PREDICTIVE RISK FACTOR FOR DIFFICULT ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY IN HUSM

By

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ACKNOWLEDGEMENTS

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ABSTRAK

Latar belakang dan objektif: Laparoskopik kolesistektomi adalah rawatan standard untuk pesakit batu karang pundi hempeda yang bergejala. Walau bagaimanapun, pembedahan laparoskopik kolesistektomi mungkin sukar oleh pelbagai faktor risiko. Mengenal pasti faktor risiko sebelum pembedahan sangat penting bagi pakar bedah dan pesakit dalam menjangkakan kesukaran semasa pembedahan. Kajian ini dilakukan untuk mengenal pasti faktor risiko klinikal, radiologi, dan perioperatif dengan pesakit laparoskopik kolesistektomi elektif yang sukar di HUSM.

Kaedah Kajian: Ini adalah kajian rekod retrospektif pesakit yang menjalani pembedahan laparoskopik kolesistektomi dari 2013-2018 di Hospital Universiti Sains Malaysia. Ciri-ciri pesakit, sejarah klinikal, data makmal, hasil ultrasonografi dan perincian intraoperatif dianalisa secara retrospektif untuk menilai ramalan laparoskopi kolesistektomi yang sukar.

Keputusan: Sebanyak 154 pesakit yang menjalani laparoskopik kolesistektomi elektif dimasukkan dalam kajian kami. Purata penukaran kepada pembedahan secara buka adalah 4.5%, purata tempoh pembedahan adalah 91.71 minit dan purata tempoh pesakit di hospital selepas pembedahan adalah satu hari.Kelaziman laparoskopik kolesistektomi elektif yang sukar di HUSM adalah 55.2% (95% CI = 47.3, 63.0). Analisa menunjukkan pesakit yang pernah menghidap kolangitis , riwayat ERCP , dinding pundi hempeda tebal pada ultrasound , lekatan padat hempedu dan segitiga calot yang secara intraoperatif mempunyai kaitan yang ketara dengan kolesistektomi laparoskopi yang sukar.

Kesimpulan: Dari kajian kami, kami dapat menyimpulkan bahawa sejarah kolangitis pesakit, sejarah ERCP, dinding pundi hempeda tebal pada ultrasound, pelekatan yang padat di antara pundi

hempedu dan juga segitiga calot yang keras secara intraoperatif didapati sebagai faktor ramalan laparoskopik kolesistektomi yang sukar dalam kajian kami.

ABSTRACT

Background : Laparoscopic cholecystectomy (LC) is a gold standard management for symptomatic cholelithiasis. However, LC might be difficult due to the various risk factors. Preoperative risk factors are very important for the surgeon and patient in anticipating of difficulty during surgery. The aim of this study to identify clinical, radiological, and perioperative risk factor with difficult elective laparoscopic cholecystectomy patient in HUSM.

Methods: This is a retrospective record review of patients who underwent elective laparoscopic cholecystectomy from 2013 to 2018 in Hospital Universiti Sains Malaysia.

The patient's characteristics, clinical history, laboratory data, ultrasonography results and intraoperative details were retrospectively analyzed to evaluate predictors of difficult LC.

Results: A total of 154 patients whom underwent elective laparoscopic cholecystectomy and fullfill the criteria were included in this study. The conversion rate to open surgey was 4.5%, the mean operative length was 91.71 minutes and the mean hospital stay post operative was one day. The prevalence of difficult elective laparoscopic cholecystectomy in HUSM was 55.2% (95% CI = 47.3, 63.0). Multivariate analysis showed that history of cholangitis , history of ERCP , thick gallbladder wall on ultrasound , dense adhesion and fibrosed Calot's triangle intraoperatively had significant association with difficult laparoscopic cholecystectomy.

Conclusion: From this study, it is concluded that patient's history of cholangitis, history of ERCP, thick gallbladder wall on ultrasound, dense adhesion and fibrosed Calot's triangle intraoperatively were found to be the predictive factors of difficult LC.

CHAPTER ONE: INTRODUCTION

1.1 LITERATURE REVIEW

Age is considered one of the significant factors for a difficult laparoscopic cholecystetctomy (LC). Reasons postulated include a long duration of disease and subsequent thickening and more contracted gallbladder (GB) wall. In such cases the cystic duct becomes foreshortened and GB may be adherent to common bile duct (CBD). According to *Fried et al* and *Pavlidis et al*, patient with older age, (65 years and above) have a significant predictor of conversion to open surgery(1, 2)

Difficult laparoscopic cholecystectomy also found in male compare to females. The increased rate of inflammatory changes in gallbladder specimens of males might depend on many factors. First, men are more negligent about their health, and they seek medical attention late. In case of cholecystitis, male patients have been shown to apply medical help after several attacks of inflammation, resulting in chronic changes that make operation more difficult (3) . Based on study by *Nidoni et al* and *O'leory et al* they found that male sex associated with higher rate of conversion to open surgery and prolonged operation time(4, 5)

Obesity and the presence of abdominal fat causes obvious difficulty in the placement of the umbilical port as the umbilicus is displaced downwards and it is difficult to identify the umbilical fascia in creating pneumoperitoneum. According to *Gupta et al,* obese patient with BMI more than 30kg/m^2 was associated with significant intraoperative difficulty (6).

History of hospitalization of recurrent attacks of acute cholecystits was found to be a significant factor for prediction of difficult LC. Patient, who require hospitalization for multiple attacks of acute cholecystitis, carries more chances of difficult laparoscopic cholecystectomy and conversion, probably due to dense adhesions at calot's triangle and gall bladder fossa (6). Furthermore, there were two other studies that found that patient with recurrent episode of admission due to acute cholecystitis had significant correlation with difficult laparoscopic cholecystectomy(3, 7).

Endoscopic retrograde cholangio pancreatography (ERCP) is a endoscopic procedure commonly for those patient with history of cholangitis as a therapeutic procedure for biliary system obstruction as the complication of gallstone disease. Inflammation of biliary system lead fibrosis formation of the gallbladder and causing adhesion of gallbladder to the adjacent structure.There were studies conclude that pre operative ERCP has increase the rate for difficult laparoscopic cholecystectomy (8, 9) whereas few other studies showed ERCP has no significant correlation with difficult LC(10).

Previous upper abdominal surgery has been listed as a concern because of adhesion formation, which causes bowel or other abdominal structures to adhere to the undersurface of the abdominal wall. The potential for bowel injury during trocar placement or difficulty in visualization of the hepatobiliary structures has dissuaded some surgeons from using the laparoscopic procedure in patients with previous abdominal surgery. In the study by *Akyurek et al*

in 192 patients who had undergone previous abdominal surgery the conversion rate was 2.0% in patients with previous abdominal surgery(11). However, the rate of conversion to open cholecystectomy and the complication rate were virtually identical to those found in the patients without prior surgery. Another study by *Goyal et al* also found history of previous abdominal surgery had significant risk for difficult laparoscopic cholecystectomy(12)

Biochemical test of liver function also found to be risk factors for difficult laparoscopic cholecystetctomy. The study by *Rattner et al* and *Sanniyasi et al* concluded that raised serum alkaline phosphatase (ALP) was associated with severe inflammation and failure of laparoscopic cholecystectomy(13, 14). Besides, few studies showed that raised serum aspartate transaminase (AST), serum alanine transaminase (ALT), total bilirubin were non significant factors for difficult laparoscopic cholecystectomy(8, 15)

Gallbladder wall thickness on sonography was found to had a high significant statistical association with difficult LC(8, 16). The most valuable assessment that ultrasound can provide is gallbladder wall thickness and GB wall thickness > 4 mm was considered as predictors of difficult LC(17, 18). Thicken GB wall is associated with difficult dissection of the GB from its bed, increase risk of bleeding and increase duration of operative time(8, 16).

Numbers of stones and stone size in a gallbladder is related with difficult LC. Multiple gallbladder calculi and large gallbladder calculi more than 2 cm associated with technical difficulty in retrieval of gallbladder via port site opening due to packed with multiple calculi and large stone

(19, 20). In contrary, few studies showed that multiple gallbladder stones and large gallbladder stone has no significant association with difficult LC(21, 22). Furthermore, impacted stone at Hartman's pouch of gallbladder makes dissection difficult because of difficulty in holding gallbladder(8, 21)

The intra operative parameters for difficult laparoscopic cholecystectomy were adhesions of gallbladder to adjacent structure, fibrosed Calot's triangle, contracted gallbladder ,intrahepatic gallbladder and cholecystoenteric fistula had significant association with longer operation time and high risk for a conversion to open cholecystectomy(12, 23-25). Furthermore, anomalous anatomy were also a significant factor of intraoperative difficulty(26).

The difficult laparoscopic cholecystectomy is characterized by longer operative time, conversion to open surgery and patient required longer post operative hospital stay. According to *Sugrue et al* and *Cinar et al*, the mean operative time for conventional elective laparoscopic cholecystectomy was 71.8 minutes and 64.6 minutes(27, 28). However study by *Ashfaq et al*, the difficult gall bladder require longer mean operative time which was 147 minutes(29). Similar to the study of predictive difficult laparoscopic cholecystectomy by the *Randhawa et al*, found that difficult laparoscopic cholecystectomy patient required 60-120minutes or longer operative time (30). Long post operative hospital stay associated with multiple risk factor pre operative and intra operatively. The study by *Ko-Iam et al*, out of 500 laparoscopic cholecystectomies, 411 (82.20%) could be discharged within 24 hours after operation, while 89 (17.80%) had a longer hospital stay(31). Similar to *Chong et al*, out of 336 laparoscopic cholecystectomy cases analyzed, 225

(67%) patients discharge on day 1 post operatively and the remaining 111 (33%) patients on day 3-18. Reasons for long hospital stay included observation of postoperative fever, surgery related causes (postoperative pain, delayed oral diet, delayed removal of abdominal drain, and postoperative complications)(32). Besides, the factors that increased the risk of a long hospital stay included patients with an ASA class 3, a history of previous acute cholecystitis, cholangitis, or pancreatitis, a history of cirrhosis.

Conversion to open surgery usually indicates a difficult procedure, and rather than being considered a complication, the decision to convert should be regarded as a sign of good judgement in the presence of adverse conditions. Conversion to an open procedure is necessary in 5–10% of patients, and is associated with increased morbidity, prolonged hospitalization and longer recovery compared to a laparoscopic approach. According to study by *Samer et al*, the conversion rate was 1.03%, whereby the study by *Sharma et al* and *Rashid et al*, the conversion rate was 8.8% and 7% accordingly(33-35). Common indications for conversion include failure to demonstrate the 'critical view of safety', or the presence of an intraoperative complication, such as intestinal perforation, haemorrhage or bile duct injury. Several factors increase the risk of conversion to open, including age,male sex,obesity,cholecystitis and previous ERCP (36).

1.2 RATIONALE OF STUDY

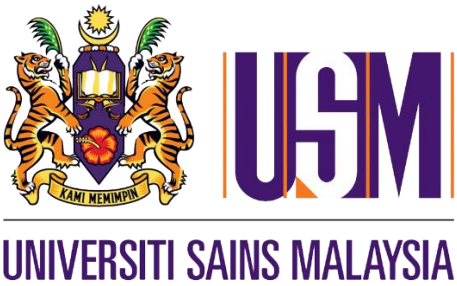
1) One of the most common causes of abdominal pain is the presence of gallstones. Cholecystectomy is the only effective management of symptomatic gallstones, with 93% of gallbladder disease problems referred to surgeons. Open cholecystectomy (OC) has been widely replaced by laparoscopic cholecystectomy (LC).However, current literature suggests that the rate of intraoperative conversion from LC to OC is 2% - 15%, and that conversion is known to increase perioperative time, complication rates, perioperative costs, the length of hospital stay, and hospital charges. Conversion is also associated with complications including death, bile duct injury, bile leak, or bleeding, requiring reoperation or transfusion. It is, therefore, essential to identify risk factors for conversion to allow for safer procedures and better surgical planning. A systematic assessment of these factors preoperatively allows determination of whether OC surgery should be performed initially, avoiding the potential complications brought through an intraoperative conversion from LC to OC. Further, effective conversion prediction models allow patients the right to be better informed of such risks before they give consent.

2) Although there were already a few studies venturing into these issues, the study of predictive score for difficult laparoscopic cholecystectomy involving Malaysia population with symptomatic cholelithiasis is still not available.

3) Different centres have different limitations and population hence may yield different results from the previous studies.

CHAPTER TWO: STUDY PROTOCOL

2.1 DOCUMENTS SUBMITTED FOR ETHICAL APPROVAL



RESEARCH TITLE:

PREDICTIVE RISK FACTORS

FOR DIFFICULT ELECTIVE

LAPAROSCOPIC CHOLECYSTECTOMY IN HUSM

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RESEARCH QUESTIONS

1. What is prevelance of difficult laparoscopic cholecystectomy among patients underwent laparoscopic cholecystectomy in HUSM?
2. What is pre operative risk factors associated with difficult laparoscopic cholecystectomy in HUSM?

OBJECTIVE

1.1 General Objective :

To identify the difficult laparoscopic cholecystectomy patient among elective laparoscopic cholecystectomy in HUSM.

1.2 Specific Objective :

To identify clinical, radiological, and peroperative risk factor with difficult elective laparoscopic cholecystectomy patient in HUSM

LITERATURE REVIEW

Age is considered one of the significant factors for a difficult LC. Reasons postulated include a long duration of disease and subsequent thickening and more contracted GB wall. In such cases the cystic duct becomes foreshortened and GB may be adherent to CBD. Fried, Clas (1) identified older age, (65 years and above) as a significant predictor of conversion. In their study of 1676 patients, 337 patients aged >65years had a conversion rate of 10.4%. Similarly Pavlidis and Pavlidis (2) in 2007 in their study (n=1263) included cut-off age limit of 65years.They also found that there is a significant difference in conversion rate in patients with age >65 years (12.38%) than those whose age was <65 years (6.78%). In other study (Goyal, 2017), conversion rate was higher in age group > 50 years old which is 65% compare to age group <50years old.

The difficult laparoscopic cholecystectomy also found in male compare to females. The increased rate of inflammatory changes in gallbladder specimens of males might depend on many factors. First, men are more negligent about their health, and they seek medical attention late. In case of cholecystitis, male patients have been shown to apply medical help after several attacks of inflammation, resulting in chronic changes that make operation more difficult . Beside, the differential effect of sex hormones might play an important role in wound healing. Based on study by Nidoni, Udachan (4), Out of total 180 patients 115 were females and 65 were males. Male: female ratio is 1: 1.76. Out of 65 male patients 7 were converted to open cholecystectomy and out of 115 females 3 were converted. The conversion rate in males was statistically significant ($p = 0.034$, 95% confidence interval).

Obesity and the presence of abdominal fat causes obvious difficulty in the placement of the umbilical port as the umbilicus is displaced downwards and there is difficult to identify the umbilical fascia in creating pneumoperitoneum. According Gupta, Ranjan (6), BMI more than 30 was associated with significant intraoperative difficulty (p value 0.048).

History of hospitalization of recurrent attacks of acute cholecystits was found to be a significant factor for prediction of difficult LC (p = 0.002) although duration of symptoms was not found to be a significant factor for predicting difficulty (P value =0.12). Ahmed, Aftab (19)found that history of acute attacks was a significant predictive factor for predicting difficulty in predicting dense adhesions at calot‘s triangle (p = 0.032). Nidoni, Udachan (4) their study data analysis revealed that there was significantly high risk of difficulty and conversion in patients with previous history of more than 2 attacks of acute cholecystitis (p=0.03, 95% confidence interval). Bourgouin, Mancini (3) showed previous cholecystitis attacks strong predictive factor of difficult LC (p = <0.001). Chandrashekhar, Seenu (37) found that one of the preoperative parameters that significantly predicted difficult LC based on the clinical criterion of was presence of previous hospitalization for acute cholecystitis (p = < 0.005).

The studies from early 1990s found significant association of conversion with previous endoscopic retrograde cholangio pancreatography (ERCP) as published by Mok, Reddy (9) as they were decided that ERCP rather than CBD stones would be included as a covariate in the logistic regression models for predicting difficult dissection and conversion to open surgery (p = < 0.001) though (38) found that preoperative ERCP was not significant cause of conversion(p=0.999) but

Solmaz, Gülçiçek (10) in a study evaluation of the parameters increasing intra operative difficulty scores of elective laparoscopic cholecystectomy found that ERCP was a significant predictive factor for LC. In the study Ghanem, Fahmy (8), it was found to be a significant factor for prediction of difficulty as history was positive in 20 patients (6.7%) and 17 patients of them (85%) had difficulty during operation.

Previous upper abdominal surgery has been listed as a concern because of adhesion formation, which causes bowel or other abdominal structures to adhere to the undersurface of the ab- dominal wall. The potential for bowel injury during trocar placement or difficulty in visualization of the hepatobiliary structures has dissuaded some surgeons from using the laparoscopic procedure in patients with previous abdominal surgery. On the other hand, the chance of unwanted " surprises," such as dense adhesions, awaiting the surgeon during LC are the same as those encountered during open cholecystectomy. In the study by Akyurek, Salman (11), 192 patients had undergone previous abdominal surgery the conversion rate was 2.0% in patients with previous abdominal surgery. The rate of conversion to open cholecystectomy and the complication rate were virtually identical to those found in the patients without prior surgery. (Goyal, 2017) also found history of previous abdominal surgery had significant risk for difficult laparoscopic cholecystectomy with p value 0.002.

Difficulty in gall bladder grasping was associated with distended gall bladder. A distended gall bladder or a gall bladder filled with stones is not easily grasped because it tends to slip away. Presence of inflammation around the gall bladder makes the wall friable and oedematous, thus posing problems to grasping. Chand, Singh (17) in their study have also found significant association of gall bladder grasping difficulty with distended gall bladder and pericholecystic inflammation. In Ghanem, Fahmy (8) two patients only had clinically palpable gallbladder and

both of them had difficulty during operation while 156 patients of 298 non palpable gallbladder patients had also difficulties during their LC so it was not a significant factor (p= 0.5) for predicting difficulty. Sugrue, Sahebally (28) published palpable gallbladder has been shown to increase the likelihood of a difficult procedure and in conformity Gupta, Ranjan (6) found it to be significant clinical predictive factor (p = 0.021) in LC. Agrawal, Singh (7) showed clinically palpable GB was found to be predictor of difficult LC.

Ghanem, Fahmy (8) study found that liver enzymes (AST and ALT) levels were abnormal in 25 patients 13 patients of them had a difficult LC and it was not significant factor for predicting DLC (p =0.6). Bat (39) found that AST, ALT, ALP, GGT and total bilirubin all of them were non significant factor for conversion to open surgery (P = 0.3, 0.6, 0.9, 0.9, 0.1 and 0.4 respectively). In conformity; Kaneko, Kuwahara (15) showed AST, ALT and total bilirubin all non significant predictors of prolonged LC in the treatment of low-grade acute cholecystitis. In contrary; Agrawal, Singh (7) in their study they found that patients found to be difficult or converted to open had high side of LFT in conformity; Lowndes, Thiels (40) had claimed the abnormal LFT for the risk factor of difficult LC but Terho, Leppaniemi (41) found that ALT, ALP and bilirubin all non significant (p= 0.214, 0.075 and 0.668 respectively).

Gallbladder wall thickness on sonography was found to had a high significant statistical association with the final outcome of LC (p<0.0001) in Ghanem, Fahmy (8). Siddiqui, Rizvi (22) claimed the most valuable assessment that ultrasound can provide is gallbladder wall thickness. Kala, Verma (18) published that GB wall thickness > 4 mm was considered as predictors of difficult LC and the same has been shown in the various literatures as Chand, Singh (17). Kumar, Ali (42) published palpable thick walled Gall bladder on USG was a significant factor for difficult

LC (p 0.036). Agrawal, Sood (43) showed increased GB wall thickness is associated with difficult dissection of the GB from its bed. Ghanem, Fahmy (8) found in their study, thickened gall bladder wall was found to be a significant predictor of difficulty ($p<0.001$) and was significantly associated with adhesions ($p<0.002$), bleeding ($p<0.0001$), increased operating time ($p<0.0001$) and all the three converted patients had thickened gall bladder. Naik and Kailas (16) published significantly intraoperative difficulty ($P <0.000$) was demonstrated in patients with GB wall thickness greater than 3 mm that may be due to difficulty during grasping the gall bladder, difficult GB bed dissection and higher incidence of bleeding.

There was a statistical significant association between Pericholecystic collection on Sonography and LC difficulty in (8) with ($p<0.01$). Kumar, Ali (42) published that evidence of pericholecystic collection on sonography was associated with difficult LC. Nidoni, Udachan (4) found that patients with pericholecystic collection had significant high rates of difficulty and conversion compared to patients without collection. Agrawal, Singh (7) pericholecystic collection was found to be a strong predictor of difficult LC. Naik and Kailas (16) found that Pericholecystic collection was not statistically significant in predicting difficulty ($P = 1.18$).

Bat (39) found that gallbladder stone number was not significant ($p = 0.5$). Kidwai, Pandit (44) found that patients with multiple GB calculi had difficulty during LC. Husain, Pathak (21) found that multiple stones were a non significant factor for difficult and very difficult LC ($p > 0.05$). However Ghanem, Fahmy (8) found that it was a significant predictive factor for difficult LC ($p<0.004$). Ahmed, Aftab (19) found that large stone was a significant predictive factor for

predicting difficulty in extraction (p = 0.022) but not significant for access to peritoneal cavity, dense adhesions at calot‘s triangle and dissection of gallbladder from it‘s bed (p = 0.23, 0.32 ,0.336 respectively). Bat (39) found that stone size was not significant (p= 0.4) in comparison of patients operated successfully with LC and converted to open surgery. Gupta, Ranjan (6) in their study difficulty in GB extraction was associated with size of GB stone >15 mm. Kidwai, Pandit (44) concluded that impacted stones at Hartmann's pouch makes dissection difficult because of difficulty in holding GB at Hartmann's pouch. Husain, Pathak (21) found that stone size more than 1 cm was a significant factor for difficult LC with (p< 0.05). In Ghanem, Fahmy (8) found that it was a significant predictive factor for difficult LC (p<0.001).

The most feared intra operative parameters for difficult laparoscopic cholecystectomy were adhesions at the Calot’s triangle which forced a conversion Menon (24). Besides, Goyal, Nagpal (12) and Atmaram and Lakshman (23) had conversions due to intrahepatic location of gall bladders.Signs of severe acute inflammation like gangrenous GB, pericholecystitic collection and friability and chronic inflammation such as contracted gallbladder were also reasons of difficulty and conversion Simopoulos, Botaitis (25). Moreover, (Vivek, 2014)(Chauhan, 2019)also found significant association between difficulty in grasping gallbladder due to contracted gallbladder. Then Genc, Sulaimanov (45) and Singh and Ohri (46) faced the problems of complications like cholecystoenteric fistula which forced conversion. Furthermore, anomalous anatomy were also a significant factor of intraoperative difficulty Vivek, Augustine (26).

The difficult laparoscopic cholecystectomy is characterized by longer operative time, conversion to open surgery and patient required longer post operative hospital stay. Difficult laproscopic cholecystectomy patient require longer operative time more than 90minutes. According to Sugrue, Coccolini (47), the mean operative time for conventional elective laparoscopic cholecystectomy was 71.8 minutes, followed by 64.6 minutes Cinar, Topgul (27) , 63.3 minutes Koirala, Simkhada (48) and 57.5 minutes Strosberg, Nguyen (49). However study by Ashfaq, Ahmadieh (29), the difficult gall bladder require longer mean operative time which was 147 minutes. Similar to the study of predictive difficult laparoscopic cholecystectomy by the Randhawa and Pujahari (30), found that difficult laparoscopic cholecystectomy patient required 60-120minutes or longer operative time. Long post operative hospital stay associated with multiple risk factor pre operative and intra operatively. The study by Ko-Iam, Sandhu (31), of the 500 laparoscopic cholecystectomies, 411 (82.20%) could be discharged within 24 hours after operation, while 89 (17.80%) had a longer hospital stay. Similar to the Chong, Lee (32), of the 336 laparoscopic cholecystectomy cases analyzed, 225 (67%) patients discharge day 1 post operatively and the remaining 111 (33%) patients on day 3-18. Reasons for long hospital stay included observation of postoperative fever, surgery related causes (postoperative pain, delayed oral diet, retained abdominal drain, and postoperative complications). Besides, the factors that increased the risk of a long hospital stay included patients with an ASA class 3, a history of previous acute cholecystitis, cholangitis, or pancreatitis, a history of cirrhosis.

Conversion to open surgery usually indicates a difficult procedure, and rather than being considered a complication, the decision to convert should be regarded as a sign of good judgement in the presence of adverse conditions. Conversion to an open procedure is necessary in 5–10% of patients, and is associated with increased morbidity, prolonged hospitalization and longer recovery compared to a laparoscopic approach. Common indications for conversion include failure to demonstrate the ‘critical view of safety’, or the presence of an intraoperative complication, such as intestinal perforation, haemorrhage or bile duct injury. Several factors increase the risk of conversion to open, including age,male sex,obesity,cholecystitis and previous ERCP Sutcliffe, Hollyman (36).

CONCEPTIONAL FRAMEWORK