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Original Research Article

An observational study to assess male gender as an isolated risk factor in the laparoscopic cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy is the procedure of choice for majority of patients with gall bladder disease. The aim of the study was to investigate the role of male gender as an isolated risk factor responsible for the increased peri-operative morbidity of laparoscopic cholecystectomy by excluding associated risk factors.
Methods: This was a prospective observational descriptive study 60 cases of elective laparoscopic cholecystectomy admitted to the S. M. S. Hospital from July 2019 to May 2020 were included.
Results: The most common age group in male was 41-50 years and in female was 51-60 years. Impacted stones and gall bladder wall thickness >4 mm was causes of difficult cholecystectomy and evenly distributed in both sexes. Operative time (p value=0.268), visual analogue score on day 1 (p value=0.307) and hospital stay (p value=0.376) was more in male group but not statistically significant.
Conclusions: Impacted stone and gall bladder wall thickness >4 mm were only factors associated with difficult laparoscopic cholecystectomy and excludes male gender as an isolated risk factor for difficult cholecystectomy however large-scale studies may provide different results.

Keywords: Gallbladder diseases, Laparoscopic cholecystectomy, Risk factors

INTRODUCTION

Cholecystectomy is the surgical removal of gall bladder. It is a common treatment of symptomatic gall stones and other gall bladder condition. It can be performed laparoscopically or by a more invasive open method. Laparoscopic cholecystectomy (LC) is the procedure of choice for majority of patients with gall bladder disease because it is associated with less pain and faster return to normal activity than after open cholecystectomy.[1]

Over the past 2 decades, identifying the risk factors accounting for the perioperative complications of LC has been of major interest.[2] For patients undergoing LC, the risk of possible perioperative complications can be estimated based on patient characteristics (gender, age, ASA score, body weight), clinical findings (acute versus chronic cholecystitis), and the surgeon's own clinical practice with LC. So, in the likelihood of a case being a 'difficult cholecystectomy', an experienced surgeon should be involved both in the decision-making process and during the operation.[2,3] There has been general agreement that increasing age, acute chole cystitis, morbid obesity, a high American Society of Anaesthesiologists (ASA) classifications and previous upper abdominal surgery are among the most important risk factors.[4-7] However, despite extensive research, the controversy surrounding the role of gender as a risk factor in LC still exists.[8]

Aim

The aim of the study was to investigate the role of male gender as an isolated risk factor responsible for the increased peri-operative morbidity of LC.

METHODS

This study was prospective observational descriptive study. All the cases of elective LC admitted to the S.M.S. Hospital from July 2019 to May 2020. For this study the sample size is calculated at 80% study power and 0.05 α-error assuming mean difference of operating time 15 minutes among male and female patients undergoing laparoscopic cholecystectomy and standard deviation 20 min [as per seed article Bazoua et al (2014) male gender impact on the outcome of laparoscopic cholecystectomy]. Minimum sample size found 28 patients of lap cholecystectomy in each group which is further rounded off to 30 such patients in each group. Simple random sampling was done.

Inclusion criteria

Patients of either sex posted only for elective laparoscopic cholecystectomy >18 years of age were included.

Exclusion criteria

Patients with (a) previous upper abdominal surgery; (b) morbid obesity; (c) who refused for laparoscopic procedures; (d) with features of obstructive jaundice; (e) diabetic patients; (f) medically unfit for laparoscopic surgery; and (f) immune-compromised patient.

After the OPD workup, socio demographic profile, present history, history of previous episodes of cholecystitis/pancreatitis, co-morbid surgery, history of previous abdominal surgery, clinical examination like weight, height, icterus, pulse, RHC tenderness, palpable lump, etc., blood and biochemical tests like complete blood count, liver function tests including S. alkaline phosphatase, total bilirubin, indirect and direct bilirubin, SGOT, SGPT, renal function test, RBS and sonological findings including gall bladder size (contracted or distended), GB wall thickness, number and size of GB calculi, impacted calculi, pericholecystic edema, CBD diameter, hepatomegaly, etc are recorded one-day prior to surgery. A GB wall thickness >4 mm on ultrasound was defined as 'increased wall thickness'. Obesity is defined as body mass index (BMI= weight in kg/height in m^2) >30 kg/m^2.

Pre-operative patient preparation was done and informed and written consent for surgery and anaesthesia of patient's relative and patient himself for laparoscopic cholecystectomy with special consent for open cholecystectomy if the need arises. Prophylactic dose of antibiotic inj. ceftriaxone 1 gm IV, 30 minutes prior to surgery or on day of surgery in morning at 6 am. All the patients were given general anaesthesia with adequate relaxation & continuous monitoring of pulse, BP, SpO_2. Supine position with elevation of head end & right-up tilt as demanded by operating surgeon (reverse Trendelenburg's position). The area of body between nipples and knees was scrubbed in supine position twice with povidone-iodine scrub solution followed by spirit with special attention being given to cleaning the umbilicus. Lastly, patient was draped with sterile linen sheets. The surgeon stood on the patient's left, the camera operator on the surgeon's left, the scrub nurse and assistant on the patient's right and the anaesthetists on head end. The North American Approach of laparoscopic cholecystectomy was used. The timing was noted from the first port site incision until the last port closure. All the intra-operative events were recorded. Post-operatively, we defined the surgical procedure as easy and difficult. Time taken for the surgery, biliary/stone spillage, injury to duct/artery or conversion to open cholecystectomy was noted. To avoid bias in surgical outcome, all patients enrolled in the study were operated by a single laparoscopic surgeon. Postoperatively cases were followed-up for any complication. Drain was removed between the 1nd and 2nd post-operative day depending upon the amount of drainage. Suture removal was done on the 10th post-operative day for all the cases taking into account all aseptic precautions.

To examine the statistical significance of association between attributes, Chi-square test and Fisher's exact test were used. The MedCalc Statistical Software version 14.8.1 was used. A probability value of less than 5% ($p<0.05$) was considered significant.

RESULTS

The observational study was conducted at Sawai Man Singh Medical College, Jaipur between July 2019 to May 2020 involving 60 patients of cholecystectomy. Maximum 23.34% patients were in 51-60 years age group in male whereas 41-50 years (20%) were in female. 10% male had hypertension whereas in females 6.66% had hypertension and 3.33% had hypothyroidism in both groups.

20% female presented with impacted stones on pre-op USG whereas 16.66% male. Mean GB wall thickness in male (4.23±0.85) was more than in female (4.03±0.80) and difference was insignificant.

In nearly half of male patients difficulty encountered during dissection of Calot's triangle whereas 33.33% females had encountered difficulty. Spillage during surgery was found in maximum 30% in male and minimum 23.33% in female. There were no cases with injury to duct, injury to artery and converted to open in both sexes.

Mean OT time 54.2±6.53 minutes, mean score of pain on day 1 (as per VAS score) 3.53±1.59, mean hospital stay of 1.66±0.71 was found in male whereas in female they were 52.36±6.21, 3.1±1.64 and 1.5±0.68 and difference was not significant. Association of GB wall thickness and OT time was highly significant ($p<0.001$) and impacted stone was statistically significant ($p=0.032$) whereas BMI ($p=0.382$) and pericholecystic collection ($p=0.804$).

Table 1: Socio-demographic profile.

Variables	Male (%)	Female (%)	Total (%)
Age (years)			
20-30	6 (20)	6 (20)	12 (20)
31-40	4 (13.33)	5 (16.67)	9 (15)
41-50	7 (23.33)	5 (16.67)	12 (20)
51-60	6 (20)	8 (26.66)	14 (23.34)
61-70	5 (16.67)	4 (13.33)	9 (15)
71-80	2 (6.67)	2 (6.67)	4 (6.66)
Co-morbidities			
Hypertension	3 (10)	2 (6.66)	5 (16.66)
Hypothyroidism	1 (3.33)	1 (3.33)	2 (6.66)
BMI			
Mean±SD	24.03±2.09	23.60±2.142	P=0.434
Pre-op findings			
Impacted stone	5 (16.66)	6 (20)	
Pericholecystic collections	2 (6.66)	0 (0)	
GB wall thickness	4.23±0.85	4.03±0.80	P=0.352

Note: SD- Standard deviation, GB- Gall bladder.

Table 2: Distribution of study population according to mean OT time, pain on day 1 (VAS score) and hospital stay.

Variables	Male	Female	P value
OT time			
Mean±SD	54.2±6.53	52.36±6.21	0.268
Pain on day 1			
Mean±SD	3.53±1.59	3.1±1.64	0.307
Hospital stay			
Mean±SD	1.66±0.71	1.5±0.68	0.376

Table 3: Association of OT time with risk factors.

GB wall thickness	OT time		P value
	Difficult (>60 min)	Easy (<60 min)	
Upto 4 mm	1	40	<0.001
>4 mm	10	9	
Impacted stone			
Present	5	6	0.032
Absent	6	43	
BMI (kg/m^2)			
Up to 25	6	36	0.382
>25	5	13	
Pericholecystic collection			
Present	1	1	0.804
Absent	10	48	

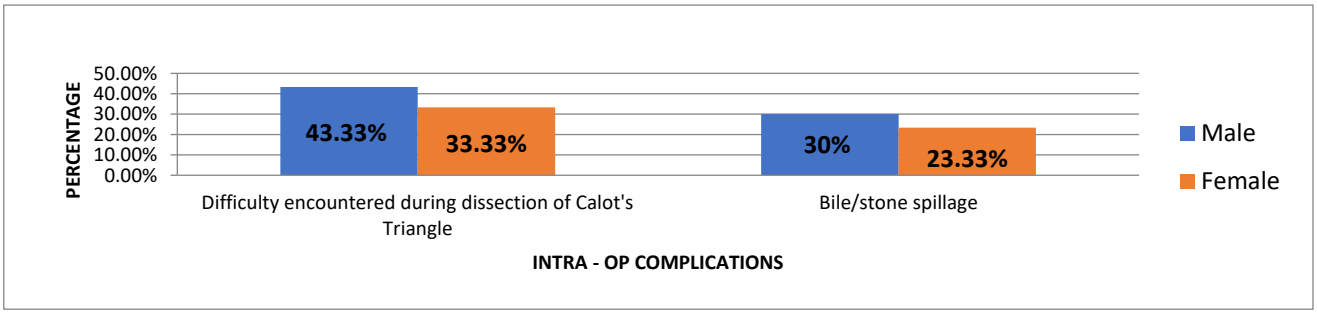

Figure 1: Distribution of study population according to intra-op complications.

DISCUSSION

This observational study was conducted at Sawai Man Singh Medical College, Jaipur between July 2019 to May 2020 involving 60 patients of cholecystectomy to determine male gender as an isolated risk factors for prediction of difficult LC. It excels in providing more consistency in the selection of the study group patients, standardized surgical practices and post follow-up. The study does not have any observer related bias as done by a single observer.

Majority of the patients in the present series were in the age group of 51-60 years of age, whereas in Herman's series and Hanif series the majority of them were in the age group of 51- 60 years and 41-50 years respectively.9,10 Above mentioned studies and our study concluding that cholelithiasis is less common in first two decades, incidence gradually increases after 21 years and reaches its peak in fifth and sixth decades.

In the present series male: female ratio was 1:1 whereas Battachary's series showed 71.4% of the patients were females and 28.6% were males.43 Sex ratio was 1:2.3seen in Hanif series.9 Women are prone for cholelithiasis in their reproductive age group because of estrogen, which increase biliary cholesterol secretion causing hyper saturated bile and stone formation.

In our study, male patients had BMI 24.03 kg/m2 and female patients had BMI 23.6 kg/m2 with the p value=0.434. Although, proportionally there were more difficult laparoscopic cholecystectomy in obese (>25 kg/m2) patients but p value was 0.382, suggestive of non-significant relationship between BMI and difficulty in laparoscopic cholecystectomy. In study conducted by Jagdish Nachnani et al found that BMI>30 kg/m2 is a significant predictor for the coversion of lap to open cholecystectomy.11,12 Study conducted by Baki et al showed BMI>27.5 kg/m2 may be a risk factor in conversion of lap to open cholecystectomy (p value=0.634).13 High BMI is associated with obesity, dyslipidemia and subsequently cholelithiasis. In grossly obese patients some technical problems are associated like, difficulty with induction of pneumoperitoneum, introduction of most lateral subcostal port, need for longer instruments and closure of fascia.

Out of total 11, 5 were male and 6 were female, rules out male gender as an isolated risk factor for difficult laparoscopic cholecystectomy. Out of 11 patients with impacted stones, 5 patient's laparoscopic cholecystectomy was considered as difficult. In the patients without impacted stone, only 6 patients out of 49 patient's laparoscopic cholecystectomy were considered as difficult. The p value was 0.032 suggestive of impacted stone in pre-operative ultrasonography as a risk factor for difficult laparoscopic cholecystectomy. The main difficulty with impacted stone at Hartman's pouch is that it hinders holding of gall bladder during dissection. Impacted stone also causes mucocele of gall bladder, which is even more difficult to hold. In these cases, the gall bladder was emptied by aspiration of contents and making the gall bladder more manageable.

Gall bladder wall thickness was also observed in USG and mean GB wall thickness in male patients was 4.23 mm and 4.03 mm in female patients. The p value for GB wall thickness was 0.352, so there was no statistical relationship between both sexes but there was strong association (p value<0.001) between gall bladder wall thickness and difficulty in laparoscopic cholecystectomy. Only one case was considered as difficult laparoscopic cholecystectomy in patients with gall bladder wall thickness up to 4 mm group but in patients with gall bladder wall thickness >4 mm, 10 out of 19 patients were considered as difficult laparoscopic cholecystectomy. In study conducted by Nachnani et al, gallbladder wall thickness >3 mm is the most common reason for conversion from lap to open cholecystectomy due to inability to delineate the anatomy.11 The thick gall bladder wall had dense adhesions to surrounding structures and in Calot's triangle. In Sharma et al series 98.3% had stones in GB and 5.2% had GB wall thickening.14 Of the 98.3%, 73.7% had multiple stones, 26.3% had solitary stones and 5.2% had bile duct stones.

All the 60 patients had stones in gallbladder, 2 male patients had pericholecystic collection. No pericholecystic collection was observed in female patients. The difficult laparoscopic cholecystectomy was present in one patient out of two patients with pericholecystic collection. There was no significant association was found between pericholecystic collection and difficulty in laparoscopic cholecystectomy. Suryawanshi et al conducted study 6.5% of cases who had peri gall bladder collection had difficult lap cholecystectomy.15 According to Lipman et al 19.6 % of patients who required conversion from lap to open had fluid collection around the gallbladder, which was statistically significant.16

In 13 male patients difficulty encountered during dissection of Calot's Triangle whereas 10 females had encountered difficulty. Spillage during surgery was found in 9 males and in 7 females. In a study by Randhawa et al, of the 228 patients studied; cases with 0 to 5 pre-op score were 178 of which 158 were easy LC, 14 were difficult LC and 6 were very difficult LC.17 The positive prediction value for easy prediction was 88.8% and for difficult prediction was 92%. The conversion rate was 3/228 i.e.; 1.315% and all were due to anomalous ducts.

There were no cases with injury to duct, injury to artery and converted to open in both sexes. This is because of operating surgeon, who is working at Rajasthan's largest tertiary care centre with maximum number of operations performed in India, the high proficiency and expertise of surgeon translated into nil major complication and conversion was recorded in this study.

Operation time was used as scale to differentiate between easy and difficult laparoscopic cholecystectomy. Operation completed within 60 minutes were considered as easy laparoscopic cholecystectomy and rest with operating time more than 60 minutes were regarded as difficult laparoscopic cholecystectomy. This criterion was also used in study conducted by Randhawa et al.[18] Among male mean OT time was 54.2 min and in females mean OT time was 52.36 minutes.

Although, OT time is marginally high in male gender group but p-value was 0.268, so there was no significant correlation between operative time and sexes. Difficulty was more common in patients with impacted stones, obesity, thick gall bladder wall and pericholecystic collection. But statistically significant association was found only with gall bladder wall thickness >4 mm and impacted stone in pre-operative ultrasonography. Similar results were found in study conducted by Bazoua et al, concluding that mean OT time was 67.9 minutes and in females 56.5 minutes.[19]

VAS on day 1 was observed and slightly more pain was observed in male, computing to mean VAS score of 3.53. among females the mean VAS pain score was 3.1. minimum VAS pain score was 1 and maximum VAS pain score was 6. The patients with VAS pain score ≥3, analgesics was continued and stayed for one more day in hospital. All patients responded to diclofenac 75 mg IV or oral. The p value was 0.307, suggestive of there was no statistical relationship between pain on day 1 and sexes.

In male patients mean hospital stay was 1.66 days and in female 1.5 days. Study by Bazoua et al mean hospital stay was 1.9 days.[19] A study conducted by Wiebke et al showed that male gender is not a risk factor for conversion of lap to open cholecystectomy.[20]

CONCLUSION

Impacted stone and gall bladder wall thickness >4 mm were only factors associated with difficult LC and excludes male gender as an isolated risk factor for difficult cholecystectomy however large-scale studies may provide different results.

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