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Original Article

Role of Laparoscopy in Treating Non-Hemolytic Pediatric Gallstone Disease

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Abstract

Introduction: Gallstone disease (GD) has been increasingly diagnosed in the pediatric population mainly owing to the widespread use of the US. Symptomatic Gitelman syndrome disease merits cholecystectomy. Laparoscopic cholecystectomy (LC) has been gaining acceptance recently.

Purpose: The purpose of this study was to study the role of laparoscopy in treating non-hemolytic pediatric GD.

Materials and Methods: We enrolled 33 children admitted in our department with age ranged between 2 years and 17 years with documented non-hemolytic pediatric GD that underwent LC and were assessed for intra-operative findings, operating time, return to activities, the requirement of analgesia postoperatively, hospital stay, and minor and major complications.

Results: All 33 cases underwent LC with a mean surgical time of 35.15 ± 10.56 min. There were a total of 5 minor complications seen during the immediate post-operative period. The mean hospital stay was 1.45 ± 0.264 days. The mean doses required were 2.63±0.78, and tolerated oral feeds and were ambulatory 12 h post-operatively.

Conclusion: The cholecystectomy rate in children without the diagnosis of hemolytic anemia has increased in recent years. Laparoscopic management of pediatric symptomatic GD is a safe and feasible procedure. It has the advantage of being less invasive, having less post-operative pain, shorter hospital stays, and cosmetically appealing scar.

Key words: Cholecystectomy, Gallstone, Laparoscopic, Non-hemolytic, Pediatric

INTRODUCTION

Pediatric cholelithiasis was viewed as a disease of prematurity, usually related to total parenteral nutrition. Other risk factors for cholelithiasis in children include hemolytic disorders, obesity, family history of gallstones, abdominal surgery, immunoglobulin A deficiency, cystic fibrosis, therapy with ceftriaxone, and Gilbert's disease.[1] However, the cholecystectomy rate in children without the diagnosis of hemolytic anemia has increased in recent years.[2] The universally used and the most accurate diagnostic test in detecting the presence of gallstones is ultrasonography. Gallstones are usually mobile, single or multiple, and characteristically cast an acoustic shadow.

The approach to cholelithiasis in infancy is different as spontaneous resolution has been reported in a significant proportion of cases (cholelithiasis almost 50% and choledocholithiasis 30%). Spontaneous resolution within 6 months is more common with idiopathic gallstones than in patients with known predisposing factors. Asymptomatic infants with idiopathic cholelithiasis should be observed for spontaneous resolution. Even for choledocholithiasis, an observation period of 1–2 weeks is recommended before active therapy as there is a chance of spontaneous resolution. Cholecystectomy is indicated for symptomatic cholelithiasis, asymptomatic cholelithiasis persisting beyond 12 months, and radiopaque calculi (10%).[3]

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In recent years, laparoscopic cholecystectomy (LC) has become the treatment of choice in the surgical management of children with symptomatic cholelithiasis. It has the advantage of being less invasive with lower morbidity and mortality and shorter hospital stay over conventional open cholecystectomy.[4]

Review of Literature

The first case of laparoscopy in pediatric surgery was reported by Stephen Gansin in 1973, in his landmark publication, "Advances in Endoscopy of Infants and Children," as a peritoneoscopy. The term peritoneoscopy was soon replaced by Pediatric Laparoscopy.[5] The first LC was performed by Prof Dr Med Erich Muhe of Germany in September 1985. Dr Tehemton Udwadia performed the first LC in India in May 1990.[6] The availability of smaller instruments expanded the role and applications of laparoscopy and thoracoscopy in very small infants and newborns. Laparoscopic repair of inguinal hernias in children was initially reserved for female patients because of the fear of damage to the vas deferens and the spermatic blood vessels. During 2001, Es Posito *et al*. conducted the study to evaluate the results and complications of LC in 110 infants having symptomatic cholelithiasis, confirmed by USG. Mean OT was 45 min, average hospital stay of 2 days. Only 15 patients required drainage. Complications were reported in 17 patients. They concluded that LC in children seems to be as effective as open cholecystectomy in cases of symptomatic cholelithiasis.[7]

Meshikhes in 2002 studied that the recent introduction of new treatment options has significantly altered the approach toward gallstone management with cholecystectomy as the treatment of choice for symptomatic gallstones. Controversy, however, exists as to the management of asymptomatic gallstones diagnosed by USG. Management poses a dilemma as conclusive evidence of the benefits of cholecystectomy is lacking. The recent introduction of LC as the treatment of choice for symptomatic gallstones has further complicated the issue of asymptomatic gallstone management.[8]

In the year 2006, Balaguer *et al*. conducted a study on children (<15 years) undergoing cholecystectomy between 1996 and 2003. He found that during the period of study, there is significant increase in the frequency of children undergoing cholecystectomy without the risk factors. The percentage undergoing cholecystectomy by laparoscopic approach increased from 77% to 91%, while no significant differences in postoperative complications and mortality were observed. LC was associated with a shorter length of stay in the hospital than OC.[2] During 2008, Della Corte *et al*. treated 117 children with ursodeoxycholic acid (UDCA) out of which 8 children got dissolution of gallstones but cholelithiasis recurred in 3 of them. Two-thirds of symptomatic patients became asymptomatic. 64 patients were treated with cholecystectomy and postoperative complications were reported in only 2 patients. He concluded that UDCA was ineffective in the dissolution of gallstones but it had a positive effect on the symptoms. LC was confirmed to be an efficacy and safe treatment for pediatric gallstones.[1] In 2012, Mehta *et al*. conducted a retrospective, cross-sectional study of children (0–18 years) and reviewed 404 cases of glycogen storage disease (GSD) and concluded that obesity and Hispanic ethnicity are strongly correlated with symptomatic pediatric gallstones whereas hemolytic disease is no longer the predominant risk factor for symptomatic gallstones in children.[9] In May 2020, Pelizzo *et al*. evaluated clinical, ultrasonography data as well as histopathological findings in children affected with symptomatic cholecystic disease who underwent LC, with the aim of defining surgical timing. They reviewed our cases that underwent elective LC (ELC) or urgent LC (ULC). They considered 26 children. Operating Timing was longer in ELC than in ULC.[10]

Aims and Objectives

The study was conducted to assess the feasibility of Laparoscopy in the Management of Non-hemolytic Pediatric gallstone disease (GD). We studied the parameters such as Operating time (in minutes), total hospital stays (in days), Return to activity (usual playful-in hours), Requirement of postoperative analgesia, Intraoperative findings such as the condition of calots anatomy, status of cystic duct, location of stones, the status of CBD and abnormal intraoperative findings other than hepatobiliary system. We also studied IO and PO early complications such as injury to adjoining structures, vessels, bleeding, infection, bilioma, intra-abdominal collection, and late one as port site hernia and adhesion obstruction.

MATERIALS AND METHODS

This was a prospective observational study. The study was conducted in the Department of General Surgery, Government Medical College, Srinagar, Jammu and Kashmir from October 2022 to April 2024 (18 months). All Patients in the age group from 2 years up to 17 years presenting with non-hemolytic symptomatic gallstone disease were included. Cases with asymptomatic GD, Patients with hemolytic GSD, Syndromic children, Parents/Guardian refusing consent for laparoscopic surgery, and any other medical condition contra-indicating laparoscopic intervention were excluded from the study. All patients within the included age group were assessed by thorough history taking especially of family history of cholelithiasis, obesity and other known risk factors and underwent general

and abdominal clinical examination. Apart from baseline investigations and USG abdomen, patients were subjected to special investigation such as Ultrasound (US) abdomen for the hepatobiliary system. Selected patients with diagnostic dilemma were subjected to magnetic resonance cholangiopancreatography. The patients were referred to the hematology department for an opinion regarding ruling out hemolytic anemia. Once the diagnosis is made, Parents/Guardian were counseled and given the option for initial medical management in cases of asymptomatic incidental finding of gallstones. For symptomatic gallstones and patients having failed medical management were subjected to LC under General Anesthesia. Proper informed consent was taken from the parents/guardian.

Classical 4 port cholecystectomy was done in all patients. Informed and written consent were taken before the performance of each procedure. Patients were kept Nil per Oral 6 h before surgery. Pre-anesthetic medication was given on the night before surgery. Part preparation was done in the morning on the day of surgery. A single dose of I.V. Ceftriaxone was given at the time of induction and all cases were conducted under general anesthesia with Endotracheal Tube/LMA. Surgical steps: Position: Supine initially with arms by the sides and later after telescope port insertion head end at 30° and right side up by 15–30°. After intubation, an orogastric 8–10 F infant feeding tube was passed into the stomach. Painting and draping: With 5% Povidone-Iodine. Creation of pneumoperitoneum was achieved after an "anti-smiling" 5-mm incision was made inside the upper margin of the umbilicus and by using pediatric Veress needle and warmed Carbon dioxide (CO_2) with intra-abdominal pressure ranging from 6 to 13 mm of Hg depending upon the age, weight, and body habitus of the child. Ports placement: A 5 mm/10 mm supra-umbilical port for the introduction of 5 mm/10 mm 30° operating camera was placed by direct insertion. Thorough abdominal surfing was done checking the adjacent bowel loops immediately for possible injury. A 10 mm epigastric port with a reducer was placed for right hand-working port and was later used for the removal of the specimen. Two 5 mm/3 mm lateral ports depending upon the age of the child were placed below the right sub-costal margin for left hand working port (along the mid-clavicular line) and gallbladder fundus retraction (along the anterior axillary line as shown in figure 1).

Cholecystectomy Technique Performed

Classical steps of 4 ports LC was performed which included dissection of the Calot's triangle, identification of cystic duct and artery before ligation (as shown in figure 2) and cutting, separation of the gallbladder from its liver bed, and extraction of the specimen. The specimen was removed through the 10-mm sleeve (epigastric port). The large fascial incision was closed with Vicryl sutures. All skin incisions were cleansed and closed with inverted intradermal Nylon/Prolene sutures. Post-operative Management: IV antibiotics and IV analgesia till the patient was admitted and followed by oral antibiotics after discharge. Orals were started as the bowel movement returned and patients were discharged once orals tolerated. Follow up: At week 1 for stitch removal, at 3 months for Check USG Abdomen, and at 6 months as routine. All the data were collected and analyzed for the parameters to be assessed and compared with the global trends. The statistics were applied wherever indicated using the Chi-square method and *P*-value.

OBSERVATION AND RESULTS

The age of the patients in the study ranged from 2 years to 17 years with a mean age of 12.48 ± 3.42 years. There was a total of 13 (39.39%) male patients and 20 (60.60%) female patients. The male-to-female ratio was 1:1.53. The majority of male children were seen in the younger age group whereas most of female children were seen in the older age group. 27 (81.81%) presented with a history of pain right hypochondrium, 1(3.03%) with epigastric pain, and 2(6.06%) with pain lower abdomen. Eleven (33.33%) patients presented with nausea, and vomiting. Fever was seen in 2 patients (6.06%). 1 patient (3.03%) had dyspepsia. On examination 24 patients (72.72%) had tenderness on palpating right hypochondrium. In our study, 15 patients had solitary calculus, while 18 patients had multiple calculi on the USG abdomen. Intra-operative findings: Based on the findings during intra-operative abdominal surfing it was revealed that: in 7 patients there were adhesions present between gallbladder, omentum, and bowel loops. In another 7 patients, calot's anatomy was not well defined (frozen calot's). In the rest of 19 patients, there were no signs of acute attack (no adhesions and the anatomy of Calot's was well defined). Operating time: The overall mean surgical time calculated was 35.15 ± 10.56 min. The correlation between operating time and return to activity (in hours) showed $P = 0.737$, i.e., not significant as shown in Table 1. Complications: There were a total of 5 minor complications seen during the immediate PO period which included transient fever in 3 patients, and port site infection in 2 cases. There were no intra-operative and

Table 1: Operating time

S. No.	Age (years)	Patient no.	<30 min	30–45 min	>45 min
1.	2–5 years	02	01	01	Nil
2.	5–10 years	06	Nil	03	03
3.	10–14 years	17	02	07	08
4.	14–17 years	08	01	06	01
Total		33	04	17	12

Correlation between OT and return to routine activities showed *P*=0.737 i.e., not significant

Table 2: Total hospital stay, return to activity and post-operative analgesia requirement

S. No.	Age (years)	Patient no.	Hospital stay days (mean)	Post-operative analgesia (doses)					Return to activities	
				01	02	03	04	05	24 h	36 h
1.	2–5 years	02	02 (1.0 day)	00	02	00	00	00	02	00
2.	5–10 years	06	08 (1.33 day)	00	04	02	00	00	04	02
3.	10–14 years	17	25 (1.47 day)	00	09	04	04	00	12	05
4.	14–17 years	08	13 (1.62 day)	00	03	03	02	00	06	02
Total		33	48 (1.45 day)	Average doses - 2.63					Mean - 23±9.2	

Correlation between the requirement of post-operative analgesia and return to routine activities showed *P*=0.001 (significant). Correlation between different age groups and return to routine activities showed *P*=0.878 (not significant)

long-term post-operative complications. Total hospital stay: Complying with the institutional protocol all children undergoing operative intervention under general anesthesia were kept overnight for observation. The mean hospital stays for the study group patients who underwent LC was 1.45 ± 0.264 days. Requirement of PO analgesia: The majority of the patients required only 2 doses of analgesia till the next morning of the day of surgery. The mean doses required were 2.63 ± 0.78. Correlation between the requirement of post-operative analgesia and return to activity (in hours) showed $P = 0.001$ i.e. Significant as shown in Table 2. Return to activities: Return to activity was assessed based on the developmental milestones appropriate for the age. Acceptance of orals, joyful interactions with the parents, and ambulation were considered normal return to activity. The majority of patients were started with and tolerated oral feeds and were ambulatory 24 and 12 h post-operatively (PO) respectively. The mean return to activity time is 23.6 ± 9.2 h. Correlation between age groups and return to activity (in hours) showed $P = 0.878$, i.e., Not significant as shown in Table 2.

DISCUSSION

Gallstone disease is a common pediatric surgical disease. In this study, we studied, performed, and observed interventions in 33 patients with non-hemolytic causes of pediatric GD. The trend of the increasing incidence of non-hemolytic cholelithiasis is also reflected in our series, with all of them belonging to the non-hemolytic category. It is presumed that the mechanism of gallstone formation in these children is probably due to a combination of interacting processes, including, dehydration, transient hepatic dysfunction, dietary, inflammatory, hereditary and endocrine influences, which affect the composition of bile.[11] As the natural history of gallstones in the children is not known and historical evidence of inflammation was present in all our cases, we suggested LC for all children with cholelithiasis. The authors also suggest that because of the expectancy of long life for children, expectant management of cholelithiasis may not be safe.[1]

Table 3: Age and sex distribution

S. No.	Age (years)	Patient no.	Males (%)	Females (%)
1.	2–5 years	02	00 (0)	02 (6.06)
2.	5–10 years	06	05 (15.15)	01 (3.03)
3.	10–14 years	17	04 (12.12)	13 (39.39)
4.	14–17 years	08	04 (12.12)	04 (12.12)
Total		33	13 (39.39)	20 (60.6)

Age distribution: [Table 3] The age range chosen for this study was between 2 years and 17 years. Patients in their first 2 years of life were excluded because of the non-availability of a pediatric ICU under a single roof of the institute. The majority of patients belonged to the age group of 10–14 years (17 cases, 51.51%). The mean age was 12.48 ± 3.42 years, which is higher than previous studies by Deepak *et al*.[12] Nesrin *et al*.,[13] and Es Posito *et al*. study.[7] Gender distribution: [Table 3] The incidence of gallstones among boys and girls is almost equal, with a slightly high incidence among boys. The male-to-female ratio in our study groups was 1:1.53. The sex ratio in our study was in favor of the females. The majority of the male children were seen in the younger age group whereas the most of female children were seen in the older age group in contrast to the results published by Nesrin *et al*.[13] and in line With Es Posito *et al*.[7]

Clinical presentation: Approximately 80% of the adults with gallstones are asymptomatic.[14] However, in children, asymptomatic gallstones are less frequent, with reported incidence of 33% and 10% in two different studies.[11] In our study, we had included only symptomatic GD cases. Our diagnostic protocol included a thorough history taking and clinical examination. Informants in the case of children were parents/guardians. Patients presented with pain right hypochondrium, nausea/vomiting, fever, and dyspepsia during acute attack. Classical right hypochondriac tenderness was present in most of the patients (72.72%). Jaundice, history of acute pancreatitis, or mucocele formation were not present in any case in our study. Ultrasonography findings: The universally used and the most accurate diagnostic test in detecting gallstone disease is ultrasonography. In our study, 15 patients had

solitary calculus, while 18 patients had multiple calculi. Ultrasonography abdomen was done in all patients pre-operatively and there were no findings suggestive of acute inflammation.[15] Intra-operative findings: All 33 cases underwent LC. Pneumo-peritoneum in young children should be of low pressure for possible hemodynamic effects and thus create a very limited working space. In our study, the pressures were maintained between 6 mmHg and 13 mm Hg based on the age and weight of the patients and in consultation with the treating anesthesiologist as per the status of the patient intra-operatively. During intra-operative abdominal surfing, it was revealed that in 7 patients, there were intra-operative findings suggested of acute cholecystitis-like adhesions (with omentum), Seven patients had frozen Calot's anatomy. Rest of the 19 patients, the gallbladder appeared normal. LC in children differs from that in adults in various aspects. First and foremost there is the constraint of working space. The importance of positioning of epigastric port in the left upper quadrant in small children cannot be over emphasized. Similarly, the working and retracting ports on the right side should be placed in the lumbar or iliac region in younger children. Second, the dissection at Calot's is relatively easier and faster in children, as fat deposits are less and the peritoneal covering layer is thin in children. Routine intra-operative assessment for CBD stones was not done in our study. Shawn *et al*. have reported that the incidence of subclinical common bile duct stones is low in children.[16] This finding has also been described in a small prospective pediatric study. In this study, as there was no evidence of common bile duct stones or altered liver function tests preoperatively in any of the patients, an intra-operative cholangiogram was not done. None of the patients had any evidence of residual ductal stones during the follow-up period. Hence, a routine intra-operative cholangiogram was not recommended for children.[12]

Operating time: [Table 1] The overall mean surgical operating time calculated was 35.15 ± 10.56 min. In Ana Cristina *et al*.[18] study, the average duration of the procedure was 80.8 min (range 40–240 min). In Es Posito *et al*.[7] study, the operating duration ranged from 25 to 75 min (median 45 min). Correlation between operating time and return to activity (in hours) showed $P = 0.737$ i.e. Not Significant. The operating time in our study is markedly increased in patients with recent attack of acute cholecystitis due to adhesions. Complications: [Table 4] LC is rapidly replacing open cholecystectomy as the method of choice in treating GD. LC is the gold standard for surgical management in symptomatic children, but it is not without complications such as hemorrhage, post-operative atelectasis, wound infections, and fluid collections. Complications unique to LC include bowel injury, injury to the biliary ductal system, retained common bile duct stones, and lost gallstones.[17] There were a total of 5 minor complications seen during the immediate post-operative period which included transient fever in three patients, port site infection in 2 cases managed conservatively with antibiotics and local wound management. There were no major intra-operative and long-term post-operative complications. Hospital stay:

Table 4: Complications

Intraoperative	
Bleeding	Nil
Injury cystic duct	Nil
Injury CBD	Nil
Injury Bowel	Nil
Immediate post-operative	
Transient fever	03
Port site infection	02
Subacute intestinal obstruction	Nil
Pain Abdomen	Nil
Late post operative	
Port site hernia	Nil
Subacute intestinal obstruction	Nil

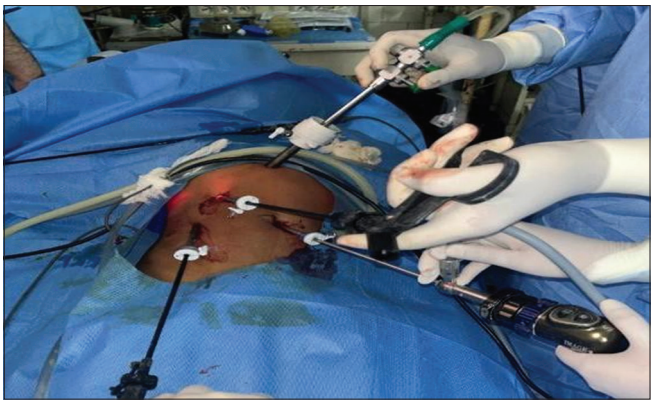

Figure 1: Port placements for pediatric laparoscopic cholecystectomy

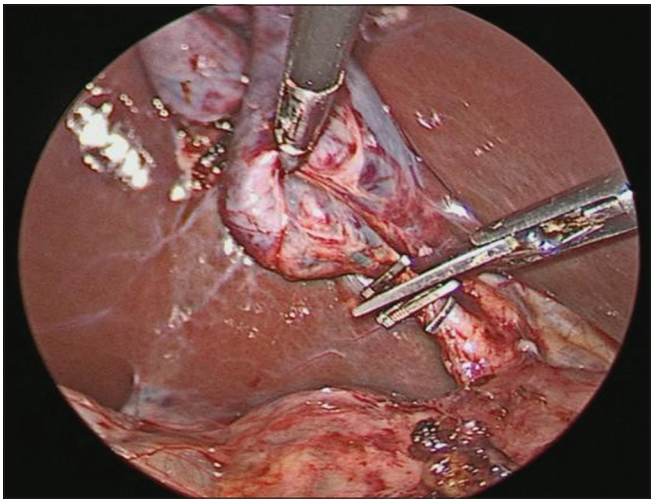

Figure 2: Clipping of cystic duct and artery

[Table 2] Complying with the institutional protocol all children undergoing operative intervention under general anesthesia were kept overnight for observation. The mean hospital stays for the study group patients who underwent LC was 1.45 ± 0.264 days. There was a longer hospital stay for patients with adhesions. In Ana Cristina A *et al.* study,[18] the average hospital stay was 1.1 days (range, 1–3 days). In El-Shahat *et al.* study,[19] the average hospital stay was 2 days (range, 1–3 days). Correlation between different age groups and hospital stay showed $P = 0.02$, i.e., Significant. Requirement of post-operative analgesia: [Table 2] LC has emerged over the open procedure as the gold standard for surgical treatment of symptomatic gallstones. The pre-eminence of LC reflects advantages in surgical morbidity, systemic complications, quality of life, and postoperative pain.[20] However, postoperative pain management remains an important issue and it is evident that clinical practice with regard to its management differs between centers, with local policies not always reflecting the best evidence-based practice. Furthermore, the management of pain following LC has implications beyond patient comfort. Pain can result in increased postoperative morbidity and may also prolong the hospital stay issues that have health, economic as well as quality of life implications, as this procedure can often be conducted on a day-care basis.[21] In our study, the majority of the patients required only 2 doses of analgesia till the next morning of the day of surgery. The mean doses required were 2.63 ± 0.78. The requirement of post-operative analgesia is markedly increased in patient who had longer operative time and intra-operative findings of adhesions. Correlation was done between the requirement of postoperative analgesia and return to activity after surgery which showed $P = 0.001$. It was found that there is a statistical significant difference, in early return of activity in children who had less analgesia doses. Return to routine activity: [Table 2] Return to activity was assessed based on the developmental milestones appropriate for the age. Acceptance of orals, joyful interactions with the parents, and ambulation were considered normal return to activity. The majority of patients were started with and tolerated oral feeds after 6 h and were ambulatory 12 h PO. Correlation between age groups ([2–10] and [10–17] years) and return to activity (in hours) showed $P = 0.878$ i.e. Not Significant. The postoperative feeding regime was not restricted, allowing patients to resume the irregular diet as tolerated. Criteria for patient discharged included comfortable mobilization, ability to tolerate oral fluid, and light diet intake 4–6 h postoperatively.[22] Cosmetic Excellence Laparoscopic scores significantly over scar formed over open cholecystectomy in children. The majority of port sites cars were found to be almost invisible at 12 weeks follow-up postoperatively as seen in photograph.

CONCLUSION

Pediatric non-hemolytic cholelithiasis is increasingly been diagnosed owing to the widespread use of USG. Symptomatic non-hemolytic pediatric GD merits surgical intervention. LC is a safe and feasible procedure for pediatric GD having less postoperative pain, shorter hospital stay, fewer complications, early return to routine activities, and better cosmetic postoperative scars.

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