10 Points Strategy for Safe Laparoscopic Cholecystectomy; a Prospective Study OF 8000 Patients at Tertiary Care Center of SMS Hospital Jaipur India.

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Abstract

Aim and Objective

To devise a strategy of 10 points for performing safe laparoscopic cholecystectomy, to share experience of more than 8000 cases without any conversion to open procedure by adopting the strategy of 10 points intraoperatively and assess its effectiveness.

Materials and methods

We analyzed data of 8000 patients prospectively from a period of 2004 to 2017. A specific point was assigned to a specific finding intraoperatively. 3 groups were created based on these points and data were analyzed pertaining to these 3 groups. Anatomical variations, time of surgery, intraoperative complications and post op complications were plotted against these 3 groups and statistical significance were calculated.

Results:

63.5% of patients were female. Not a single case of conversion to open cholecystectomy was found. Youngest patient was 2 years old and oldest was 109 years old. Longest gall bladder(GB) was 30 cms and smallest was 9 mms. Maximum stones recovered from a single GB 11860. No mortality occurred, and morbidity was negligible. No significant complications were recorded. Group one with 1 - 4 points had high risk patients and group 3(8-10) had low risk patient and group 2(5-7) with equivocalnumbers.

Conclusions:

This experience shows that if laparoscopic cholecystectomies performed keeping these 10 points in mind with patience and precautions chances of conversion to open surgery can be reduced to zero. Meticulously performing the surgery reduces the complication rate to minimal. Make it a rule that wherever there is difficult anatomy go gentle and slow to safeguard from injuries. With due care and caution during cholecystectomy, attention towards achieving the critical view of safety and a standardized technique, complications can be avoided.

Key words: Laparoscopic - cholecystectomy, conversion to open, Gall bladder stones, Cholelithiasis, single surgeon experience.

Date of Submission: 17-03-2020	Date of Acceptance: 02-04-2020

I. Introduction:

Cholelithiasis is one of the commonest biliary tract disease worldwide^{1, 2}. It is the commonest surgical condition requiring intervention^{3, 4}.Laparoscopic cholecystectomy(LC) was introduced around 3 decades ago and since then it has become the gold standard^{5,6}.Cholelithiasis can be symptomatic as well asymptomatic, and almost 90% cholecystectomies are performed laparoscopically^{7,8}. Multiple factors those can be patient related or surgeon related can lead to multiple complications and conversion to open cholecystectomy^{4,9,10}Usually an open cholecystectomy is performed in patients with gallbladder mass or suspicion of gall bladder malignancy, late third trimester of pregnancy, multiple previous upper abdominal surgeries, age >60 years, male sex, diabetic patients, history of endoscopic retrograde cholangiopancreatography, dilated common bile duct, gallbladder status and when laparoscopic approach fails^{7,11, 12}. With LaparoscopicCholecystectomy(LC) the complication rate seems higher than open cholecystectomy despite the experience, but complication rates with open cholecystectomy are increasing due to decrease exposer to open procedure.^{7, 8, 13, 14}

With Due care and caution during laparoscopic procedure complication rates can be reduced^{11, 15} As the surgeon's experience increases the complication rate and the conversion rates decreases^{11,16.}

Aim of this study was to share the experience of a single surgeon to perform safe laparoscopic cholecystectomy and how to decrease complication and conversion rates.

II. Materials and Methods

A retrospective study of laparoscopic cholecystectomies in 8000 patients performed by single surgeon from a period 2004 to 2017. The SMS hospital's surgical center performs most of the cholecystectomy by laparoscopy except few special cases where open cholecystectomy is beneficial. The center has 8 surgical units and the study was conducted by one unit only, in this unit around 15 laparoscopic cholecystectomies are performed in a week. Institutional Ethical Committee approval was also taken before starting the study.

Most of the patients were admitted for elective procedure. Patients with symptoms of acute cholecystitis were either operated within 2-3 days of presentation or 6 weeks after the resolution of symptoms. Detailed history of onset of symptoms duration progression was taken. Patients were properly investigated with routine blood investigations that include complete blood count, liver function test, kidney function test, Serum electrolytes, HIV, HBSAg, HCV, bleeding time, clotting time PT INR studies. Serum amylase lipase were also done to rule out pancreatitis and serum Alkaline phosphatase was also done to rule our biliary obstruction. Imaging such as ultrasonogram was performed. In some doubtful cases MRCP and CT scans were performed to look for other pathology. Those with CBD stones in USG were sent for MRCP and ERCP for stone clearance and operated after 6 weeks.

Patients were monitored post operatively for hospital stay, post op pain, nausea vomiting, oral intake and other complication.

10 points strategy: A10 points protocol was devised to perform laparoscopic cholecystectomy based on the visible anatomy on entering the abdomen, pointswere assigned as shown in the table 1. After creating pneumoperitoneum and placement of camera port, proper inspection of the peritoneal cavity was performed to rule out other pathology. Than the remaining ports were placed and patient was positioned in slight right lateral and head up position. GB fossa was inspected after removing or retracting omentum and gut from the fossa. 1. First thing examined was the CBD if it was properly visualized, 3 points were assigned, expecting surgery would be safe. If CBD was not visualized no points were assigned. Reason for non-visualization of CBD was presence of adhesions. If CBD was visualized after dissection of adhesion 3 points were still given. Based on ease of dissection adhesion were divided into minimal adhesions and dense adhesions. 2. Next in the procedure was Rouviere's sulcus, if dissection above Rouviere's sulcus was possible 1 point was given. If Rouviere's sulcus was not visible either due to adhesions or absence but safe dissection was possible by holding the infundibulum/Hartman pouch than also 1 point was given. 3. While holding the infundibulum/Hartman pouch, anatomy of cystic duct and artery and Calot's triangle was assessed. Presence of aberrant artery or variation in cystic duct and artery were confirmed. If 2 structures seen entering into GB on inspection than 1 point was assigned. If there were variations in anatomy or if 2 structures were not visible clearly either due to adhesion or variation, no point was assigned. 4. After confirming above parameters dissection of the Calot's triangle was started. Anterior dissection was started first in majority of patients in this study to clear the Calot's triangle. It included dissection around the cystic duct and artery and LN of Lund while clearing the peritoneum and soft fibrofatty tissue around the duct and artery. Posterior dissection was followed similarly to dissect the peritoneum and soft fibrofatty tissue to clear the duct and artery. If 2 structures were clearly visible free of fibrofatty tissue the Calot's triangle was considered Cleared and 2 points were assigned. If due to adhesions or anatomical variation the Calot's triangle was not cleared as described no point was assigned. 5. Posterior dissection was extended further upwards towards cholecystic plate. 1/3 of cholecystic plate was cleared as a rule in all patients and 2 points were assigned and if 1/3 cholecystic plate not cleared no point were assigned. 6. Following all the dissection mentioned above a rule was made to lift and gently pull the infundibulum to give it an appearance of Lord Ganesha or elephant head, seeing this sign 1 point was assigned. If Lord Ganesha sign was not there due to adhesions or obliteration of Calot's triangle, no point was assigned.

In all patients these 10 points were collectively calculated and 3 groups were made. Group one with 1 - 4 points was considered as risky procedure, Group 2 with 5 - 7 points was considered as somewhat risky and group 3 with 8 - 10 points was considered as safe procedure.

CBD visualized	3
Dissection above Rouviere's sulcus	1
2 structures entering into GB, Cystic duct and Cystic artery exposed	1
Calot's triangle clear	2
1/3 of cholecystic plate cleared	2
Elephant head appearance	1
	10
1-4	Unsafe
5-7	Safety +/-
8-10	Safe Cholecystectomy

Table 1: 10-point distribution (Kankaria's scoring)

III. Results:

Total of 8000 patients with 63.5% female were selected for the study purpose. Youngest patient operated was 2 years old and oldest was 109 years old. No significant complications were recorded. Table1 and 2 shows age and sex distribution in all 3 groups.Image 2 shows various etiologies for which LC was performed. Not a single case of conversion to open cholecystectomy was found. Complications while performing surgery with treatment are discussed in table 4 and five. Complication were divided into intraop and post op periods.No mortality occurred, and morbidity was negligible.

Total Points	Mean Age		
	Mean	SD	
1-4	34.51	12.06	
5-7	31.09	10.09	
8-10	32.72	11.64	

Distribution of age according to 3 groups

Distribution of sex according to 3 groups

Total Points	Sex			
	Male	%	Female	%
1-4	176	2.2	384	4.8
5-7	392	4.9	640	8
8-10	2352	29.4	4056	50.7
Total	2920	36.5	5080	63.5

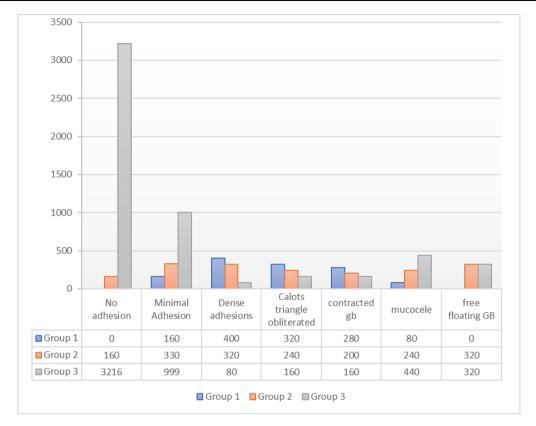
Image 2 Diagnoses included in study

1-4	5-7	8-10
ACC 80	160	100
CCC 400	320	1120
GSP 80	160	480
EMP 0	320	640
SGBS 0	80	960
ASGS 0	0	1360
GBP 0	0	1040

Keeping these 3 groups in view different variables were analyzed and compared. Anatomical variations (table 2) such as presence of adhesions, obliteration of Calot's triangle, contracted GB

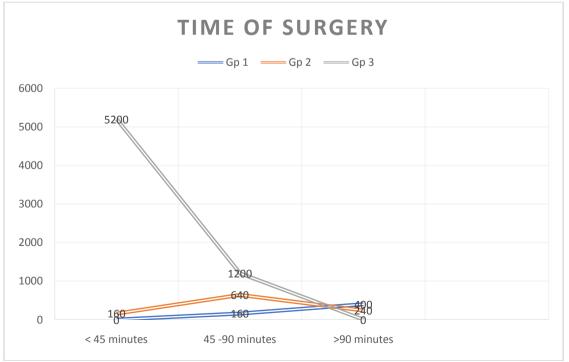
and presence of mucocele or free-floating gallbladder were analyzed.

Variation	Group 1(1-4)	Group 2	Group 3	X ² test with 2 ⁰ of	P value
		(5-7)	(8-10)	freedom	
No Adhesions	0	160	3216	885.483	0.0000(s)
Minimal Adhesions	160	330	992	211.961	0.000(s)
Dense Adhesions	400	320	80	3390.843	0.000(s)
Calot's triangle	320	240	160	1888.098	0.000(s)
obliterated					
Contracted GB	280	200	160	1637.966	0.000(s)
Mucocele	80	240	440	253.480	0.000(s)



Timing of surgery was evaluated to know which group needed more time for safe surgery. Table 3:

Table 3:					
Variation	Group 1(1-4)	Group 2	Group 3	X ² test with 2 ⁰ of	P value
		(5-7)	(8-10)	freedom	
< 45 minutes	0	160	5200	2977.907	0.000 (S)
45 -90 minutes	160	640	1200	877.656	0.000 (S)
>90 minutes	400	240	0	3938.844	0.000 (S)



Intraop complications were also evaluated in all 3 groups as shown in table 4

Complications	Groups		
	1-4	5-7	8-10
PERFORATION OF GB	147	63	30
STONES SPILLED	80	0	80
SPILLED BILE	80	80	80
SOILING OF WOUND BY BILE/STONES	166	83	71
SLIPPED CYSTIC DUCT LIGATURE	16	10	0
CYSTIC ARTERY BLEEDING	28	13	2
BOWEL INJURY	0	0	0

Table 4: INTRAOP COMPLICATIONS

Chi-square = 147.323 with 12 degrees of freedom; P = 0.000 (S)

Post op Copmlication: Table 5 POST OP COMPLICATIONS

Complications	Groups			
_	1-4	5-7	8-10	
EXCESS PAIN	131	100	82	
PROLONGED DRAINAGE	20	3	0	
PROLONGED ILEUS	0	0	0	
NAUSEA/VOMITTING	160	330	962	
SUBHEPATIC COLLECTION	5	6	3	
WOUND INFECTION	163	81	13	
POST OP FEVER	81	81	87	
JAUNDICE	0	0	0	
RETAINED STONES	4	4	0	

Chi-square = 622.554 with 16 degrees of freedom; P = 0.000 (S)

As a rule, this 10-point principle was followed in all surgeries. So as a rule, during the procedure wherever there was feeling of difficult anatomy the surgeon went slow and gentlein dissection so proper anatomy can be delineated and these 10 points can be achieved and injuries can be safeguarded.

Comparing the 3 groups, maximum number of patients with complicated anatomy were present in group one followed by group 2. While group 3 included most patients with simple anatomy.

Group one needed more time to perform safe surgery because of presence of complicated anatomy followed by group 2. Maximum number of surgeries in group 3 patients were performed within stipulated time of 45 minutes.

Analyzing complication rate in all 3 groups showed that group one had maximum number of cases of complications and group 3 had least number of complications while group 2 in-betweens.

This shows that if surgery is followed with the steps described and points assigned accordingly, as the points go up chances of safe surgery go up.

IV. Discussion

The present study shows the author's experience as a chief surgeon with laparoscopic cholecystectomy, in a teachinghospital, over a period of more than 14 years. While performing surgery, keep these 10 points in mind and go step by step and whenever there is difficult anatomy just go gentle and slow in dissection to delineate anatomy and to safeguard from injuries. By this approach even GB with most difficult anatomy can be removed with laparoscopy without converting it into open.

Gall stones are one of the most common and costly surgical disease^{17, 18, 19}. Although there are a variety of non surgical treatments described and tried but most of them do not work for the patient so surgery has become the most utilized modality for the treatment of symptomatic gall bladder disease^{20,21, 22}. Laparoscopic Cholecystectomy has become the gold standard for removal of GB²³. With increase in use of laparoscopic cholecystectomies, it's obvious that certain complications rarely seen with OC were more frequent when LC was performed. These complications included intestinal and vascular injuriesfrom trocar or Veress needle insertion and majorbile duct injuries^{24, 25, 26}

This study also shows that if LCs are performed with patience the complication rate can be reduced to minimal and the conversion rate can be reduced to zero.

Bile Duct injury is one of the most dreaded complications during LC than in $OCs^{27, 28, 29, 30, 31}$. First iatrogenic biliary duct injury was described by Sprengel in 1891. In the infancy of (LC), CBD injury occurred more frequently duringLC than during OC.Although the incidence of CBD injury during LC is no longer as high as it was initially, it still exceeds that of open cholecystectomy (0.1 % to 0.5 % in LC vs 0.2 % in OC)³²

Risk Factors for CBD injury are Lack of experience (learning curve), Misidentification of biliary anatomy, Intra-operative bleeding, Lack of recognition of anatomical variation of biliary tree and improperly

functioning instruments. Other factors areAcute and chronic cholecystitis, Empyema, Long standing recurrent disease,Advancedage,Obesity and Previous surgery.^{31, 32, 33}.

There are few steps that need to be taken during LCs to avoid complications rate. Critical view of safety introduced by Professor Steven Strassberg is one of the important landmarks. Several studies confirm that routine use of these techniques eliminates the chances of complication such as CBD injury. Clearing the fat and fibrous tissue from the Calot's triangle, freeing up the lower third of the GB from the liver bed/cystic plate and confirming that two and only two structures are seen entering the GB are three requirements for the critical view of safety. No tubular structure duct should be clipped divided unless the critical view of safety is achieved^{34, 35}

Always use 30 degree telescope with HD camera or with good endo-vision system36. When entering the port, first visualize where and how the CBD is located (to create a rough image in mind)³⁷. Retraction of fundus Apply firm cephalic traction on the fundus and lateral traction on the infundibulum so that the cystic duct is perpendicular to the CBD³⁷. Separation of omental adhesions – Always from CBD towards fundus³⁸. Use Cystic Lymph Node of Lund as valuable landmark for identifying the cystic artery. Use Rouviere's Sulcus as valuable anatomical landmark for lap Cholecystectomy³⁹. Always keep the dissection near the gallbladder. Do anterior dissections for ease of process or on complementary basis but as a rule, always do posterior dissection before clipping of cystic artery and cystic duct. Do posterior dissection with clearance of cholecystic plate at least 5 cm. The Gallbladder - duct junction is fully mobilized to give the "elephant head" appearance. Clarify the Calot's triangle³⁸. Check again and again to delineate the curvature of infundibulum and cystic duct for removing the possibility of CBD. Any vessel that pulsates before cutting is hepatic artery and one which pulsates after cutting is cystic artery. Follow Strasberg's rule of 'Critical View of Safety'. Clear the stones from the cystic duct. Apply clips on cystic duct and artery separately and never together. Cutting of cystic duct and artery by using scissors only and not any kind of energy sources. If bleeding occurs then keep your patience, never use any type of energy sources until the clearance of structures. It is better to stop the bleeding using gauze piece. And of course, wait for sometime. Always recheck the area of CBD after removal of gallbladder specimen. (to see any bile leek, bleeding or even clip dislocation). Use cholangiogram or ICG Dye when presence of doubts, if facilities are available. Do partial cholecystectomy and save the life of the patient rather than risking it, whenever there is a doubt⁴⁰. Never hesitate to convert into open surgery whenever necessary, life of the patient is worth more than a challenge for you^{34, 41, 42, 43,44, 45}

V. Conclusion:

The study shows experience of laparoscopic cholecystectomy by keeping the 10 point in mind while performing the surgery step by step, and whenever there is complicated anatomy the surgeon should become gentle and slow in dissection and rewind the 10 points again to delineate the proper anatomy and to safeguard from injury.

This study shows that if laparoscopic cholecystectomies performed with precautions and patience chances of conversion to open surgery can be reduced to zero. Meticulously performing the surgery reduces the complication rate to minimal. With due care and caution during cholecystectomy, attention towards achieving the critical view of safety and a standardized technique, complications can be avoided. This study has discussed some simple steps to follow to perform safe laparoscopic cholecystectomy. Every surgeon must include these steps in their practice.

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