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# Is intra-operative cholangiography necessary during laparoscopic cholecystectomy? A multicentre rural experience from a developing world country

Iqbal Saleem Mir, Mir Mohsin, Omar Kirmani, Tafazul Majid, Khurshid Wani, Mehmood-ul Hassan, Javed Naqshbandi, Mohammed Maqbool

Iqbal Saleem Mir, Mir Mohsin, Tafazul Majid, Khurshid Wani, Mohammed Maqbool, Minimal Access Surgery Unit, Government Gousia Hospital, Khanyar, Kashmir 190010, India Mehmood-ul Hasan, Javed Naqshbandi, Anaesthesia Unit, Government Gousia Hospital, Khanyar, Kashmir 190010, India Omar Kirmani, Department of Radiology, Government Gousia Hospital, Khanyar, Kashmir 190010, India

Correspondence to: Dr. Iqbal Saleem Mir, Minimal Access Surgery Unit, Government Gousia Hospital, Khanyar, Kashmir 190010, India. iqbalsurg@rediffmail.com

Telephone: +94-1-9002750

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## Abstract

**AIM:** To evaluate the feasibility and safety of performing laparoscopic cholecystectomy (LC) in non-teaching rural hospitals of a developing country without intra-operative cholangiography (IOC). To evaluate the possibility of reduction of costs and hospital stay for patients undergoing LC.

**METHODS:** A prospective analysis of patients with symptomatic benign diseases of gall bladder undergoing LC in three non-teaching rural hospitals of Kashmir Valley from Jan 2001 to Jan 2007. The cohort represented a sample of patients requiring LC, aged 13 to 78 (mean 47.2) years. Main outcome parameters included mortality, complications, re-operation, conversion to open procedure without resorting to IOC, reduction in costs borne by the hospital, and the duration of hospital stay.

**RESULTS:** Twelve hundred and sixty-seven patients (976 females/291 males) underwent laparoscopic cholecystectomy. Twenty-three cases were converted to open procedures; 12 patients developed port site infection, nobody died because of the procedure. One patient had common bile duct (CBD) injury, 4 patients had biliary leak, and 4 patients had subcutaneous emphysema. One cholecystohepatic duct was detected and managed intraoperatively, 1 patient had retained CBD stones, while 1 patient had retained cystic duct stones. Incidental gallbladder malignancy was detected in 2 cases. No long-term complications were detected up to now.

CONCLUSION: LC can be performed safely even in non-

teaching rural hospitals of a developing country provided proper equipment is available and the surgeons and other team members are well trained in the procedure. It is stressed that IOC is not essential to prevent biliary tract injuries and missed CBD stones. The costs to the patient and the hospital can be minimized by using reusable instruments, intracorporeal sutures, and condoms instead of titanium clips and endobags.

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Key words: Laparoscopic cholecystectomy; Intraoperative cholangiography

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## INTRODUCTION

Laparoscopic cholecystectomy (LC) is the gold standard for the treatment of symptomatic gallstones and other benign diseases of the gallbladder. It is the commonest operation performed laparoscopically worldwide<sup>[1-3]</sup>. Initially there were some concerns about its safety owing to its rapid adoption by untrained surgeons. However, when a careful, correct technique is employed, the operation is extremely safe<sup>[1]</sup>. The advantages of LC over open cholecystectomy in terms of minimal postoperative pain and postoperative pulmonary dysfunction, reduction in hospital stay, recovery periods, and improved cosmetic results have been established in a number of studies<sup>[2,4-8]</sup>. Large series of LC have been reported with few complications<sup>[6,9-12]</sup> and most surgeons and patients prefer LC to open cholecystectomy now.

The first operative cholangiography was reported in 1936 by Micken. Mirrizi in 1937 performed the first cystic duct cholangiography and this procedure remains the most accepted method for performing intra-operative cholangiography (IOC) today<sup>[13]</sup>. IOC has high sensitivity in detecting CBD stones, but its routine use is associated with increased costs and operation room time. The routine use of IOC in all cases of LC is still controversial<sup>[14]</sup> with some authors supporting routine IOC<sup>[2,15,16]</sup>, some favoring selective IOC<sup>[17-19]</sup>, while others reporting no advantage of IOC<sup>[20-24]</sup> in preventing biliary injuries and missed CBD stones.

Unfortunately, access to laparoscopic surgery is limited in most of the rural areas of the state of Jammu and Kashmir. There are only two teaching hospitals offering the facility of laparoscopic surgery to a population of nearly 60 lakhs since 1995. Due to the absence of trained laparoscopic surgeons and the non-availability of laparoscopic equipment, the concept of minimal access surgery could not reach the underprivileged rural population with incomes of less than two dollars a day. Another major hurdle that had to be overcome was the misinformation prevalent both among surgeons and patients regarding the costs and the complication rate of LC.

It was only in Jan 2001 that laparoscopic equipment was installed in three non-teaching hospitals in the rural areas of Kashmir to cater the underprivileged population. A strategy had to be evolved to train the staff and to perform LC safely without the use of costly disposables, titanium clips, and endobags as the hospitals could not bear the extra expenses of these equipments. Taking into consideration the financial status of the population, the facility was provided free of cost.

This multicentre prospective study was conducted from Jan 2001 till Jan 2007 with the following aims: To evaluate the feasibility of performing LC in rural health centers of Kashmir without resorting to IOC and to evaluate the means to decrease the costs incurred by the hospitals.

#### MATERIALS AND METHODS

Patients undergoing LC for benign disorders of gall bladder in three non-teaching rural hospitals of Kashmir valley from Jan 2001 to Jan 2007 were included in the study.

To begin, only few surgeons were trained in laparoscopic surgery. The other team members were made familiar with the electronic equipment and the hand instruments. Seminars including video clips of various laparoscopic procedures and proper ways of troubleshooting the equipment and managing complications were conducted as a part of training. Emphasis was laid on the safety of the patient and the equipment. An indigenous costless endotrainer (Figure 1) was designed from a cardboard carton of 5% Dextrose bottles, to train the team members including paramedical personnel in the theatre.

Patient selection for surgery was made pre-operatively on the basis of history, physical examination, and radiological and laboratory diagnostic evidence of gall bladder disease. Ultrasonography was focused on the characteristics of any gallstones (size, number, and location), gallbladder polyps, the status of the common bile duct, the size of the gallbladder, the thickness of the gallbladder wall, and assessment of the liver and pancreas.

Exclusion criteria: (1) cases of acute cholecystitis after 48 h of the attack, (2) multiple previous upper abdominal



Figure 1 Indigenous endotrainer used for training the staff.

operations, (3) coagulopathies, (4) and ASA grade II and onwards.

Those patients who had ultrasound documented choledocholithiasis or who had a history of jaundice with raised alkaline phosphatase and ultrasound documented CBD of more than 9 mm in diameter were sent to the nearest tertiary care centre for ERCP prior to taking them up for laparoscopic cholecystectomy.

At least one of the donor's and patient's blood samples was cross matched. Informed consent was obtained after a detailed discussion was held with the patient and attendants about the benefits and possible complications of LC.

To reduce the duration of the hospital stay, patients were admitted on the day of surgery and were allowed to have liquids up to 6 h before the operation.

Patients were asked to void urine before surgery and a Foley's catheter was not used.

#### Procedure

All operations were performed under general endotracheal anesthesia. In early cases standard four port LC was done. The Sulcus of Ruvier was used as a guide for location of Calot's triangle. The dissection of the cystic pedicle was initiated by lifting the posterior fold of peritoneum and creating a wide posterior window in the Calot's triangle. The gallbladder-cystic duct junction (the critical anatomical landmark) was identified. No attempts were made to dissect at cystic duct-CBD junction to avoid inadvertent injury. In patients in whom the Calot's triangle could not be clearly identified fundus first dissection was done by Berci's spatula. IOC facilities were not available so IOC was not performed. In cases having multiple small stones the cystic duct was partially opened and milking was done by a laparoscopic right angled forceps. Mostly 00 Vicryl sutures were placed both on cystic duct and cystic artery before cutting in between. This was done because of fear of internalization of clips into the common bile duct as reported by some authors<sup>[25]</sup> and to reduce the costs of the titanium clips. A fan retractor placed through an additional 5 mm port and a 30 degree telescope were used in grossly obese patients to obtain a clear view of anatomy. Gall bladder was removed through epigastric port after reducing the stone load. In case of infected or thick walled gallbladders specimens were removed in low cost condoms

Table 1 Patient characteristics and other observations				
S. No.	Observation	Variable		
1	Age (yr)	47.2 (13 to 78)		
2	Female/Male	976/291		
3	Previous abdominal surgeries	519		
4	Preoperative ERCP	49		
5	Mean operation time	39 min (11 min to 190 min)		
6	Conversion to open Cholecystectomy	23		
7	Drain (yes/no)	184/1083		
8	Mean duration of analgesic requirement	3 d (1 d to 5 d)		
9	Mean hospital stay	26 h (18 to 72 h)		

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Table 7	Infraonerafi	ve and post	operative cor	nplications
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S. No.	Complications	No. of patients	%
1	Shoulder tip pain	213	17.12
2	Perforation of gallbladder with Stone spill	109	8.76
3	Port site infections	27	2.17
4	Cystic duct stones	17	1.37
5	Significant bleeding	12	0.96
6	Subcutaneous emphysema	4	0.32
7	Controlled biliary Leak	4	0.32
8	Undetected GB malignancy	2	0.16
9	Bile duct injury	1	0.08
10	Retained CBD stones	1	0.08
11	Cholecystohepatic duct	1	0.08
12	Drop in oxygen saturation	1	0.08

instead of costly endopouches.

Drains were placed selectively. All port wounds were infiltrated with long-acting local anesthetic. Antibiotic prophylaxis was ensured with 2 peri-operative doses of third generation cephalosporin intravenously. Postoperative analgesia was achieved with Diclofenac (p.o, 50 mg 3 times a day). All patients had oral liquids and were encouraged to have food in the evening after the operation, provided there was no nausea or vomiting.

The drain was usually removed after 24 h if drainage was minimal. The majority of patients were discharged on the first postoperative day if they lived in the area. Those living in outlying communities were encouraged to stay in town for 48 h. Patients were reviewed at weeks 1 and 4 postoperatively in the surgical OPD.

### RESULTS

This series involved 1267 patients with symptomatic diseases of gall bladder from ages 13 to 78 years, (mean 47.2) who presented to Government Gousia hospital, District Hospital Baramulla and Ahmed's Hospital, Kashmir for LC from Jan 2001 till Jan 2007. The female to male ratio was 3.4:1. About 41% patients had undergone previous abdominal or pelvic surgery (commonest being lower segment cesarean section). Accordingly, the insertion point of the Veress needle and the first trocar was adjusted to avoid the risk of bowel perforation or injury.

The average operating time from insertion of Veress needle till closure of all ports was 39 minutes (ranging

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S. No.	Causes of conversion	No. of patients	%
1	Dense adhesions at Calot's	11	0.86
2	Significant bleeding	6	0.47
3	CBD injury	1	0.08
4	CBD stone	1	0.08
5	Drop in oxygen saturation	1	0.08
6	Extensive subcutaneous emphysema	1	0.08
7	Inability to achieve working space due to dense intra-abdominal adhesions	1	0.08
8	Faulty equipment	1	0.08
	Total	23	1.82

from 11 min to 190 min), and the mean length of postoperative hospital stay was 26 h (ranging from 18 h to 72 h). Two cases of incidental gallbladder malignancy were detected by histopathological examination of the specimens.

The outcomes of this series are reported in Tables 1 and 2. There was no mortality in our series. Only one common bile duct injury was sustained during our 6 years experience which was identified peri-operatively, repaired and a T tube placed after conversion to open procedure. Twenty seven patients had port site infections but none had evidence of deep space or systemic infection. The most common post-operative complaint was right shoulder tip pain which usually lasted for 3 to 5 d. Twenty three cases were converted to open cholecystectomy after failed laparoscopic technique early in the series (Table 3).

#### DISCUSSION

The first LC was performed in 1986 by Muhe<sup>[26]</sup>. LC has become the operation of choice for benign disorders of gallbladder<sup>[2,6,27]</sup>. Numerous publications, mostly from large surgical centres, have exhaustively dealt with the operative technique, complications and the benefits of LC. The results of this case series of LC performed in non-teaching rural hospitals of a developing country are comparable to those from tertiary care settings and rural hospitals<sup>[2,4,5,8-13,28]</sup>.

The low rate of morbidity and nosocomial infections may be due to reduced hospital stay, the favorable staffto-patient ratio, attention to aseptic technique, and environmental sanitation. Surgeons and patients prefer LC to open cholecystectomy now and this procedure is cost-effective, cosmetically superior, and produces far less morbidity, as substantiated by other studies from rural hospitals of developing countries<sup>[4,8,27,28]</sup>. Access to LC is equally important for rural communities of the developing world.

Nonetheless, several limitations are worth noting. The relatively high start-up costs (the capital equipment and training of medical and nursing staff) have to be considered. These can be minimized by using a costless indigenous endotrainer. It is possible to decrease the costs of the procedure both for the patient as well as the hospital by using reusable trocars and cannulae, reusable instruments, intracorporeal ligatures instead of costly titanium clips, and condoms in place of endobags as reported by other studies too<sup>[5]</sup>. To prevent injuries due to blunting of the tip, the trocars have to be sharpened after every 30-40 procedures.

Laparoscopy and LC are invasive procedures associated with a range of minor and major complications<sup>[29]</sup>. Bleeding is one of the most frequent and dangerous complications of LC. Clinically significant bleeding occurs in 0.5% of LC<sup>[6]</sup>. In our series, bleeding was observed in 12 (0.95%) patients, but in most cases it was controlled laparoscopically. Only 6 (0.47%) patients had significant bleeding that required conversion to the open procedure. Though bleeding is a potentially catastrophic complication inherent to the laparoscopic technique, it is also the most preventable one, as it is largely related to operator technique. In our study 1 (0.08%) patient suffered injury to the common bile duct. The frequency of this complication is 0%-0.8% in LC<sup>[9,10,11,12,15]</sup>. The low number of major bile duct injuries without resorting to IOC as reported in our study is comparable to results from other centres which recommend routine or selective IOC and questions the value of operative cholangiography during LC.

The reported rate of conversion to open cholecystectomy ranges between 1.88% to  $10.1\%^{[6,9,15,27,31]}$ . In our series, 23 (1.82%) of all procedures were converted to the open technique (Table 3). In most cases, uncontrollable bleeding and dense adhesions at Calot's were the main reasons for conversion to the open procedure.

A controversial topic that was addressed in our study is whether IOC is helpful in preventing biliary tract injuries and missed CBD stones. Even though some authors are of the view that IOC is essential to detect biliary tract injuries and detect missed CBD stones<sup>[2,15,16]</sup>, others feel that it is an unnecessary step<sup>[20-24]</sup>. Some authors recommend selective use of IOC<sup>[17,18,19]</sup>. Choledocholithiasis occurs in 3.4% of</sup></sup> patients undergoing LC but more than one third of these pass the calculi spontaneously within 6 wk of operation<sup>[31]</sup>. Collins C concluded that treatment decision based on assessment by operative cholangiography alone would result in unnecessary intervention in 50% of patients who had either false positive studies or subsequently passed the calculi. The other arguments against IOC are that the biliary tract injury has already occurred before IOC can be performed. Routine IOC picks up unsuspected stones in 1%-4% of cases only, needs additional radiological personnel and more cost; hence routine IOC is not advisable<sup>[20]</sup>.

The patient should be evaluated thoroughly for detection of any CBD stones before surgery. Pre-operative ERCP followed by immediate LC is the treatment of choice for such cases. High quality pre-operative ultrasound imaging is unlikely to miss any stones more than 3-4 mm in size. These stones usually migrate into the duodenum and may not require any immediate therapeutic approach<sup>[20]</sup>. In our series we had one case of retained CBD stones which were managed by post-operative ERCP. In our opinion proper case selection and sticking to the basic principals of LC like identification of Sulcus of Ruvier, making a wide posterior window, decompressing a tense gallbladder<sup>[32]</sup>, proper traction, hydrodissection with saline, and using the fundus first technique in difficult cases<sup>[3,6]</sup> all can help to minimize the CBD injuries, need

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for IOC, and conversion to open procedure.

Cystic duct stones (CDS) should be suspected in all cases having a wide cystic duct in the presence of multiple small gall bladder calculi. Careful retraction and manipulation should therefore be done to minimize the risk of CDS slipping into the CBD<sup>[33]</sup>. The partial opening of cystic duct with milking of stones by a laparoscopic right angled forceps should be employed in such cases. After missing a stone in the cystic duct early in our series it has become a policy in our unit to routinely perform this maneuver in all cases having a wide cystic duct in the presence of multiple small gallbladder calculi.

Port site infection, usually involving the umbilical cannulation site through which the gallbladder is extracted, occurs in 0.3%-9.0% of cases<sup>[27,34,35]</sup>. Port site infection was seen in 12 (0.95%) of our patients, and all of these were treated successfully with local wound toilet and oral antibiotics.

Since the patients were admitted only on the day of surgery and early ambulation and feeding was instituted, the average duration of hospital stay was 26 h. Recent studies have demonstrated that laparoscopic cholecystectomy can be performed as one day-surgery<sup>[7,36]</sup>. In our series, this was true in most of the cases.

Successful performance of laparoscopic cholecystectomy requires proper training, discipline, skills and technology, and ongoing maintenance of competency. We believe this series demonstrates that procedural training and ongoing practice assessment can provide timely, safe, and appropriate access to this latest surgical technique even in rural hospitals of developing countries. The success and complication rate in this consecutive series of 1267 attempted LCs (23 conversions to open cholecystectomy, 1244 successfully completed LCs associated with minor complications) without IOC competes favorably with results achieved in tertiary care centres and rural hospitals<sup>[2,4,5,8-13,28]</sup>.

#### CONCLUSION

The outcomes of this series of LCs conducted in three non-teaching rural hospitals of a developing state (Jammu and Kashmir) are similar to those of other case series from tertiary care centres and meet the published standards of care. It is hereby concluded that laparoscopic cholecystectomy can be performed safely even in rural health centres of a developing country provided proper equipment is available. The surgeons and other team members should be well trained in the procedure for which even an indigenously built costless endotrainer can be used. The case selection at the start should be stringent until enough experience is gained to manage difficult cases. IOC is not essential to prevent biliary tract injuries or missed CBD stones. This operation can be made more cost effective especially in rural sector of a developing country like India by using intracorporeal knotting in place of costly titanium clips and condoms in place of endobags. Using properly sterilized resharpened metallic trocars and cannulae can further reduce the costs without increasing the incidence of port site sepsis as substantiated by the results of our series.

The minimal hospital stay and early return to work with the resultant positive financial implications after LC for those patients who are bread earners for their families are significant. The authors strongly suggest that LC should be the surgical treatment of choice for patients of benign disorders of gallbladder. It is up to the governments of these underdeveloped countries to provide the facility free of cost to its citizens.

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