

Outcomes and Safety of Open vs.
Laparoscopic Surgery in Patients with
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Article Information

Received date: Mar 23, 2015

Accepted date: Aug 28, 2015

Published date: Sep 15, 2015

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Keywords Cirrhosis; Laparoscopic surgery; MELD score; Child-Pugh score

Abstract

Background & Aims: The risk of laparoscopic surgery in cirrhotics remains unclear. We report on outcome and safety of open versus laparoscopic surgery in cirrhotics.

Methods: Retrospective review of cirrhotics undergoing abdominal or pelvic surgery at a university hospital from 2000 to 2010. Pre-, intra-, and post-operative data was collected. Open and laparoscopic patients were compared for post-operative outcomes including minor and major complications, hepatic decompensation, and mortality. Patients were stratified by Child-Pugh and MELD scores, and emergent vs. elective surgery. 164 total patients were identified (131 open and 31 laparoscopic).

Results: There was significantly more intra-operative blood loss ($p < 0.001$) and minor complications ($p = 0.043$) in the open group, but no other significant differences between the laparoscopic and open patients. All 5 deaths occurred in open patients ($p = 0.58$). Increasing Child and MELD scores were predictive of adverse events. Overall complications, hepatic decompensation ($p = 0.015$) and death ($p < 0.022$) were more common in open emergent compared to open elective cases. In open emergent Child C patients, 100% had major complications and hepatic decompensation and 67% died. Of emergent open MELD > 20 patients, 100% had major complications, 67% had hepatic decompensation, and 33% died.

Conclusion: Open and laparoscopic surgical approaches for cirrhotics yielded similar safety and outcomes. Child and MELD scores were predictive of adverse outcomes. Emergent cases were more likely to have complications than elective cases. Further studies including larger numbers of emergent laparoscopic patients are needed to better ascertain the risk of laparoscopy in cirrhotics.

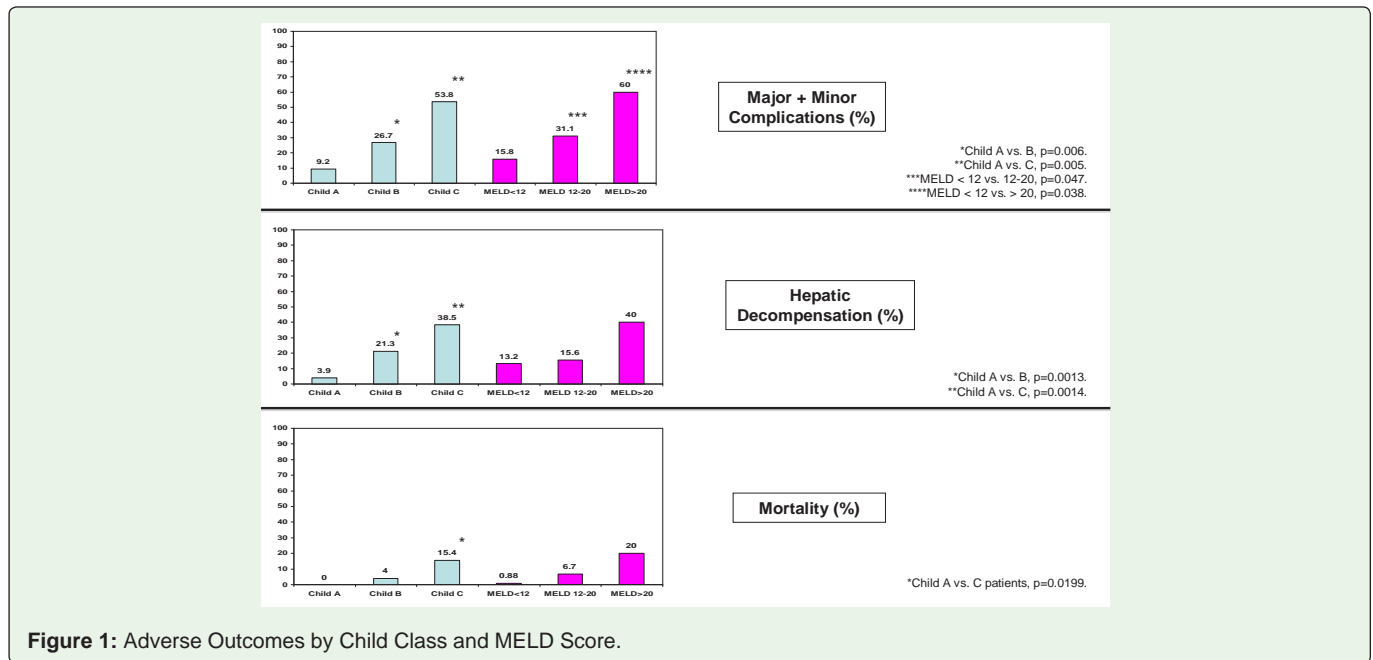
Abbreviations: ASA: American Association of Anesthesiologists; ERCP: Endoscopic Retrograde Cholangiopancreatogram; HD: Hepatic Decompensation; ICU: Intensive Care Unit; INR: International Normalized Ratio; MELD: Model for End-Stage Liver Disease; NIH: National Institutes of Health

Introduction

Despite advances in surgical management, surgery in cirrhotic patients still portends high morbidity and mortality [1-6]. Nevertheless, there remains a persistent need for surgery in these patients. Cirrhotic patients have a significant prevalence of cholelithiasis placing them at potentially greater need for cholecystectomy [7]. In addition, cirrhotic patients can have abdominal hernias, often exacerbated by ascites, which may require surgery. However, there have only been a limited number of studies that have delineated these risks and identified mechanisms to attenuate them. These studies have proposed several scoring systems to approximate the operative risk for open surgery. The most readily used is the Child-Pugh classification. Prior studies have shown significant post-operative mortality of 10%, 20-30%, and 60-80% in Child A, B, and C cirrhotic patients, respectively [2-4]. However, a more recent report did demonstrate much lower post-operative mortality rates of 2%, 12%, and 12% for Child A, B, and C patients, respectively [8].

The Model for End-Stage Liver Disease (MELD) score has also been utilized to estimate perioperative risk and mortality in cirrhotic patients [5,6,8,9]. Similar to the Child-Pugh data, post-operative mortality increased with higher MELD scores. Patients undergoing surgery with MELD scores of ≥ 17 had 30-day post-operative mortality of approximately 50-60% [5,6]. An odds ratio of 6.9 for post-operative mortality in cirrhotic patients with a MELD score > 17 undergoing surgery was reported [8].

Since the first laparoscopic cholecystectomy in 1985, this procedure has become the preferred approach for gallbladder removal. In 1992, the National Institute of Health (NIH) consensus statement indicated that patients with end-stage cirrhosis and portal hypertension



were “usually not candidates for laparoscopic cholecystectomy [10].” However, several studies have shown that laparoscopy can be safe for patients with compensated cirrhosis when performed by experienced surgeons [11-14]. The majority of these studies were relatively small and retrospective. Some were uncontrolled while others used age- and sex-matched non-cirrhotic controls.

Although this data has led to a paradigm shift regarding cholecystectomy in patients with cirrhosis, only a few studies have looked at the safety and outcomes of other laparoscopic intra-abdominal and pelvic surgeries in cirrhotic patients [15-22]. In addition, these studies have been limited by relatively small sample sizes or lacked control groups of cirrhotic patients undergoing similar open procedures.

The purpose of this manuscript is to report the results from a large, single-center experience evaluating outcomes and adverse events in cirrhotic patients undergoing open and laparoscopic intra-abdominal and pelvic surgeries. The paper also focuses on comparing the adverse events between the open and laparoscopic groups.

Methods

A retrospective review was performed of all cirrhotic patients undergoing abdominal and pelvic surgery from 2000 to 2010 at a single university hospital. This protocol was approved by the hospital’s Institutional Review Board.

Cirrhotics who underwent any abdominal or pelvic surgery were identified from the electronic medical record database using appropriate ICD-9 codes. The electronic and paper charts were reviewed to confirm the diagnosis of cirrhosis (either based on laboratory studies, imaging and/or liver biopsy) and to capture clinical data regarding the surgical procedures including open vs. laparoscopic technique, emergent vs. elective nature of these procedures, and their outcomes. Liver transplantation surgery was excluded.

Data collected included pre-operative, intra-operative, and post-operative characteristics. Baseline characteristics including age, gender, etiology of cirrhosis, coagulation parameters, renal function, presence of encephalopathy, presence of ascites, albumin, bilirubin and the American Society of Anesthesiologists (ASA) score were obtained. An immediate pre-operative Child-Pugh and MELD score were calculated. Intra-operative variables included estimated blood loss, operative time, blood transfusion requirements, minor and major complications, and mortality. In patients undergoing laparoscopic procedures, the need for conversion to open surgery was also noted. Post-operative variables included 30-day mortality, hepatic decompensation, minor and major complications, and length of hospital stay.

Adverse events were defined as major complications, minor complications, hepatic decompensation, or death.

Major complications in the intra-operative period included significant hemodynamic changes in the patient, blood loss necessitating blood transfusion, or death. Major complications in the post-operative period included significant hemodynamic changes (resulting in transfer to the ICU setting or prevention of transfer to the floor from the ICU), any event necessitating transfer from the floor to the ICU, renal failure, severe infection/sepsis, need for repeat surgery, or mortality.

Minor complications were complications that did not meet the major complications criteria including mild-moderate hemodynamic alterations which did not result in transfer to the ICU or resolved with little or no intervention, post-operative ileus, and mild infections.

Hepatic decompensation included clinical development of signs or symptoms of worsening liver disease including significant worsening or development of bilirubin elevation (jaundice), hepatic encephalopathy, INR elevation, ascites, or variceal bleeding.

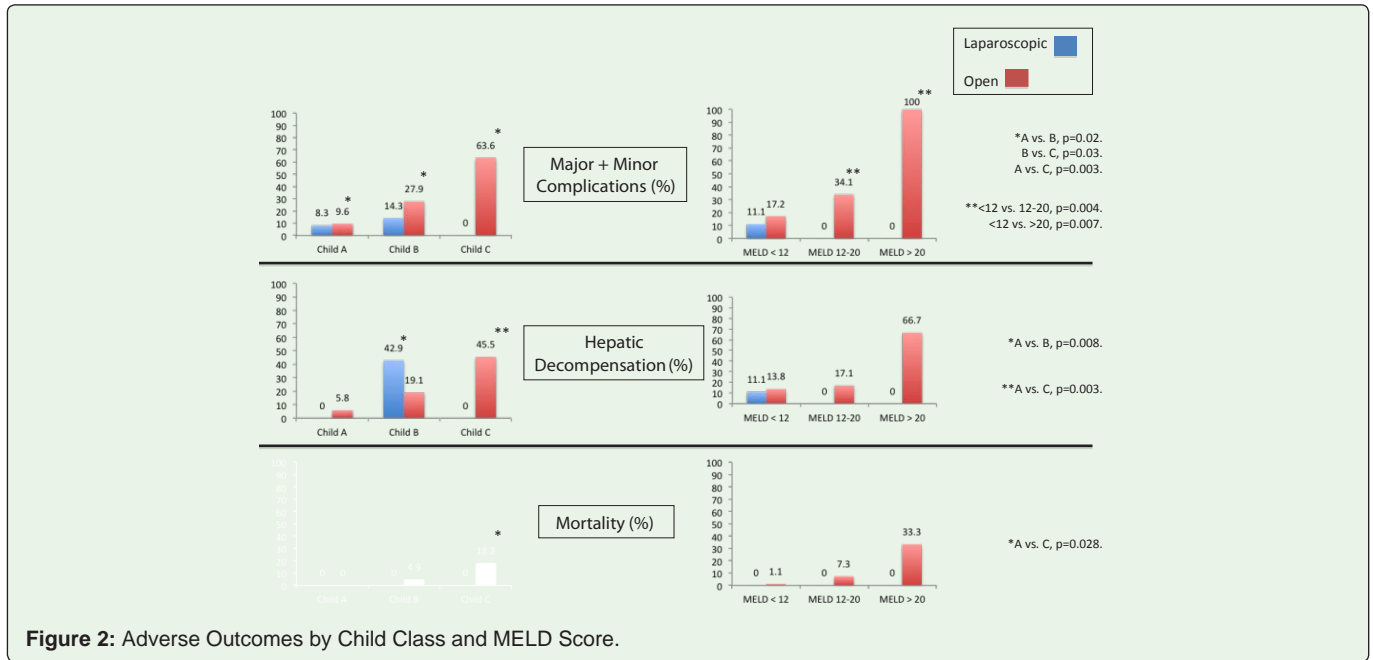


Figure 2: Adverse Outcomes by Child Class and MELD Score.

Patients were divided by type of surgery (open versus laparoscopic), timing of surgery (emergent versus elective), and stratified by their Child and MELD scores. Emergent surgeries were defined as such in the operative report or as any surgery deemed necessary to prevent further immediate clinical compromise.

Statistical analysis was performed using Fisher-Exact, Student's t-test and Mann-Whitney tests. A p-value of < 0.05 was considered to be statistically significant.

Table 1: Baseline Characteristics.

	Laparoscopic (n=33)	Open (n=131)	p-value
Age	60.0	60.1	0.541
Sex Ratio (M : F)	12 : 21	77 : 54	0.030
Albumin	3.3	2.9	0.464
ASA Class	2.8	3.1	0.746
Ascites	6 (18%)	40 (31%)	0.196
Bilirubin	1.2	1.9	0.763
Creatinine	1.3	1.1	0.425
Encephalopathy	1 (3%)	8 (6%)	0.688
INR	1.16	1.26	0.863
Child Score (mean)	6.1	6.9	0.998
Child A	24 (73%)	52 (40%)	0.0008
Child B	7 (21%)	68 (52%)	0.0017
Child C	2 (6%)	11 (8%)	1.000
MELD (mean)	9.8	11.5	0.984
MELD < 12	27 (82%)	87 (66%)	0.095
MELD 12-20	4 (12%)	41 (31%)	0.030
MELD > 20	2 (6%)	3 (2%)	0.264

Results

164 cirrhotic patients underwent abdominal or pelvic surgery and met study entry criteria. Of these, 131 underwent open and 33 underwent laparoscopic surgery. The baseline characteristics are shown in Table 1. There were significantly more Child A patients in the laparoscopic group, and more Child B, MELD 12-20 and men in the open group.

There were a variety of cirrhosis etiologies. The only statistically significant differences were more patients with hepatitis C in the open group, and more patients with non-alcoholic fatty liver disease and autoimmune hepatitis in the laparoscopic group.

A wide variety of abdominal and pelvic surgeries were performed. These are shown in Table 2.

Median operative times were similar between the open and laparoscopic groups (159 vs. 146 minutes, respectively). Median intra-operative blood loss was significantly higher in the open group [200 vs. 30 cc, p<0.001].

Three of the laparoscopic cases were converted to open procedures. One was a trauma patient with significant intra-abdominal bleeding at laparoscopy who was converted to better evaluate and treat the bleeding sources. The other two patients were converted to allow better visualization due to significant adhesions.

Figure 1 shows the adverse outcomes in the total cohort (open + laparoscopic) by Child class as well as MELD score. All aspects of adverse outcomes (major + minor complications, hepatic decompensation, and mortality) showed increases with worsening Child class and MELD score. For overall (major + minor) complications, there were statistically significant differences seen between Child A and B and Child A and C patients and between MELD < 12 and 12-20 and MELD < 12 and > 20 patients. Regarding hepatic decompensation, statistically significant differences were

Table 2: Types of Surgery.

Type of Surgery	Laparoscopic Emergent (n=1)	Open Emergent (n=19)	Laparoscopic Elective (n=32)	Open Elective (n=112)
Hernia Repair	-	5	4	21
Exploratory Laparotomy	-	5	-	-
Cholecystectomy	-	4	14	15
Bowel Resection	-	3	1	9
Hysterectomy	-	1	2	6
Rupture Left Iliac Artery Repair	-	1	-	-
Hepatic Lobectomy	-	-	-	28
Hepatic Lobectomy + Cholecystectomy	-	-	-	5
Roux-en-Y Gastric Bypass + Cholecystectomy	-	-	-	3
Splenectomy	-	-	-	3
Nephrectomy	-	-	5	2
Cholecystectomy + Hernia Repair	-	-	-	2
Whipple Procedure	-	-	-	3
Subtotal Gastrectomy	-	-	-	2
Small Bowel Anastomosis	-	-	-	1
Abdominal Aortic Aneurysm Repair	-	-	-	1
Hepatic Lobectomy + Hernia Repair	-	-	-	1
Hepatic Lobectomy + Cholecystectomy + Hernia Repair	-	-	-	1
Left Hemicolectomy + Cholecystectomy + Hernia Repair	-	-	-	1
Intra-Abdominal Abscess Drainage	-	-	-	1
Pancreaticoduodenectomy	-	-	-	1
Cesarean Section	-	-	-	1
Transverse Loop Colostomy	-	-	-	1
Splenectomy + Cholecystectomy	-	-	-	1
PEG removal + Liver Biopsy	-	-	-	1
Pancreatectomy	-	-	1	1
Retroperitoneal Lymphadenectomy	-	-	-	1
Diagnostic Laparoscopy	-	-	2	-
Cystectomy	-	-	1	-
Appendectomy	1	-	1	-
Left Adrenalectomy	-	-	1	-

noted between Child A and B and Child A and C patients. Regarding mortality, statistical significance was only demonstrated between Child A and C patients.

Comparing open to laparoscopic patients, minor complications were seen significantly more often in the open group (11.5% vs. 0%, $p=0.043$). There were no significant differences in major complications (13% vs. 9.1%, $p=0.767$) or hepatic decompensation (16% vs. 9.1%, $p=0.313$) between the groups. Overall 30-day mortality was numerically greater in the open group, but did not reach statistical significance (3.8% vs. 0%), $p=0.25$).

Figure 2 shows the adverse outcomes in the open group versus the laparoscopic group, stratified by Child class and MELD score. Overall (major + minor) complications in the open group significantly increased as Child and MELD class worsened. The MELD 12-20 group had numerically less complications than the MELD >20 group, but this did not reach statistical significance ($p=0.051$). No significant differences were demonstrated among the laparoscopic groups.

Hepatic decompensation increased in the open group as Child class increased. This was only significantly different between the open

Table 3: Overall Adverse Events in Open Emergent vs. Open Elective Patients Based on Child-Pugh score and MELD score.

Event	Open Emergent		Open Elective		p-value	Open Emergent		Open Elective		p-value
	CPS A (n=3)	CPS B (n=13)	CPS A (n=49)	CPS B (n=55)		MELD<12 (n=5)	MELD 12-20 (n=11)	MELD<12 (n=82)	MELD 12-20 (n=30)	
Minor	0 (0%)		2 (4.1%)		1.000	1 (20.0%)		5 (6.1%)		0.307
Minor	6 (46.2%)		5 (9.1%)		0.004	4 (36.4%)		4 (13.3%)		0.178
Minor	0 (0%)		2 (25%)		1.000	0 (0%)		-		NA
Major	1 (33.3%)		1 (2%)		0.113	2 (40.0%)		7 (8.5%)		0.081
Major	3 (23.1%)		6 (10.9%)		0.358	2 (18.2%)		4 (13.3%)		0.651
Major	3 (100%)		3 (37.5%)		0.182	3 (100%)		-		NA
HD	1 (33.3%)		2 (4.1%)		0.166	3 (60.0%)		9 (11.0%)		0.018
HD	3 (23.1%)		10 (18.2%)		0.703	2 (18.2%)		5 (16.7%)		0.694
HD	3 (100%)		2 (25%)		0.061	2 (66.7%)		-		NA
Mortality	0 (0%)		0 (0%)		1.000	0 (0%)		1.2 (1%)		1.000
Mortality	1 (7.7%)		2 (3.6%)		0.477	2 (18.2%)		1 (3.3%)		0.170
Mortality	2 (66.7%)		0 (0%)		0.054	1 (33.3%)		-		NA

Child A and C patients. In the laparoscopic group, Child B patients had significantly more hepatic decompensation than Child A patients. No significant differences could be demonstrated with increasing MELD score in either the open or the laparoscopic groups.

Mortality in Child A open patients was significantly lower than in Child C open patients. Despite numerical trends, there were no significant differences seen with worsening of MELD score.

The data was then evaluated to look for significant differences between the open and laparoscopic groups based on elective or emergent surgery. No adverse outcomes were noted in the single emergent laparoscopic patient while the elective

laparoscopic patients had 9.4% major complications, 9.4% hepatic decompensation, and no mortality. The number of subjects was also too small to allow statistical comparisons.

Multiple adverse outcomes were seen in the open surgery groups. In the open emergent group, this included major complications in 36.8%, hepatic decompensation in 36.8%, and a 30-day mortality rate of 15.8%. Table 3 shows this data stratified by Child class and MELD score. The only statistically significant differences were more minor complications in the open emergent Child B patients, and more hepatic decompensation in the open emergent MELD < 12 patients. Of the 3 open emergent Child C patients, all had major complications and hepatic decompensation, and 2 died. These were numerically, but not significantly, higher than the elective Child C

adverse outcomes. Of the 3 open emergent MELD > 20 patients, all had major complications, 2 had hepatic decompensation, and 1 died. Due to no open elective MELD > 20 patients in the study, statistical comparisons could not be made with this group.

Discussion

The operative risk for cirrhotic patients undergoing abdominal and pelvic surgery remains high despite improvements in medical and surgical care. Contributing factors include severity of the underlying liver disease as characterized by Child-Pugh and MELD scores, type of surgery, emergent versus elective surgery, and other non-liver comorbid medical conditions.

The majority of previous laparoscopic surgery outcome studies in cirrhotic patients have been limited to cholecystectomy. A meta-analysis of 2005 cirrhotic patients compared laparoscopic and open cholecystectomy and showed mortality of 0.74% and 2%, respectively [23]. However, the authors felt that the quality of the evidence comparing laparoscopic and open cholecystectomy was “poor.” In addition, there was only minimal data on laparoscopic cholecystectomy in patients with decompensated (Child class B-C) cirrhosis. Data on cirrhotic patients undergoing non-cholecystectomy laparoscopic surgeries is even more limited.

Our current study looked at all cirrhotic patients undergoing any laparoscopic or open abdominal or pelvic surgery (except liver transplantation) between 2000 and 2010. We compared patients based on Child-Pugh and MELD stratifications and on emergent versus elective surgery.

As shown in Figure 1, combining laparoscopic and open patients, we confirmed what has been demonstrated in prior studies: Patients have more overall adverse events with worsening liver function. This was true for both Child-Pugh and MELD classifications.

Comparing open to laparoscopic patients, operative times were similar. However, intra-operative blood loss was significantly higher in the open group. Only 3 laparoscopic patients required conversion to open surgery, and none were related to surgical complications. In terms of comparing overall adverse outcomes, there were significantly more minor complications in the open group. There were no statistically significant differences between the groups for rates of major complications, hepatic decompensation, or mortality. All of the deaths (a total of 5 or 3.8%) occurred in open patients.

Regarding complications based on Child-Pugh class, there were no significant differences between the open and laparoscopic groups. However, there were significant differences within each group. In the open group, worsening Child class was associated with more overall (major + minor) complications, hepatic decompensation, and mortality (0% Child A vs. 18.2% Child C). In the laparoscopic group, worsening Child class was associated with significantly more hepatic decompensation ($p=0.008$ for Child B vs. A).

Similar findings were shown when the data was stratified by MELD class. Overall, there were no significant differences between the open and laparoscopic groups. However, within the open group, worsening MELD groups had more overall (major + minor) complications, hepatic decompensation, and mortality.

Emergent surgery is a known risk factor for worsening outcome in cirrhotic patients [5,6,8,9]. We noted a significant number of adverse events in the open emergent patients. There were numerically more minor complications, major complications, hepatic decompensation, and mortality in the open emergent (vs. open elective) group. 100% of Child C open emergent patients had major complications or hepatic decompensation, and 66.7% died. Similarly, in emergent open patients with MELD > 20, 100% had major complications, 66.7% had hepatic decompensation, and 33.3% died.

The strengths of this study were the large number and diversity of surgical procedures, the large number of laparoscopic cases, and the large number of comparison cirrhotic patients undergoing open surgery. Overall, there were 131 non-cholecystectomy cases, including 19 in the laparoscopy group. Unlike most prior studies, we looked at both Child-Pugh class and MELD score in evaluating the results. Despite a relatively small number of MELD > 20 and Child C patients, there were a large percentage of patients with Child-Pugh class B (46%).

The study was limited by its retrospective design with the attendant potential for selection bias. The decision of open versus laparoscopic approach was at the discretion of the surgeon. There was no way to capture the thought process used for these decisions. It is possible that many of the sicker patients underwent a more traditional open surgical approach.

The study was also limited by only a single patient undergoing emergent laparoscopic surgery and a relatively small number of patients with Child C or MELD > 20. This latter fact was most evident in open emergent patients (3 each with Child C and MELD > 20) where we saw large percentages of overall adverse events but couldn't demonstrate statistical significance.

An additional limitation is whether this data can be generalized to other medical centers, especially community medical centers. In addition to the primary surgeon, our center had dedicated hepatobiliary surgeons, liver transplant surgeons, and a supporting team of hepatologists and anesthesiologists familiar with the care of cirrhotic patients. Such personnel may not be available in other centers.

In conclusion, in this group of cirrhotic patients who underwent surgery in a large, tertiary care center, there were no significant differences between open and laparoscopic approaches in terms of operative times, major complications, hepatic decompensation, and death. Emergent cases were more likely to have complications than elective cases. The risk of major and adverse outcomes increased with worsening Child-Pugh and MELD scores. Overall, Child-Pugh and MELD scores were more predictive of complications and hepatic decompensation than the surgical approach. There was no statistical difference between using Child or MELD scores to determine a risk of adverse events.

Ideally, prospective studies are needed with larger cohorts of cirrhotic patients undergoing laparoscopy to more definitively demonstrate the safety and efficacy of this approach. In the interim, accumulation of clinical experience such as this report will aid in the acceptance of laparoscopy in cirrhotic patients and assist in defining its optimal role in this challenging patient population.

Author Contributions

SM Cohen – study design and concept, analysis of data, drafting of paper, study supervision

A. Dholakia – acquisition of data, interpretation of data, drafting of paper

J. Ahn – study concept and design, analysis of data, drafting of paper

T VanderHeyden – acquisition of data

A. Pillai – study concept and design, critical review and revision of paper

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