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Critical View of Safety on Bile Duct Injuries During Laparoscopic Cholecystectomy: A Retrospective Study

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Abstract
Background: Laparoscopic cholecystectomy helps treat gallbladder stones with injuries in the bile duct (BDI). A critical view of safety (CVS) is introduced to reduce the risk of misidentification of BDI. Thus, this study aims to evaluate the routine use of CVS on bile duct injuries during laparoscopic surgery in the surgical unit of Almgreaf Ajdabiya Teaching Central Hospital in Libya. **Method:** The study included 138 randomly selected patients aged 70-79 years, diagnosed with gallbladder stones and admitted to one surgical unit. These patients underwent laparoscopic cholecystectomy from January 2018 to December 2018. **Result:** The findings revealed that a critical view of Safety (CVS) was achieved in 135 cases, while no injuries in the bile duct were reported within the cases. The majority of patients were aged 30–39 years (n = 48, 34.8%), and most of them were female (45/48). The lowest frequency was observed in the 70–79-year age group (n = 3, 2.2%). Overall, females constituted 120 cases (87.0%), while males accounted for 18 cases (13.0%). Compared to males, females had a higher incidence of biliary colic, chronic calculus cholecystitis, empyema of the gallbladder, and gallbladder polyps. Furthermore, females presented with a greater number of preoperative diagnoses than male patients. **Conclusion:** The study concluded that routine use of a critical view of safety during laparoscopic cholecystectomy is a safer and reproducible technique for identifying the biliary anatomy and its association with minor bile duct injuries.
Keywords: Bile Duct Injuries, Critical View Of Safety, Laparoscopic Cholecystectomy, Open Surgery, Nassar Grading.

Introduction

aparoscopic cholecystectomy (LC) is a minimally invasive surgical method to remove the gallbladder. However, earlier, an open cholecystectomy was considered the standard surgical method to remove gallbladders. [1] Open surgery was performed through large abdominal openings of approximately 15-20 cm long. Prior to laparoscopic cholecystectomy, tiny incisions of approximately 0.5-1.5 cm long are made at different abdominal sites. [2] Although both surgeries are used to remove the gallbladder, significant differences exist between the surgeries with respect to their surgical procedures.

Since 1980, surgeons have adopted the use of laparoscopic cholecystectomy to remove gallbladders. [3] This procedure is largely supported and preferred by patients. According to a research study, the global rate of laparoscopic surgery is approximately 18 million. [19] Moreover, laparoscopic cholecystectomy is more advantageous than an open procedure. It is associated with shorter hospital stays, reduced costs, and higher patient satisfaction of patients. [3, 4] Additionally, post-operative outcomes of laparoscopic cholecystectomy show lowered mortality and morbidity rates. [20] Despite the evident advantages of LC, surgeons, due to certain factors, adopt open cholecystectomy to remove the gallbladders. The factors include increased infection and adhesive inflammation in the gallbladder, which causes the laparoscopic cholecystectomy to convert into an open cholecystectomy. [21]

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The introduction of laparoscopic cholecystectomy led to a 0.5% increased risk of bile duct injuries. [5] This increase, however, was lower in open cholecystectomy. Bile duct injuries possess potential complications and life-threatening conditions. [22] The intra-operative misidentification of biliary ductal anatomy is the root cause of BDI. [6] Moreover, bile duct injuries (BDI) are life-threatening, which increases the risk of long-term mortality/morbidity rates and a significant compromise in quality of life. However, these injuries occur due to inflammatory dissection perceptions in Calot's triangle, anatomy misidentification, and improper instrument usage [5, 6].

Additionally, several identification methods are used to dissect and analyze cystic ducts. The infundibular technique is the oldest and most commonly used method, also known as 'infundibular cystic. [7] In order to avoid the risk of biliary injury, the infundibular technique is performed nearest to the gallbladder infundibulum. Hence, the hidden cystic duct misrepresents the false infundibulum appearance, ultimately misleading the surgeon to identify the common bile duct in BDI [7]. Another technique in LC includes the fundus-first technique, in which dissection begins from the gallbladder fundus and moves towards the infundibulum of the gallbladder [6].

The Critical View of Safety (CVS) was introduced by Strasberg in 1995 to reduce the BDI risk factor [8]. This technique was introduced to inhibit the common bile duct misidentification within the cystic duct. Therefore,

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numerous surgeons acknowledged the CVS technique to perform a safer cholecystectomy [9]. Moreover, the critical view of safety includes three criteria as follows;

1. The Calot's/hepatocystic triangle is cleared of fat and fibroid tissues.
2. The cystic plate's lower third is separated from the gallbladder
3. Two structures should be seen entering the gallbladder [10].

Numerous studies recognized the significance of a critical view of safety for safer identification in laparoscopic cholecystectomy. In 2017, SAGES promoted the use of the CVS technique in the "safe cholecystectomy program" as a universal culture of safety to minimize the risk of BDI in cholecystectomy [11]. Additionally, Yegiyants et al. (2008) conducted a study on 3042 patients over a period of five years to investigate the rate of BDI identification. Their findings revealed that only one patient incurred a ductal injury, while one was diagnosed with BDI, thus highly recommending the adoption of a critical view of safety [12]. Previous guidelines support the efficacious use of a critical view of safety. However, limited research studies favor CVS in laparoscopic cholecystectomy. Precisely, none of the level-one evidence exists for reduced bile duct injury from a critical safety view. Lower bile duct injuries pose difficulties in achieving evidence to adequately power a prospective randomized trial [11].

Material and Methods

The study adopted a retrospective approach to examine the impact of routinely obtained critical view of safety (CVS) on Bile duct injury incidence during Laparoscopic cholecystectomy. The single-center study was conducted at the surgical unit of Almgreaf Ajdabiya Teaching Central Hospital, Libya.

Sample Population. The study included 138 randomly selected patients aged 10-79 years who were diagnosed with gallbladder stones. The patients were admitted to the surgical unit of Almgreaf Ajdabiya Teaching Central Hospital, Libya. All patients underwent laparoscopic cholecystectomy from January 2018 to December 2018.

Inclusion Criteria

The research included patients diagnosed with cholelithiasis who underwent laparoscopic cholecystectomy. Moreover, patients who underwent laparoscopic surgery, which was later converted to open surgery, were also included. The research also included patients categorized under Nassar grading I and II.

Exclusion Criteria. The research excluded patients **categorized as** ASA Grade III and above. Patients with a medical history of upper abdominal surgery, cardiovascular or pulmonary diseases, and gallbladder mass were also excluded. Furthermore, patients with symptoms and signs of suggestive common bile duct stones, chronic liver disease or viral hepatitis, and coagulation disorders were also excluded.

Surgical Procedure

The medical history of patients was collected and analyzed in terms of their pre-operative data, operative data sheet, post-operative data, and discharge sheet. Patient demographics, including age, sex, pre-operative diagnosis, operative time, duration of hospital stay, post-operative complications, including bile duct injuries (BDI), and mortality, were assessed. Moreover, the intra-operative findings in terms of anatomy and surgical difficulties were analyzed through the Nassar score, while assessing the CVS achievement alongside.

Ethical Considerations

Data collection was authorized by the hospital administration and the scientific committee, "Ethics Board." Verbal and written informed consent was obtained from all the patients. The possibility of conversion to open cholecystectomy and the risk of complications such as bleeding, bile duct injury, bile leak, and infection were also assessed.

Results

Table 1 presents the demographic characteristics of the study participants. A total of 138 patients were included, comprising 120 females (87%) and 18 males (13%). The mean age of the patients was 40.92 ± 6.45 years. The operative time ranged from 1 to 1.5 hours. Body mass index (BMI) was not recorded for the study participants.

Table 1: Demographic Data of the Studies Cases

Age (years), Mean ± SD	Patients (N=138)
Age (years)	40.92 ± 6.45
Gender (male/female)	18/120
Percentage of male (%)	13%
Percentage of female (%)	87%
Body Mass index (BMI) (kg/m^2)	Not recorded

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Table 2 reveals the distribution of the patients according to age and gender. The majority of patients, 48 (66%), were aged between 30 and 39 years, of whom 3 and 45 patients were males and females, respectively. Contrarily, 4% of cases (1 male and 2 females) were between 70 and 79 years.

Age in years	Male	Female	Total	
10-19	**1**	**4**	**5**	6%
20-29	4	**20**	**24**	33%
30-39	**3**	**45**	**48**	66 %
40-49	**6**	**22**	28	37%
50-59	**1**	**19**	**20**	27%
60-69	**2**	**8**	**10**	13%
70-79	**1**	**2**	**3**	4%
Total	**18**	**120**	**138**	

Table 2: Distribution of Cases According to Age and Gender

Table 3 indicates the pre-operative diagnosis of the patients. 104 (75%) (13 males and 91 females) were diagnosed with biliary colic disease, while 30 (21%); (4 males and 26 females) were diagnosed with Chronic calcular cholecystitis. Moreover, 2 females were diagnosed with Gallbladder polyp, while 2 (2%) (1 male and 1 female) were diagnosed with empyema gallbladder.

Table 3: Pre-operative Diagnosis

Diagnosis	Male	Female	Total	Percentage
Biliary colic	13	91	104	75%
Chronic calcular cholecystitis	**4**	26	**30**	21%
Empyema gallbladder	**1**	**1**	**2**	2%
Gallbladder polyp	**0**	**2**	**2**	2%
Total	**18**	**120**	**138**	100%

Table 4 represents the grading of anatomy difficulty based on Nassar grades, along with patients whose critical view of safety was either achieved/unachieved. However, a critical view of safety was achieved in 130 patients who belonged to Grade I. Moreover, 5 cases belonging to Grade II achieved CVS. On the contrary, 2 cases belonging to Grade III and 1 case belonging to Grade IV could not achieve CVS. i.e., 3 (2%)of the total cases. These cases could not achieve CVS due to dense inflammatory connections. Moreover, the ductal identification failures and bail-out procedures were converted to open cholecystectomy, which prevented the respective patients from achieving CVS. One of the cases showed the effects of Mirizzi syndrome type 3, while possessing unclear biliary anatomy with inflammation and fusion. Overall, Table 4 indicates that 135 (98%) patients could achieve CVS.

Table 4: Grading of Anatomy Difficulty and CVS Achieved

Nassar grade	No. of cases	CVS could be achieved	CVS couldn't be achieved

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Grade I	**130**	**130**	**0**
Grade II	**5**	**5**	**0**
Grade III	**2**	**0**	**2**
Grade IV	**1**	**0**	**1**
Percentage %	138 cases	135 (98%) cases	3 (2%) cases

Table 5 shows the post-operative complications of the patients who underwent laparoscopic cholecystectomy. One patient developed a minor mile leak, which was managed conservatively with a sub-hepatic drain. Another case reported port site hernias, while 2 (2.7%) cases developed atelectasis that was managed with chest physiotherapy. Overall, no mortality or major bile duct injuries were reported among the patients. However, 2 cases developed post-operative atelectasis, which was managed with chest physiotherapy, while none of the cases reported mortality due to bile duct injuries.

Table 5: Post-operative Complications

Complications	Number of cases	Percentage
Mortality	**0**	**0**
Bile leak(Minor)	**1**	1.3%
Atelectasis	**2**	2.7 %
Major BDI	**0**	**0**
Port site hernias	**1**	1.3%

Discussion

The present study discussed the identification method of the critical view of safety during laparoscopic cholecystectomy. The analysis was based on gender, age, pre-operative diagnosis, and post-operative complications after conducting laparoscopic cholecystectomy on bile duct injuries.

Most of the patients were aged 30-39 years. Conversely, Duepree et al. (2002) incorporated patients diagnosed with ileocecal Crohn's, with 21 and 24 patients who underwent laparoscopic and open cholecystectomy, respectively. The results revealed that most patients aged 39 years who underwent open cholecystectomy. [13] Consistently, Gabash and Muzhir (2021) showed that the majority of the female patients were diagnosed with biliary colic disease; 23 (14.7%); however, 156 patients were diagnosed with gallstones. [14]

A critical view of safety in laparoscopic cholecystectomy was achieved in 135 out of 138 cases. The results showed contradictions with respect to results deduced in previously published research studies, which acknowledged the use of CVS. Araya et al. (2022) indicated that a critical view of safety prevented fewer conversions to open surgery. Moreover, the findings failed to recognize the advantages of CVS in the prevention of bile duct injury development. [15] However, another study by Vettoretto et al. (2011) performed a comparison study between the critical view of safety and the infundibular technique among 174 patients. The findings implied a significant difference between the operative times of both techniques. Further, the results favored the critical view of safety in each gallbladder disease. [16] Additionally, Avgerinos et al. (2008) performed CVS on 998 patients. The results implied a conversion rate of 2.6%, which is slightly different from the present study, i.e., 2.7% rate of conversion [17].

A critical view of safety is pivotal to preventing (BDI) bile duct injuries. Moreover, CVS essentially prevents ductal anatomy misinterpretation in order to reduce BDI. However, a bail-out process is attempted as 'Culture of safety in cholecystectomy (COSIC),' among cases diagnosed with severe inflammation in acute cholecystitis, dense fibroid calot's triangle, and Mirizzi syndrome type II and III.

A limited number of cases reported post-operative complications, where 1 case reported bile leak in a minor quantity. Contrarily, Duca et al. (2003) performed a retrospective study on 9542 cases and revealed bile leakage as one of the main post-operative complications among 54 cases [18]. However, another study indicated bile leakage in post-operative cholecystectomy among five patients, which gradually became less significant after 2-14 days [17]. Nonetheless, the present study reported a gradual insignificance of bile leak after 24 hours post-operative.

Conclusion

A critical view of safety is an identification method of bile duct injuries in invasive operative surgeries. The study encouraged the routine use of CVS in laparoscopic cholecystectomy. The findings suggested that this ductal identification method is safe and reproducible for identifying the biliary anatomy and is associated with no major bile duct injuries. The critical view of safety achieved in 135 cases of the study highly supports the technique in laparoscopy to prevent bile duct

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misidentification with the cystic duct. Moreover, the gender analysis suggested a greater number of females in the study cases, along with the common age group of 30-39 years. Additionally, a critical view of safety is a safe method of identifying ductal structure as a part of the Culture of safety in cholecystectomy.

Limitations

1. The research was limited to a small sample size, which was insufficient to analyze the outcome of the bile duct injury rate; the lower incidence is attributed to a smaller sample size and the ineffectiveness of CVS in ductal identification.
2. The research was limited to specifically including patients of ASA Grade I and II due to the low rate of diseases. However, the specific exclusion of ASA Grade III patients and onwards was essential as it would hinder the efficacy of CVS in laparoscopic cholecystectomy.

Future Recommendations

1. Future studies should incorporate a larger sample size for a broader and more comprehensive understanding of the bile duct injury rate of outcome.
2. Future research should include patients' cases with previous surgery histories to assess the effectiveness of laparoscopic cholecystectomy and the critical view of safety.
3. Future studies should include ASA Grade III and above patients who are diagnosed with higher inflammatory diseases. This is paramount to identify CVS sufficiency in patients undergoing laparoscopic cholecystectomy.

Declaration of interest statement: There are no relevant financial or non-financial competing interests to report.

Abbreviations

CVS: Critical view of safety
BDI: Bile duct injuries
CBD: Common bile duct
LC: Laparoscopic cholecystectomy
COSIC: Culture of Safety in Cholecystectomy
SAGES: The Society of American Gastrointestinal and Endoscopic Surgeons
ASA: American Society of Anesthesiologists

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