Original article

Muscle-splitting mini-incision cholecystectomy under spinal anesthesia: cost-effective equitable minimally invasive surgery in laparoscopy era

Jay Shah[1], Ram Dayal Mandal[2], Jenifei Shah[3], Jesifei Shah[3]

Abstract

Introduction

Conventional open cholecystectomy has been increasingly replaced by laparoscopy which requires resources for expensive equipment, training, and maintenance. Muscle-splitting mini-incision cholecystectomy under spinal anesthesia has comparable outcomes to laparoscopy and requires fewer resources. This study analyzes the feasibility and outcome of muscle-splitting mini-incision cholecystectomy under spinal anesthesia.

Methods

All consecutive cases of muscle-splitting mini-incision cholecystectomy (MC) performed for symptomatic cholelithiasis during three years ending in December 2019, at a periphery hospital in Janakpur, province-2, Nepal, were included. Complicated cholelithiasis (biliary pancreatitis, jaundice, cholangitis, dilated common bile duct) was excluded. Written informed consents were obtained. The need for general anesthesia, complications during and after surgery, and patient satisfaction were analyzed descriptively. Ethical approval was obtained.

Results

Out of 148 MC completed under spinal anesthesia, six (4.1%) required fentanyl for shoulder discomfort. Mild post-operative pain was reported by 124 (83.8%) at six hours and 146 (98.6%) at 12 hours. The intravenous drip was stopped after surgery and oral liquid with analgesics started in two hours in 143 patients (96.6%). Post-operative antibiotic was given in nine, for 2(1.4%) cholecysto-duodenal fistulas, 4(2.7%) diabetics, and 3(2%) mucoceles. The mean hospital stay was one night. Wound complications occurred in 6(2.8%). Overall, 144 (97.3%) were satisfied and would recommend the procedure to others. Histopathology revealed adenocarcinoma in one case. There was no bile-duct injury, re-surgery, or mortality.

Conclusion

Muscle-splitting mini-incision open cholecystectomy (MC) under spinal anesthesia is safe and effective with early feeding, short hospital stays, less demand for resources, and good patient satisfaction.

Keywords: Cholelithiasis; Laparoscopy; Muscle-Splitting Mini-Incision Cholecystectomy; Spinal Anesthesia.

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Disclosures:

Ethical Clearance: Taken

Conflict of interest: None

Financial aid: None

How to cite this article:

Shah J, Mandal RD, Shah J, Shah J. Muscle-splitting mini-incision cholecystectomy under spinal anesthesia: cost-effective equitable minimally invasive surgery in laparoscopy era. J Soc Surg Nep. 2021 Jul; 24(1):2-9.

DOI:
https://doi.org/10.3126/jssn.v24i1.41026

Introduction

Cholecystectomy for symptomatic gallstones using open (OC) or laparoscopic (LC) technique as definitive treatment continues to be modified to optimize the outcome of surgery. With few narrow retractors and modifications, mini-incision cholecystectomy (MC) introduced in the early 1980s has shown to achieve the benefits of minimally invasive surgery (MIS) in line with the enhanced recovery after surgery (ERAS).[1-5] Use of muscle-splitting incision has shown to further reduce trauma.[2,6,7] Spinal anesthesia (SA) is a safe and effective option for MC and does not compromise pulmonary function and peri-operative events due to neuroendocrine stress encountered in general anesthesia (GA).[8-11]

Quest for an efficient and effective clinical approach at a reduced cost is desirable for all, be it a resource-rich or poor country.[12,13] The system planners and healthcare service providers need to consider the social context, the demand for resources, sustainability in pursuit of technology, minimize the high-tech colonialism of societies in low- and middle-income countries (LMICs).[14]

This study aims to analyze the feasibility and outcome of muscle-splitting MC under SA, which can be performed with less demand on resources.

Methods

This was a cross-sectional study of prospectively collected data on mini-incision open cholecystectomy (MC) from June 2016 to December 2019 at Care Medical Center, Janakpur, in province-2, Nepal. Patients with symptomatic cholelithiasis, American Society of Anesthesiologists (ASA) I or II were included. Complicated cholelithiasis (biliary pancreatitis, jaundice, cholangitis, dilated common bile duct with or without stone) was excluded. Patients and families were counseled for MC under SA, that patients can take oral liquid after two hours of surgery and could go home the next morning in most cases, and there will be no need to remove stitches. Written informed consent was obtained from patients, or guardians for minors or who could not read and write.

The MC was performed under SA by the author experienced both in open and laparoscopic cholecystectomy. A transverse muscle-splitting mini-incision of 2x2x2 i.e. 2-fingers (4-6 cm) long, 2-fingers below the right costal, and 2-fingers lateral to the midline was made. After incising the sheath, the rectus muscle was retracted medially from its lateral border with the help of a right-angle retractor (Langenbeck) to enter the abdomen. In muscular heavy patients, the rectus muscle was split and retracted. The incision was quick and bloodless, rarely requiring electrocautery.

The space around GB was packed with a surgical gauge swab (locally prepared 8-ply 10x10 cm) to retract bowel and omentum by a narrow-blade Deaver retractor. The gauge was held with Kocher's forceps outside the abdomen. The liver was retracted with a narrow blade Richardson retractor. The tense, difficult to hold GB was aspirated with a syringe, impacted stones evacuated, and fundus first approach was used as required. The Hartman's pouch was held by plain ovum forceps to visualize Calot's triangle. An opening on the serosa at the apex of the triangle away from the bile-duct was created. The free end of the suture (a round needle 1/0 Polyglyconate later used for wound closure) was looped around the cystic duct-artery complex with the help of a right-angle Lahey forceps for ligation.[15] A long heavy artery forceps were used to clamp the cystic duct-artery complex distal to the ligature to ensure a ≥0.5 cm stump. The GB was dissected from the liver, leaving 0.5 cm of serosa using scissors, cautery, 'peanut' pusher in combination. The wound was closed in layers with a subcuticular skin suture using the Polyglyconate remaining from earlier ligature (**Figure 1A-D**).

Anesthesia was provided by a nurse anesthetist with a diploma training of anesthesia assistant (AA).[16] He has experience of both spinal and intubation GA and has been providing anesthesia in the provincial hospital and local private hospitals. The basic equipment and drugs for intubation were on standby, also an electric generator due to frequent disruption of electricity.

Patients were fasted for six hours and allowed clear liquid until two hours before surgery.[17] A non-invasive monitor for blood pressure (BP), pulse, and oxygen saturation was used during surgery. A preload with 500 ml of normal saline, Midazolam 2 mg IV (1 mg for a patient weighing less than 40 kg), and Ceftriaxone 1 gm prophylaxis were given (this was a modification to the author's usual practice of using Cefazoline 1 gm which is not available locally). In L2-L3 intervertebral space in a left lateral position, 2 ml of 0.5% hyperbaric Bupivacaine was injected by 25-G spinal needle. The patient was turned supine immediately, legs flexed for 5-10 minutes to stabilize the block up to T4 level to achieve SA. The induction time, injection-to-block, was recorded.

During surgery, the fall in BP (systolic <90mmHg or 20% drop) was managed by IV fluid and additional inj. Mephentine as required. For bradycardia (HR <60/min) fluid and inj. Atropine was used. Oxygen was administered by a nasal prong or face mask to maintain a saturation above 90%. Fentanyl was given for shoulder discomfort. Surgery time of skin-to-skin was recorded.

The IV-cannula was locked before patients were shifted out with instruction for nurses to run the fluid when required (systolic BP <90 mmHg, or persistent vomiting).[19] A post-operative vital monitoring chart was kept in the patient's file to record BP, pulse, SpO2 frequently. During 1st hour recorded at intervals of 5, 15, 30, and 60 min, then every 6 hourly. Nurses were instructed to repeat the readings if in doubt and inform the on-duty doctor. These measures were devised owing to the lack of a recovery ward. Early oral

feeding was initiated no later than 2 hours, starting with plain water then to full liquid.[20] Analgesic (tab Ibuprofen 400 mg plus Paracetamol 325 mg, and tab Ketorolac 10 mg) 8-hourly were started with oral liquid. Tramadol 50 mg I.V. was kept for rescue analgesia. Ondansetron 8 mg was given for persistent postoperative nausea vomiting (PONV). Patients were encouraged to move their legs once they had sensation, sit on the bed, and get out of bed gradually assisted by nurses or family. Nurses were instructed to encourage patients to pass urine after 4 hours of arrival in the ward, i.e., 5-6 hours after SA. Catheterization was done only when the patient could not void (in the toilet or bedpan) despite repeated attempts.

Patient perception of pain was recorded at 6 hours and 12 hours (or 9 am the next day before discharge). Pain was graded as mild (pain on coughing), moderate (on sitting up or walking), and severe (pain while lying in bed). Patient's satisfaction was recorded on a Likert scale (3-satisfied will recommend; 2-satisfied, with reservation for recommendation; 1-undecided).

Patients were discharged the next morning. Postoperative antibiotics (oral Ciprofloxacin 500 mg bid for 5-days or I.V. when NPO) were given for diabetes and complicated surgery (mucocele, empyema, or additional procedures). Acid suppression therapy (AST) with proton pump inhibitor (PPI) of omeprazole 20 mg BID oral was given or I.V. pantoprazole for persistent PONV or prolonged NPO of more than one day, e.g., cholecysto-duodenal fistula repair, or a history of acid peptic disease on regular PPI. Take home instruction: oral analgesic same as above, soft diet progressing to full diet as tolerated. Patients were advised for a follow-up to the hospital (or visit a local health facility) on 3rd day to open the dressing to observe the wound and thereafter leave it uncovered. For wound complications (redness, swelling, pain) or concerns patients were advised to come to the hospital.

The specimen was sent for histopathology selectively for suspicious lesions (focal thickening, growth, ulcer) after macroscopic observation by the surgeon.[21] Patient demand for histopathology was also considered. There is a lack of histopathology facilities locally and sending out costs 3-times the charges in the capital city of Kathmandu.

The outcome of anesthesia, events during and after surgery, length of hospital stay, patient satisfaction, and wound complication were descriptively analyzed for frequency and percentage using Microsoft Excel.

Results

All 148 MC were completed under SA, average age 40 years, and female 140 (94.6%) (Table 1). The duration of surgery was 35 minutes (range 25-90 minutes). Fentanyl was required for shoulder discomfort in 6(2.8%). Oral liquid and analgesic initiated within 2 hours were tolerated by 143 (96.6%). Mild pain was reported by 124 (83.8%) at 6 hours. The PONV occurred in 56(37.8%), 14(25%) required Ondansetron. Three (5.4% of PONV) required overnight I.V. drip. Mild spinal headache occurred in 4(2.7%), and all improved on conservative measures. Postoperative antibiotics were continued in 9(6.1%), and PPI in 2(1.4%). The mean hospital stay was one night (**Table 2**).

Wound complications occurred in 4(2.7%). Two had skin partially left open following cholecysto-duodenal fistula repair (were on antibiotic Ciprofloxacin and Metronidazole). Two patients (one diabetic and one mucocele) presented with pain and redness of the wound on 3rd day. Both had their antibiotics continued for 5 days, and healed spontaneously.

Two patients with cholecysto-duodenal fistulas required additional procedures. One small fistula of 3 mm size was closed primarily by interrupted sutures (Polyglyconate 3/0). Another fistula of 6 mm size with a friable duodenum had a T-tube duodenostomy. The duration of surgery was 70 min in primary repair and 90 min in tube-duodenostomy. Both required extension of incision and were given top-up inj. Ketamine. A subhepatic tube drain was put in both.

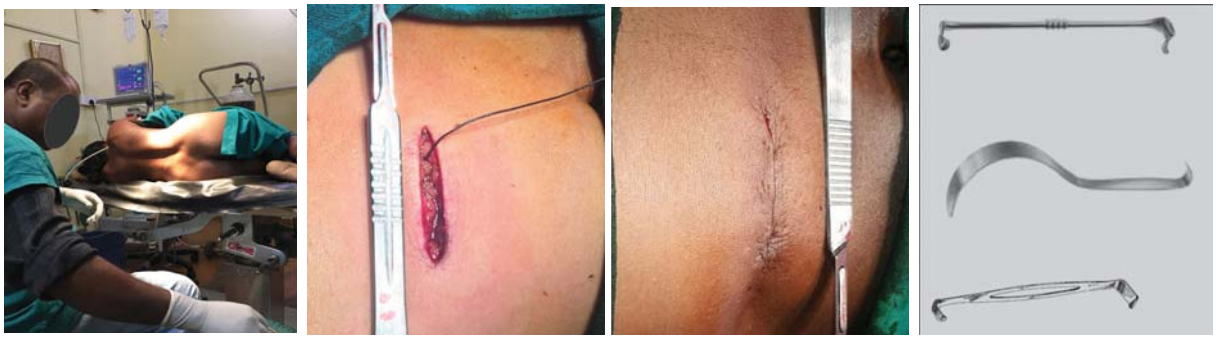

Figure 1A-D. Muscle-splitting mini-incision open-cholecystectomy- MC under spinal anesthesia (SA).
A. SA L2-L3, non-invasive monitor, oxygen cylinder and basic general anesthesia set with halothane vaporizer and Benz circuit on standby; B. A 2x2x2 finger right subcoastal transverse MC closed in layer with continuous suture (round needle 1/0 Polyglyconate earlier used for ligation of cystic duct & artery); C. Completion of subcutaneous skin suture; D. Commonly used narrow blade retractors are sufficient- Richardson, Deaver and Right-angle (Langenbeck).

Skin wounds were loosely approximated by a single stitch. Both fistula patients were kept NPO for 48 hours, and I.V. Ciprofloxacin and Metronidazole. Oral clear liquid was started on the 3rd day. Both were discharged with the drain (<20 ml of serous fluid) and oral antibiotics, on the 5th day. Drains were removed on the 8th day.

Table 1. Patient profile of muscle-splitting mini-incision open cholecystectomy (MC) under spinal anesthesia (SA), N=148

Variables	Findings	N	%
Gender	Male	8	5.4
	Female	140	94.6
Age in year, 40 (range16-74)	≤30	32	21.6
	31-60	112	75.7
	≥60	4	2.7
BMI, 20.7 (range 18.1-24.2)	<20	6	4.1
	20-25	110	74.3
	26-30	32	21.6
Comorbidities	Diabetes	4	2.7
	Hypertension	7	4.7
	Hypothyroidism	2	1.4
	Hyperthyroidism	2	1.4

One patient had a subtotal cholecystectomy. Separation of adhered omentum revealed a thick wall friable GB with necrosis at the fundus. Calot's triangle was obscured. Stones were cleared, mucosa cauterized and remnant GB closed by interrupted suture. A subhepatic drain was placed. On the 2nd day, the patient was discharged with drain (no output) and removed on the 7th day.

Selective histopathology was sent in 3(2%) for grossly suspicious GB (1-thickened friable necrosed wall, 1-polyp, 1-patient's request-a female paramedic). One friable necrosed GB (33.3% of 3 selective and 0.7% of 148 total) revealed adenocarcinoma stage-III. After discussion with the patient and family, no further intervention was done. The other two were reported as polyp and chronic cholecystitis.

There was no bile duct injury, bile leak, re-surgery, or mortality.

Discussion

Our findings show muscle splitting mini-incision cholecystectomy 'MC' under SA was safe with no bile duct injury, leak, re-surgery, or mortality. Similar to LC, it has the benefits and outcome of minimally invasive surgery (MIS) characterized by a short hospital stay, less pain, satisfactory wound healing, and good patient satisfaction. The added advantage of less demand on resources and cost is obvious. This is an attractive procedure for wider applicability both in resource-rich and poor countries.

In the present study, the hospital stay was short (16 h). Patients stayed in the hospital overnight because of the rurality and poor transportation facility. The Cochrane review has shown no differences in the primary outcome after LC and MC for the hospital stay, complications, and recovery time.[22] Expertise-based randomized controlled trial (RCT) has shown similar health-related Quality of Life but significantly higher costs in LC.[23,24] Our conversion rate for intubation GA was nil.

Cost reduction was obvious in our series with the use of a single suture to complete the procedure, early feeding within 2 hours avoiding I.V. drip (in 96.6%), no need for wound dressing and suture removal, and no routine antibiotics and PPI. Traditionally, the 'cost-effectiveness' of LC has been analyzed in the view of a developed economy for hospital stay and return to work, which needs to be reviewed in resource-poor low-income countries for the social cost, allocation of resources, training, and maintenance of technology, etc. In one RCT from India, despite laparoscopy costing twice that of MC, the LC was concluded cost-effective. The study had included rectus muscle cutting incision of 10 cm and reported unusually 62% wound complications, with an infection rate of 25%.[24]

All countries, rich or poor strive to develop ways to meet the needs of the people.[14,25] New technology requires resources, training, and maintenance of equipment, an issue in LMICs. The globalization and aggressive marketing of technology without consideration to sustainable and equitable delivery of surgical services are a burden and considered neocolonialism.[14] The 'Third World' concept meant for 'underdeveloped countries to be exploited and despised as a Third Estate' should be seen in a broader concept of global health.[14] The recommendation to 'build on outcome-directed research' often fails to include LMICs.[26] Thailand's study has revealed that LC can be cost-effective only at three times the per capita GDP for the majority of LMICs.[27] Switching to MC requires simple modifications of technique without additional resources and has a similar outcome to that of LC, benefitting patients, hospitals, and society.[23,24,28-30] The LMICs have one-third of the global population, but only 3.5-5% of surgeries, which requires health policymakers to look for ways to narrow down the gaps between rich and poor countries and also within the country itself for equitable distribution of resource.[31,32]

After the introduction of laparoscopy during the 80s and successful first laparoscopic cholecystectomy in Germany in 1985, LC has overtaken open surgery for cholelithiasis as a technological revolution even though smaller incision open cholecystectomy, introduced in early 1982 had shown successful outcome with a shorter convalescence.[4,5,33] Open cholecystectomies have stayed and are performed with a modified smaller incision in most parts of the world for less cost, the need of equipment, and training.[1-7] The studies comparing conventional OC and LC continue to unfairly judge the benefits of MC.

Table 2. Outcome of muscle-splitting mini-incision open cholecystectomy (MC) under spinal anesthesia (SA),N=148

Variables	Findings	N	%
SA induction time in minutes	6 (range 4-8)	-	-
SA conversion to intubation GA	0[a]	0	0
Surgery time 35 minutes (range 28-90[b])	≤30	32	21.6
	31-60	112	75.7
	≥ 60[b]	4	2.7
Events during surgery, 24 (11%)	Hypotension requiring drug	4	2.7
	SPO2 fall requiring oxygen	14	9.5
	Shoulder pain/discomfort requiring drug	6	4.1
Events after surgery, 10 (4.6%)	PONV requiring intervention[c]	3	2.0
	Spinal headache requiring intervention[d]	4	2.7
	Urine retention requiring catheterization	3	2.0
Additional procedure during surgery	Repair cholecystoduodenal fistula	2	1.4
Surgical complication	Bile duct injury	0	0.0
	Bile leak	0	0.0
Post-operative IV fluid[e]	Stopped after surgery	143	96.6
	continued after surgery	5	3.4
Antibiotic[f]	Intravenous then oral ciprofloxacin	2	1.4
	Oral ciprofloxacin	7	4.7
AST/PPI[g]	Intravenous pantoprazole	2	1.4
	Oral pantoprazole	6	4.1
Pain at 6 hours	1-Mild pain	124	83.8
	2-Moderate, pain on getting out of bed	20	13.5
	3-Severe, pain on lying	4	2.7
Pain at 12 h/discharge	Mild pain	146	98.6
	Moderate, pain on getting out of bed	2	1.4
	Severe, pain on lying	0	0.0
LOS nights (average 16 h)[h]	1 night	144	97.3
	>1 night[h]	4	2.7
Patient's satisfaction	3-satisfied will recommend	144	97.3
	2-satisfied reservation to recommend	2	1.4
	1-Undecided	2	1.4
Wound complications[i]	Delayed healing and inflammation[i]	4	2.7
Selective histopathology sent in 3[j]	Adenocarcinoma of gallbladder	1	0.7

Note:
[a,b]All MC under SA, top-up I.V. ketamine in 2-cholecysto-duodenal fistula prolonged surgeries.
[c]Postoperative Nausea and Vomiting (PONV) 56 (37.8%), Ondansetron required in 14 (25% of PONVs)
[d]Spinal headaches were mild, managed by increased oral fluid, analgesic.
[e]Post-operative IV drips in 2 cholecysto-duodenal fistulas, and 3 PONVs.
[f]Postoperative I.V. Ciprofloxacin in 2-fistulas, oral antibiotics for 5d in diabetes.
[g]I.V. Pantoprazole 40 mg bid in 2 fistula repairs; oral Omeprazole for 5d in diabetes.
[h]Length of stay (LOS) calculated for night stays (owing to the rurality and transportation constrain)
[i]Total 4 wound complications- 2 were delayed healings in 2 fistula patients, 1-DM, 1-mucocele
[j]Selective histopathology sent in 3 (2%)-- suspicious GB 2 (thick wall, ulcer, mass) and 1 patient request; 1(33.3% of 3 selective histopathologies i.e., 0.7% of total 148) revealed adenocarcinoma stage-III.

The MC is comparable to LC.[3] Earlier studies popularized the technology of LC and 'value for money by comparing with the conventional cholecystectomy, unlike muscle-splitting MC.[28,30,34] Also, a thin physique (in the Asian population), makes access to the abdominal cavity easier via a small incision and lower wound complications. In our series, BMI was below 24.2, average 20.7 (**Table 1**). The MC under local lignocaine augmented by fentanyl and midazolam was successful in 95% (out of 42) of gallstones (BMI 20.5, range 17.6–23.4) from Bangkok, Thailand.[35]

The shortage of trained health manpower has consequences for adequate surgery delivery in LMICs.[36] The concept of 'task-shifting of non-physician to perform designated tasks as recommended by the WHO is worth promoting as shown by systematic analysis.[37] This safe and sustainable concept optimizes the available resources and is applicable for both low- and high-income countries, though debate of safety and patient rights continue possibly due to competing for professional interests.[38] Our series show SA was successfully provided by a trained anesthesia assistant[16]; scrub with a surgical assistant by the OT boy/staff trained by the surgeon. The SA also further extends pain relief after surgery, improves breathing, and reduces pulmonary complications, and morbidity.[8-11,39] We had no serious perioperative events, and patients reported only mild pain (83.8%) at 6 hours and before discharge the next morning.

The MC is also safe and feasible in acute cases. The study from Russia reports 93.2% MC, out of 383 cases including acute cholecystitis, were successfully completed with a low complication rate and concluded the technique as a better choice of surgery.[40] Our series included planned cases only, yet we successfully managed mucocele and fistulas with MC.

Selective histopathology, though controversial, is safe and cost-effective. A recent systematic review reports that truly incidental carcinoma (without preoperative or intraoperative suspicion) was of early-stage (T1a) and would not change the outcome not requiring further intervention.[21]

Patient expectations affect the overall outcome and help decrease hospital stay. Counseling, including the elements of the surgical care pathway, like in our series with a detailed explanation to patients and family about the small incision, reduced pain and better wound healing, early oral feeding, and no drip, no antibiotics, and only an overnight hospital stay were helpful for patient satisfaction.[17,19] The MC can very well be performed as day surgery as the average hospital stays in our series was 16 h and overnight stay was due to rurality with poor transport, and access to health facilities.

Mastery of MC is practical and beneficial for the general surgeon as an index surgical skill training, also useful when a conversion is needed from LC. The MC can be easily adapted by surgeons experienced in open cholecystectomy. It is a feasible and safe alternative of MIS with wider applicability at reduced cost and resources, a viable addition to the LC for both low and high-income countries.

Conclusion

Muscle-splitting mini-incision open-cholecystectomy, under spinal anesthesia, is a safe and effective minimally invasive surgical technique for the treatment of cholelithiasis. It achieves a shorter hospital stay similar to daycare surgery and most of the patients (97.3%) were satisfied and would recommend the procedure.

Acknowledgments

We thank Mr. Suresh Yadav, the OT boy/staff for scrub, an assistant during surgery, and managing operation theater. We are thankful to the nurses for their hard work in collecting data for pain scores and patient satisfaction.

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