exact test
Drain	5 (71.43)	1 (3.03)	6 (15)		
Wash and drain	1 (14.29)	2 (6.06)	3 (7.50)		
Time taken for GB bed dissection (minutes)					
Median (25^{th}-75^{th} percentile)	30 (30-32.5)	20 (15-30)	20 (15-30)	0.007	Mann Whitney test; 40.5

Table 5: Per operative findings with Nassar grading on laparoscopic GB status.

Nassar operative grade	I (n=22) (%)	II (n=5) (%)	III (n=6) (%)	IV (n=7) (%)	Total (%)	P value	Test performed
Aspiration of gall bladder							
No	21 (95.45)	2 (40)	5 (83.33)	3 (42.86)	31 (77.50)	0.002	Fisher exact test
Yes	1 (4.55)	3 (60)	1 (16.67)	4 (57.14)	9 (22.50)		
Gall bladder difficult to hold							
No	22 (100)	5 (100)	2 (33.33)	1 (14.29)	30 (75)	<0.0001	Fisher exact test
Yes	0 (0)	0 (0)	4 (66.67)	6 (85.71)	10 (25)		
Gall bladder difficult to hold because of adhesions/full of stones							
Difficult (packed stones)	5 (22.73)	3 (60)	1 (16.67)	1 (14.29)	10 (25)	0.001	Fisher exact test
Difficult (contracted fibrosed GB)	0 (0)	0 (0)	3 (50)	4 (57.14)	7 (17.50)		
Normal	17 (77.27)	2 (40)	2 (33.33)	2 (28.57)	23 (57.50)		
Calot's dissection							
Frozen calot's	1 (4.55)	0 (0%)	6 (100%)	6 (85.71)	13 (32.50)	<0.0001	Fisher Exact test
Not difficult	21 (95.45)	5 (100)	0 (0)	1 (14.29)	27 (67.50)		
Extra time taken for GB bed dissection							
No	19 (86.36)	4 (80)	1 (16.67)	1 (14.29)	25 (62.50)	0.0001	Fisher Exact test
Yes	3 (13.64)	1 (20)	5 (83.33)	6 (85.71)	15 (37.50)		
Spillage of stones							
No	20 (90.91)	5 (100)	6 (100)	6 (85.71)	37 (92.50)	1	Fisher Exact test
Yes	2 (9.09)	0 (0)	0 (0)	1 (14.29)	3 (7.50)		
Conversion to open							
Conversion	0 (0)	0 (0)	0 (0)	7 (100)	7 (17.50)	<0.0001	Fisher Exact test
Lap cholecystectomy	22 (100)	5 (100)	6 (100)	0 (0)	33 (82.50)		
Wash/drain							
No wash	19 (86.36)	5 (100)	6 (100)	1 (14.29)	31 (77.50)	0.001	Fisher Exact test
Drain	1 (4.55)	0 (0)	0 (0)	5 (71.43)	6 (15)		
Wash and drain	2 (9.09)	0 (0)	0 (0)	1 (14.29)	3 (7.50)		
Time taken for GB bed dissection (minutes)							
Median (25^{th}-75^{th} percentile)	18 (14.25-20.75)	15 (12-18)	30 (30-33.75)	30 (30-32.5)	20 (15-30)	0.0005	Kruskal Wallis test; chi square=17.913

Aspiration of gall bladder was mandatory in 22.50% of cases as GB was difficult to hold initially in 25% cases while fibrosis contributed to another 17.50% cases. Calot's dissection was difficult with frozen anatomy encountered in 13 cases while 7 cases converted to open procedure belonged to Nassar grade 4 at initial evaluation of GB, cystic duct and Calot's anatomy and adhesions. Time was taken for GB bed dissection in 15 cases was more due to fibrosis, shrunken GB.

Aspiration of GB to proceed with laparoscopically is not significant while GB difficult to hold because of distorted anatomy, adhesions, fibrosis making is important and p=0.008 is significant as for deciding completion of LC. Also, fibrosis, contracted the tGB or packed GB calculus contribute significantly to successful completion of laparoscopic approach with p=0.009. Extra time for GB bed dissection is significant with p=0.008. Nassar operative grading is highly significant in deciding the difficult LC with p=0.0002.

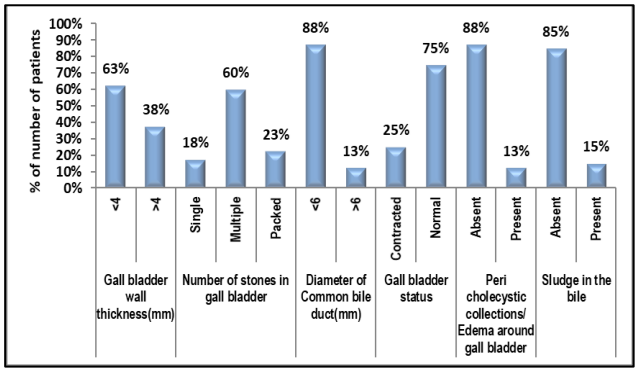

Figure 1: Distribution of USG findings of study subjects.

Table 6: Sensitivity, specificity, PPV and NPV of USG predictions for difficult cholecystectomy.

Conversion to open	USG prediction of difficult cholecystectomy (%)
Sensitivity (95% CI)	100 (59.04 to 100)
Specificity (95% CI)	60.61 (42.14 to 77.09)
AUC (95% CI)	0.8 (0.65 to 0.91)
PPV (95% CI)	35 (15.39 to 59.22)
NPV (95% CI)	100 (83.16 to 100)
Diagnostic accuracy	67.50

Fisher extract test with operative difficulty in all cases which were converted to open reveals that GB anatomy, cystic pedicle, adhesions of GB, adhesions, fistulas with GB and surrounding organs are contributing factors deciding operative challenges and conversion with significant p<0.05.

Spillage of stones is not a significant criterion for difficult cholecystectomy with p value more than 0.05. Aspiration of GB for decompression, GB difficult to hold because of packed stones/fibrosis/ contracted GB, frozen calot's, Extra time taken for GB bed dissection, Drain placed and conversions to open procedures are important factors for difficult cholecystectomy with p<0.05.

The sensitivity of USG prediction for difficult cholecystectomy was 100% with specificity of 60.61% taking 95% CI with PPV of 35% and NPV of 100% The diagnostic accuracy of USG prediction was 67.50% in our study.

DISCUSSION

Analysis of 65 subjects with USG predicting difficult LC was with the sensitivity 94.3%; specificity 50.8% with actually, difficult LC seen in 66% were while in our series sensitivity was 100% and specificity was 60.61% with accuracy of 67.50%.[2]

Per operative Nassar grading is a simple tool for intra-operative stratification of difficulty in LC with advantage of analyzing operative strategy with planning, comparison of different research studies, facilitating risk adjustments for surgical outcomes and providing guidelines to trainees' surgeons with monitoring of progression of training.[3] Per Operative difficulty of LC was evaluated with 30 day outcome in 2 prospective multicentre trials of cohorts of 8820 cases (Chole study) and 4089 cases from a single surgeon series from Feb 92 to July 2014. Nassar operative grade evaluated in single surgeon series with grade I (33.70%), grade II (31.20%), grade III (19.90%) and grade IV (15, 20%) while in Chole series grade I (40.60%), grade II (30%), grade III (20.40%) while grade IV was (9%) while in our series grade I was (55%), grade II (12, 50%), grade III (15%) and grade IV was (17.50%).[3] All cases of Nassar grade IV per operatively were conversions in our series while grade IV was 15.20%; 20.40% in two large series while 17.50%in our series signifying difficulty in proceeding to completion of procedure laparoscopically.

Predictors of difficult LC included elderly people, repeated cholecystitis, thickened GB, multiple stones, and pericholecystic collections.[4] Abdominal operations with scars, lump, tenderness predict difficult dissection.[5] Lal et at reported PPV of 80.95% for difficult LC with distended GB , mucocele, fibrosis, contracted , stone impacted at neck adding to difficult dissection and an informed consent makes less challenging task for the surgeon.[6] Haldeniya et al evaluated 400 cases with preoperative USG had 6% conversion with 36% difficult prediction but actually difficulty observed in 4.75% cases.[7] This contradicts with our series wherein the conversion rate was 17.50% while prediction on USG was 50%. Kapoor et al evaluated with prior USG for difficult LC in 300 cases with PPV of 80.95%.[8] In another series of 1000 cases the conversion rate was 4.8% only.[9] Ghadhban et al at Baghdad did evaluation of 100 cases for prediction for difficult LC in 58% while only 7% were actually difficult.[10]

A large series of 6147 cases of LC analyzed for difficult LC prediction seen in 21.50% but successfully completion done 99.65% of cases with conversion in 22 cases (0.36 %) were actually acute cholecystitis cases while overall difficult LC was 1.66%.[11] In yet another series with acute cases taken up in emergency for LC as per literature recommendations; the conversion was 0.62% only.[12] Chand et al predicted difficult LC in 14 cases; intra-operative difficult LC was seen in 11 cases conversion required in one cases only in a series of 50 cases evaluated with USG; PPV(91.67%) and sensitivity (78.57%) with accuracy 84%; stone at GB neck encountered with accuracy 82%; mobile gall stones with difficulty seen in 9 cases with accuracy 82%.[13]

Gadacz et alnoted GB wall thickness as predictor of difficult LC with sensitivity (66.7%), specificity (94.10%) PPV (84.2%).[14] Talukder et al evaluated 160 cases and encountered difficult LC (43.75 %) conversion done in (3.75%) with thick GB wall (15%), difficult to hold GB (75%), contracted GB (16.25%), difficult calot's dissection (12.50%) difficult GB bed dissection encountered (15%) cases while only 17.50% were conversions in our series.[15] Bhattacharjee et al evaluated 100 cases of LC with conversion of 8%. With male gender, liver fibrosis, large solitary calculus as predictors of difficult LC.[16] Patient should be apprised of possible complications and safe conversions with proper space and time to adjust their expectations and options.[17] The limitation of the present study was the small sample size and may be in a large population it may be evidence-based model for the surgeon in challenging situations for completion of the procedure safely.

CONCLUSION

Nassar operative grading is a simple tool for intra-operative stratification of difficulty LC in challenging situations. Clinical evaluation, lab and imaging parameters done a day prior to surgery helps in predicting the successful outcome of surgery (laparoscopic/open) and mentally prepare the patient and the surgeon for completion of the procedure safely. Surgeon should have a low threshold of conversion to open cholecystectomy in the better interest and safety of the patient though always informed consent helps surgeons in challenging situations.

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