



ORIGINAL RESEARCH PAPER

Surgery

ROLE OF LAPAROSCOPIC CHOLECYSTECTOMY IN THE MANAGEMENT OF PATIENTS WITH METABOLIC SYNDROME IN A THIRD WORLD COUNTRY, PROSPECTIVE HOSPITAL BASED STUDY.

KEY WORDS: Laparoscopic Cholecystectomy, Cholelithiasis, Metabolic Syndrome, Mortality.

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ABSTRACT

Background: Gallstones are the most common biliary pathology. It is estimated that Gallstones affect 10-15% population in western societies. They are asymptomatic in majority of cases in more than 80%. **Aim:** To study the intra and post-operative complications and duration of hospital stay with associated mortality. **Methods:** 150 patients who had metabolic syndrome and were admitted for Laparoscopic Cholecystectomy for Cholelithiasis were operated in Department of General Surgery, Govt. Medical College, Srinagar and were followed up in the study. Patients with a confirmed diagnosis of cholelithiasis were admitted for laparoscopic cholecystectomy in our OPD and were then evaluated for metabolic syndrome using ATP III criteria which is the most widely followed criteria worldwide for evaluation of metabolic syndrome. Informed consent was obtained from all the patients before proceeding for the surgery. **Results:** The age of the patients in our study ranged from 22-63 years with a mean age of 45.23 years. Majority of the patients (39.3%) were in the age group of 36-45 years followed by 46-55 years (34.7%). The youngest patient was 22 years of age. Dyspepsia and/ bloating were the most common (68.7%) indication for surgery in our study followed by Multiple tiny calculi (45.3%), Vague upper abdominal pain in (45.3%), Stone ≥ 15 mm in (28.7%) patients, acute cholecystitis in (17.3%) of patients, Obstructive jaundice in (3.3%), history of acute pancreatitis in (2.7%). Hypertension was the most common comorbid condition present in 44% of the patients followed by hypothyroidism in 42.7% and type 2 diabetes mellitus in 36% of the patients respectively. 5 patient (3.3%) suffered from post-operative bile leak, 4 patient (2.7%) suffered from post-operative bleeding, Port site hernia was present in 3 patient (2%) and 2 patients (1.3%) developed surgical site infection. **Conclusion:** Minimally invasive Laparoscopic Cholecystectomy for Cholelithiasis in patients with Metabolic Syndrome is an effective procedure which gives excellent functional outcome with very few complications.

Introduction:

Gallstone Disease (GSD) represents a significant burden for healthcare systems worldwide and is one of the most common disorders among patients presenting to emergency rooms with abdominal discomfort.[1] Gall Stones occur most commonly in western world, however in recent years, increased incidence in India is noted, reason being lifestyle changes and diet and widespread use of ultrasonography.[2] The prevalence differs not only between countries but also between different ethnic groups. Age and gender also influence the prevalence of GSD. The prevalence of Gallbladder stones in India is 6.12 % (Men-3.07% and Women-9.6%).[3] The prevalence was more common in Northern Indians than Southern Indians.[4]

Approximately 1-2% of asymptomatic patients will develop symptoms requiring surgery per year, making cholecystectomy one of the most common operations performed by general surgeons.[5]

Cholecystectomy is one of the most commonly performed abdominal surgical procedures. Laparoscopic Cholecystectomy is considered the "gold standard" for the surgical treatment of Gall Stone Disease[1]. This procedure results in less postoperative pain, better cosmesis, and shorter hospital stay than open cholecystectomy.[6]

Research suggests metabolic syndrome is an important risk factor for gallstones. The metabolic syndrome includes type 2 diabetes mellitus caused by insulin resistance, dyslipidemia, and hypertension. Patients with this constellation of problems are obese, with central body obesity being the primary essential feature (waist circumference >35 inches in women and >40 inches in men). The syndrome is characterized by impaired hepatic uptake of insulin, systemic hyperinsulinemia, and tissue resistance to insulin. Patients

with metabolic syndrome are at high risk for early cardiovascular death.[7]

The general prevalence of metabolic syndrome is 33% worldwide out of which prevalence in males = 24.9%, 42.3% in females. Older age, female gender, general obesity, inadequate fruit intake, hypercholesterolemia and middle to high socio-economic status significantly contributes to increased risk of metabolic syndrome. [8]

Methods:

A prospective observational study that was conducted in Post Graduate Department of General Surgery, SMHS Hospital, Govt. Medical College, Srinagar in patients with metabolic syndrome undergoing laparoscopic cholecystectomy for cholelithiasis from September 2020 to September 2022 following approval by institutional ethical committee.

Patients with a confirmed diagnosis of cholelithiasis were admitted for laparoscopic cholecystectomy in our OPD and were then evaluated for metabolic syndrome using ATP III criteria which is the most widely followed criteria worldwide for evaluation of metabolic syndrome. Informed consent was obtained from all the patients before proceeding for the surgery. A total of 150 cases both male and female in the age group of 18 and above were included in this study.

PRE-OPERATIVE ASSESEMENT

All patients meeting the inclusion criteria were admitted in the Postgraduate Department of Surgery and evaluated as under: Detailed history regarding, Age, Sex and Occupation, any specific drug history e.g., steroids, hormone replacement therapy, anti-cancer agents, recent radiotherapy, anti-coagulant therapy (warfarin, aspirin, or heparin), history of statin intake, anti-hypertensives, hypoglycemic agents, anti-epileptics etc. History of allergy to any drugs that were to be

used during the management e.g., analgesics, antibiotics, anesthetic agents etc. Previous surgical history.

Detailed physical examination which includes:

General physical examination e.g., built, any gross deformity, nutritional status, weight, height etc. Vitals – Pulse, Blood Pressure, RR and Temperature. Systemic examination including Central Nervous System, Cardio Vascular System, Respiratory, Gastrointestinal and Urogenital system, to rule out any systemic disorder. Specific workup of metabolic syndrome according to ATP III criteria i.e any three of the following traits in the same individual meets the criteria for the metabolic syndrome;

Ultrasonography of abdomen was done, especially for hepatobiliary system in particular to diagnose gallbladder stone disease and fatty liver. Any other necessary investigation deemed feasible during work up.

SURGICAL PROCEDURE

A bolus dose of antibiotic (1.5-gram intravenous cefuroxime – after test dose) was given half an hour before the surgery. The surgery was done under general anesthesia.

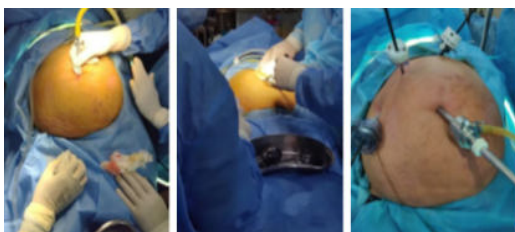
Procedure was done in supine/ reverse trendelenburg position. After that preparation and draping of the abdomen was done. Following that, umbilical camera complex port was placed, pneumoperitoneum was created, camera was inserted and rest of ports was introduced under direct vision. Following standard steps of dissection, critical view of safety was established which was cross checked by a senior surgeon who was called for on table re assessment, cystic duct and artery were then clipped and transected.

Gall Bladder was dissected off the cystic plate using proper planes of dissection between Gall Bladder and Liver. The Gall Bladder was then extracted by placing it in an entrapment bag and extracted out through the wall/one of the ports. In cases where the specimen size was small or the stone burden in GB was low, the specimen was extracted via the epigastric port.

The suction- irrigation catheter was used to remove any blood or debris that accumulated during dissection at any point during the surgery. Also operative field was flushed with normal saline irrigation in case of spillage during surgery. The ligated stumps of cystic duct and the artery were then examined to ensure that there is no leakage of bile or blood and that the clips are placed in a proper way. Sub hepatic drain was placed in patients with difficult dissection or in patients with frozen/unclear anatomy at Calot's Triangle.

After removing the ports and deflating the pneumoperitoneum, each port site incision was then infiltrated with Bupivacaine for post operative analgesia. The fascia of the umbilical incision was then closed with absorbable sutures in interrupted or figure-of-8 fashion. The skin of the port site incisions was then closed with non absorbable sutures.

In a few cases where conversion to open was required, pneumoperitoneum was deflated, trocars were removed and right subcostal(Kocher's incision) was made and proceeded accordingly.



POSTOPERATIVE MANAGEMENT

0th Post-operative Day

Patients were put on parenteral fluids besides antibiotics (Injection Ceftriaxone 1gm). Parenteral Analgesics (Injection Paracetamol 100 cc intravenous slow and/or Injection Diclofenac 75mg Intramuscular) to alleviate pain as and when needed.

Orals were started in patients on 0th post-operative day, after 6 to 8 hours in most of the cases. Ambulation was encouraged 4 hours after surgery.

1st post-operative day:

Drain was removed (if any) after proper assessment of contents and quantity of drain. Most of the patients were discharged on 1st post-operative day.

ADVICE ON DISCHARGE

Few of the patients were put on oral antibiotics (Cefuroxime 500 mg) twice daily for 5 days and analgesics and were advised to return to routine work after two weeks in most of the cases.

FOLLOW UP

Patients were followed 1 week after discharge then at 2 weeks, then at 3rd month and final assessment was done at 6th month.

Conflict of interest: Nil

Funding: Nil

Results:

One hundred and fifty patients who underwent laparoscopic cholecystectomy by elective surgery were recruited; 66.7% (n= 100) were women and 33.3% (n= 50) were men, median age of 45 years. 54.0% (n=81) belong to rural area and 46.0% (n=69) belong to urban area [Table].

Table 1: Demographic profile of the study population

| Variables | Frequency | % |
|--------------------------------|-----------|-----------|
| Sex M/F | 100/50 | 66.7/33.3 |
| Rural / Urban | 81/69 | 54/46 |
| Mean Age±SD=45.23±8.49 (22-63) | | |

With regard to comorbidities among the study population, Hypertension was present in 44% of the patients followed by Hypothyroidism Diabetes Mellitus which was present in 42.7% of the patients, Diabetes Mellitus was present in 36% of the patients [Table 2].

Table 2: Co-morbidities among study participants

| Co-morbidity | Status | Frequency | Percent |
|-------------------|---------|-----------|---------|
| Diabetes Mellitus | Absent | 96 | 64.0 |
| | Present | 54 | 36.0 |
| Hypertension | Absent | 84 | 56.0 |
| | Present | 66 | 44.0 |
| Hypothyroidism | Absent | 86 | 57.3 |
| | Present | 64 | 42.7 |

One hundred thirty five out of 150 (90%) of the patients exceeded the waist circumference cut off for metabolic syndrome according to ATP III criteria. 119 patients (79.3%) had Serum Triglyceride levels exceeding 150mg/dl or on treatment for same, HDL ≤ 40mg/dl in men and ≤ 50mg /dl in women was found in total of 104 (69.3%) patients, a total of 77 patients (51.3%) had blood pressure ≥ 130/85 mmhg or on anti hypertensives. Blood Sugar ≥ 100mg/dl or on hypoglycemic drugs were 60 (40%) patients [Table3].

Table 3: Distribution of study participants according to different traits of metabolic syndrome

| Characteristic | Frequency | Percent |
|----------------|-----------|---------|
|----------------|-----------|---------|

| | | |
|---|-----|------|
| Blood Pressure ≥ 130/85 mmhg or On Anti Hypertensives | 77 | 51.3 |
| Blood Sugar ≥ 100mg/dl or On Hypoglycemic Drugs | 60 | 40 |
| HDL ≤ 40mg/dl in Men And ≤ 50mg /dl in Women | 104 | 69.3 |
| Triglycerides ≥ 150mg/dl or On Treatment For Same | 119 | 79.3 |
| Waist Circumference ≥ 102 cm In Men And ≥ 88 Cm In Women / BMI ≥ 25 | 135 | 90 |

Dyspepsia and/ bloating were the most common (68.7%) indication for surgery in our study followed by Multiple tiny calculi (45.3%) , Vague upper abdominal pain in (45.3%), Stone ≥15mm in (28.7%) patients, acute cholecystitis in (17.3%)of patients, Obstructive jaundice in (3.3%), history of acute pancreatitis in (2.7%) [Fig 1].

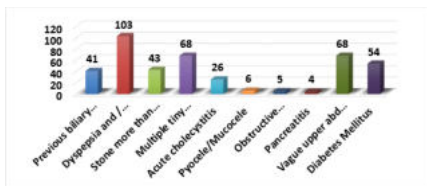


Fig 1

The maximum operative time was 121 minutes and the minimum operative time was 29 minutes with the mean operative time being 59.12 minutes. The mean number of days in hospital stay was 1.74 days with 9 days as maximum length of hospital stay and 1 day being minimum. The mean no. of days to start routine work was 10.3 days with 40 days being the maximum and 7 days being the minimum [Table 4].

Table4: Distribution of Operative Time, Length of hospital stay and No of days to start routine work among study participants.

| Measure | Operative Time in Minutes | Length of hospital stay in days | No of days to start routine work |
|----------------|---------------------------|---------------------------------|----------------------------------|
| Minimum | 29 | 1 | 7 |
| Maximum | 121 | 9 | 40 |
| Mean | 59.12 | 1.74 | 10.3 |
| Std. Deviation | 17.34 | 1.3 | 5.09 |
| Median | 58 | 1 | 8.4 |
| IQR | 46 -68 | 1 - 2 | 7 - 13 |

Five patients (3.3%) suffered from post- operative bile leak, 4 patient (2.7%) suffered from post- operative bleeding, Port site hernia was present in 3 patient (2%) and 2 patients (1.3%) developed surgical site infection [Fig 2].

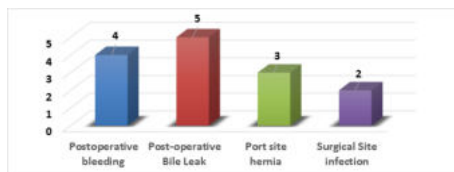


Fig 2

Discussion:

Gallstone formation being multifactorial in origin, certain risk factors for gallstones is immutable: female gender, increasing age andethnicity/family (genetic traits). Others are modifiable: obesity, the metabolic syndrome, rapid weight loss, certain diseases (cirrhosis, Crohn's disease) and gallbladder stasis (from spinal cord injury or drugs like

somatostatin). The only established dietary high risk factor is a high caloric intake. Risk of gallstones increases with age in all ethnic groups. Gender is a prominent risk factor with women having a greater risk of gallstone disease with female-to-male ratio ranging from 10:1 in pima Indians to 2-3:1 in European women; this ratio declines after the fifth decade. [9] We included a total of 150 patients in our study with 100 females and 50 males, in the ratio of 1.5:1. Our results are similar to the results of study conducted by Shen c et al (2014) [10] and Duman K et al (2013),[11] where the F:M ratio was 2.2:1 and 1.6:1 respectively. Our results are correlating with the results and observations of the studies conducted by Tavalae M et al (2022) [12] and Ahmed F et al (2017), [13] both having female predominance in the ratio of 3:1 and 3.6:1 respectively.

In our study, 46% of the patients belonged to urban areas while as 54% of the patients were from rural areas. Our observations are similar to the results of the study conducted by Ahmed F et al (2017) [13] with 62.5% of the patients belonging to urban areas and 37.5% of patients were from rural areas.

In our study, the age of the patients was ranging from 22 – 63 years with a mean age of 45.23 years which was similar to the study conducted by Duman K et al (2013) [11] wherein the age range was 24 – 72 years with a mean of 42.6 years. Al Mulhim ARS et al (2010) [14] in their study had patients in the age range of 15 – 64 years with a mean age of 32.9 ± 12.7 years which was comparable to our results.

In our study, hypertension was the most common comorbid condition present in 44% of the patients followed by hypothyroidism in 42.7% and type 2 diabetes mellitus in 36% of the patients respectively. The results of our study are in coherence with the results of study conducted by Kumar N et al (2019) [15] wherein 39% of the patients had hypertension and 42% of the patients had type 2 diabetes mellitus. 69.3% of the patients in our study had HDL ≤40 mg/dl in men and ≤50 mg/dl in women which was quite similar to the results of Kumar N et al (2019) [15] wherein 66% of the patients had HDL ≤40 mg/dl in men and ≤50 mg/dl in women.

In our study, Dyspepsia and/ bloating were the most common (68.7%) indication for surgery in our study followed by Multiple tiny calculi (45.3%) , Vague upper abdominal pain in (45.3%), Stone ≥15mm in (28.7%) patients, acute cholecystitis in (17.3%)of patients, Obstructive jaundice in (3.3%), history of acute pancreatitis in (2.7). Our results were in coherence with the results of study conducted by Gui GPH et al (1998) [16] with 42.4% patients having previous biliary colic, 23.9% with acute cholecystitis, 14.1% with history of acute pancreatitis and 7.6% of patients with obstructive jaundice.

In our study, the maximum operative time was 121 minutes and the minimum operative time was 29 minutes with the mean operative time being 59.12 minutes. The mean number of days in hospital stay was 1.74 days with 9 days as maximum length of hospital stay and 1 day being minimum. The mean no. of days to start routine work was 10.3 days with 40 days being the maximum and 7 days being the minimum. The mean time of surgery in our study was comparable to the results of study conducted by Talki A et al (2018) [17] and Hershkovitz Y et al (2016) [18] as 65 minutes and 57 minutes respectively. The mean operative time in another study conducted by Southern Surgeons Club (1991) [19] was 90 minutes which was high as compared to our study. The possible reason for lesser mean time in our study could be the improving laparoscopic surgical expertise in recent years. The results of studies conducted by Talki A et al (2018) [17] and Hershkovitz Y et al (2016) [18] with mean hospital stay of 2.6 ± 1.5 days and 1.5 – 2.2 days respectively. In another study conducted by Southern Surgeons Club (1991) [19] mean

hospital stay was 1 to 2 days which is similar to our study. The study conducted by Tamhankar A et al (2010) [20] wherein the mean time to return to routine work was 16 days in their study is accordance with our study. The result of the study conducted by Victorzon M et al (1999) [21] were similar to our study with the mean time of 15 days in their study with the range being 2 to 49 days.

In our study, a total of 5 patients (3.3%) were converted to open cholecystectomy, which was similar to the results obtained by Chang W T et al (2009) [25] and Ammori BJ et al (2001) [6] with conversion rates of 4.6% and 4.3% in their studies respectively. In another study conducted by Simpolous et al (2005), [22] the rate of conversion to conventional open cholecystectomy was 5.2% which is higher as compared to our study. The reason of conversion to conventional open cholecystectomy in our study was mainly because of distorted anatomy near Gall Bladder as a result of inflammation and difficult access through abdominal wall in an obese patient.

In our study, 2 patients (1.3%) suffered from surgical/port site infection which was managed by daily dressings, topical and systemic antibiotics, 4 patient (2.7%) had post operative bleeding, which was from port/trocar site and was managed conservatively, 5 patient (3.3%) from our study suffered from bile leak, which was managed conservatively with iv fluids and iv antibiotics. 3 patient (2%) from our study suffered from umbilical port hernia.

CONCLUSION

Minimally invasive Laparoscopic Cholecystectomy for Cholelithiasis in patients with Metabolic Syndrome is an effective procedure which gives excellent functional outcome with very few complications. The minimally invasive technique gives an additional advantage of less operative time, less intra operative blood loss, less wound complications, less damage to the soft tissues, less duration of hospital stay and early return to routine work and improved cosmesis.

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