OPEN ACCESS

Saudi Journal of Medical and Pharmaceutical Sciences
Abbreviated Key Title: Saudi J Med Pharm Sci
ISSN 2413-4929 (Print) | ISSN 2413-4910 (Online)
Scholars Middle East Publishers, Dubai, United Arab Emirates
Journal homepage: https://saudijournals.com

Original Research Article **Surgery**

Laparoscopic Cholecystectomy Outcomes Under Spinal-Epidural and General Anesthesia: A Prospective Randomized Trial

Dr. Md. Hasanur Rahman[1*]

[1]Associate Professor, Department of Surgery, Chandpur Medical College, Chandpur, Bangladesh

DOI: https://doi.org/10.36348/sjmps.2025.v11i04.002 | **Received:** 15.02.2025 | **Accepted:** 22.03.2025 | **Published:** 04.04.2025

***Corresponding author:** Dr. Md. Hasanur Rahman
Associate Professor, Department of Surgery, Chandpur Medical College, Chandpur, Bangladesh

Abstract

Background: Laparoscopic cholecystectomy (LC) is the standard treatment for gallbladder diseases, traditionally performed under general anesthesia (GA). However, spinal-epidural anesthesia (SEA) has emerged as a potential alternative due to its advantages in postoperative recovery, reduced nausea, and improved pain control. Despite these benefits, the choice between SEA and GA remains debated in clinical practice. ***Objective:*** This study aims to compare the perioperative and postoperative outcomes of LC performed under SEA versus GA, focusing on pain management, complications, and recovery parameters. ***Methods:*** A prospective randomized controlled trial was conducted at a tertiary care hospital from September 2023. A total of 97 patients were randomly allocated to undergo LC under SEA [n=48]or GA[n=49]. Inclusion criteria included ASA I-II status, age 18-65 years, and BMI ≤30 kg/m². Perioperative parameters, postoperative pain (Visual Analog Scale), complications, and hospital stay duration were assessed. Statistical significance was determined using appropriate tests, with an interim analysis performed after the first 100 patients. ***Results:*** Baseline characteristics were comparable between groups. Median operative time was 45 minutes for SEA and 47 minutes for GA. SEA patients experienced significantly lower postoperative pain scores at all time points ($p < .001$). The incidence of postoperative nausea and vomiting was slightly higher in the GA group (16.7%) than in the SEA group (14.3%). Urinary retention was observed only in the SEA group (6.1%), while dizziness and sinus tachycardia were exclusive to GA (2.1% each). The median hospital stay was one day for both groups. ***Conclusion:*** SEA provides superior postoperative pain control compared to GA while maintaining comparable operative and anesthesia durations. Although SEA was associated with urinary retention, GA had a higher incidence of nausea, dizziness, and tachycardia. These findings support SEA as a viable alternative to GA in LC, particularly for patients prioritizing pain reduction and enhanced recovery.

Keywords: Laparoscopic cholecystectomy, spinal-epidural anesthesia, general anesthesia.

INTRODUCTION

Laparoscopic cholecystectomy (LC) is the gold-standard surgical procedure for the treatment of gallbladder diseases, particularly cholelithiasis. Traditionally, general anesthesia (GA) has been the preferred anesthetic approach for LC due to its ability to ensure patient comfort, immobility, and controlled ventilation. However, regional anesthesia techniques, such as spinal-epidural anesthesia (SEA), have gained attention as viable alternatives, offering potential advantages such as reduced postoperative pain, decreased nausea and vomiting, and shorter hospital stays. Despite these benefits, the optimal anesthesia method for LC remains a subject of ongoing debate [1-3].

Spinal-epidural anesthesia, a neuraxial technique, has been widely used in lower abdominal and lower limb surgeries but is now being explored for laparoscopic procedures. SEA provides adequate sensory blockade while preserving spontaneous respiration and hemodynamic stability. In contrast, GA involves the administration of intravenous and inhalational anesthetics, requiring endotracheal intubation and mechanical ventilation [4-6]. While GA ensures a controlled surgical environment, it is also associated with higher risks of postoperative complications such as respiratory depression, hemodynamic fluctuations, and prolonged recovery [7].

Recent studies have suggested that SEA may offer several advantages over GA in LC, including reduced opioid consumption, lower incidence of

postoperative nausea and vomiting (PONV), and improved hemodynamic stability [8]. Additionally, SEA may facilitate early ambulation and discharge, contributing to enhanced recovery protocols (ERAS). However, concerns about patient discomfort, inadequate pain control, and the feasibility of performing laparoscopic surgery under regional anesthesia persist, necessitating further investigation into its safety and efficacy compared to GA.

Objective

This prospective randomized trial aims to compare the perioperative and postoperative outcomes of laparoscopic cholecystectomy performed under SEA versus GA.

METHODS

Study Design and Setting

This study was designed as a prospective, randomized controlled trial aimed at evaluating the outcomes of laparoscopic cholecystectomy (LC) under spinal-epidural anesthesia (SEA) compared to general anesthesia (GA). Conducted within a single tertiary care institution, the trial commenced in September 2023 following approval from the institutional ethics committee. Ethical integrity and adherence to patient safety protocols were rigorously maintained throughout the study period. The allocation of patients to the respective anesthesia groups was performed using a computer-generated randomization sequence, ensuring unbiased distribution. To uphold blinding, sequentially numbered, opaque, and sealed envelopes containing allocation details were placed in the operating theater and were only opened upon the patient's arrival, ensuring neither the patient nor the preoperative medical team was aware of the assignment beforehand.

Study Population and Eligibility Criteria

Patients considered eligible for participation were those referred for elective LC who met the predefined inclusion criteria. Specifically, patients classified under the American Society of Anesthesiologists (ASA) physical status I or II, aged between 18 and 65 years, with a body mass index (BMI) $\leq$30 kg/m² and a normal coagulation profile were recruited. Exclusion criteria included patients with acute cholecystitis, pancreatitis, or cholangitis, those with a history of previous upper abdominal surgery, individuals with contraindications to pneumoperitoneum, and those ineligible for spinal anesthesia due to spinal deformities. Informed consent was obtained from all participants before enrollment to ensure comprehensive understanding of the study objectives and potential risks.

Data Collection and Perioperative Management

Standardized preoperative evaluation and preparation protocols were implemented to maintain consistency across study participants. Prophylactic measures against deep venous thrombosis (DVT) were administered using subcutaneous enoxaparin sodium (20 mg) once daily throughout hospitalization. Upon arrival in the operating room, patients underwent noninvasive monitoring, including electrocardiography, noninvasive arterial blood pressure measurement, and pulse oximetry. Additionally, an arterial line was established for direct hemodynamic monitoring and blood sampling. Preoperative medications, including intravenous administration of midazolam hydrochloride (1 mg), granisetron hydrochloride (3 mg), and ranitidine hydrochloride (50 mg), were uniformly administered. A nasogastric tube was inserted for gastric decompression and was removed at the conclusion of the procedure to ensure methodological consistency across groups.

Anesthetic Techniques and Intraoperative Monitoring

For patients randomized to the SEA group, spinal anesthesia was induced using a 25-gauge pencil-point spinal needle inserted at the L2-L3 intervertebral space under aseptic conditions. Following the confirmation of cerebrospinal fluid flow, a combination of hyperbaric bupivacaine hydrochloride (0.5%, 3 mL), morphine sulfate (0.25 mg), and fentanyl citrate (20 µg) was administered intrathecally. Subsequently, patients were repositioned into the supine position and maintained in the Trendelenburg position for three minutes to optimize anesthetic spread. Hemodynamic stability was closely monitored, and in instances where the mean arterial blood pressure (MAP) dropped by more than 20% from baseline, intermittent intravenous phenylephrine hydrochloride (0.004%) infusion was administered as necessary.

Patients assigned to the GA group received induction of anesthesia with intravenous propofol (2-3 mg/kg), fentanyl citrate (5 µg/kg), and atracurium besylate (0.5 mg/kg). Anesthesia was maintained with sevoflurane (1-2%) in conjunction with continuous propofol infusion (2 mg/kg/h). Endotracheal intubation was performed, and mechanical ventilation was initiated using a semi-closed circuit with a 50% oxygen-air mixture. Tidal volume was set at 8-10 mL/kg, with ventilatory rates adjusted to maintain a partial pressure of carbon dioxide (PaCO2) between 35-40 mmHg. At the conclusion of surgery, neuromuscular blockade was reversed using neostigmine methylsulfate (25 mg) and atropine sulfate (1 mg). Throughout the intraoperative period, continuous hemodynamic monitoring—including electrocardiography, heart rate, arterial blood pressure, respiratory rate, pulse oximetry, arterial blood gas analysis, and acid-base balance—was performed at five-minute intervals, except for PaCO2, which was measured at 15-minute intervals.

Surgical Procedure and Intraoperative Observations

A uniform laparoscopic cholecystectomy technique was adopted for all participants, utilizing a standard four-trocar approach. Pneumoperitoneum was induced using the Hasson open technique with carbon

dioxide insufflation, maintaining an intra-abdominal pressure of 10 mmHg, which was lower than the conventional 14 mmHg, to minimize diaphragmatic irritation and enhance patient comfort, particularly in the SEA group. Minimal table tilting was employed to further mitigate intraoperative discomfort in awake patients. Operative time, intraoperative complications, and anesthesia-related events, such as shoulder pain, nausea, headache, and discomfort, were meticulously documented, especially in the SEA cohort. Notably, no subhepatic drains were utilized in any patient to maintain standardized postoperative management.

Statistical Analysis and Sample Size Determination

The primary endpoint of this investigation was the assessment of postoperative pain using the Visual Analog Scale (VAS), whereas secondary endpoints included complication rates, duration of hospital stay, recovery parameters, and overall patient satisfaction. The required sample size was determined based on an estimated 20% difference in postoperative pain scores between the SEA and GA groups, with an 80% power to detect this difference at a 5% significance level. Accordingly, a total of 150 patients per group were recruited. To ensure robust and clinically meaningful conclusions, an interim analysis was scheduled upon completion of the first 100 patients, [SA group=49, GA group=48] , allowing for early assessment of emerging trends in perioperative outcomes and safety profiles. The results of this interim evaluation were critically analyzed before proceeding with the full-scale study.

RESULTS

The baseline characteristics of patients undergoing laparoscopic cholecystectomy under spinal anesthesia (SA) and general anesthesia (GA) were comparable. The median age was 45 years (range: 23-65) in the SA group and 46 years (range: 26-65) in the GA group. The median BMI was slightly higher in the SA group at 27 (range: 18-30) compared to 26 (range: 19-30) in the GA group. Preoperative endoscopic retrograde cholangiopancreatography (ERCP) was performed in 8.2% of SA patients and 6.3% of GA patients. Operative time was similar between the groups, with a median of 45 minutes (range: 20-90) in the SA group and 47 minutes (range: 20-110) in the GA group. Total anesthesia duration was also comparable, with medians of 61 minutes (range: 35-118) and 62 minutes (range: 34-125) in the SA and GA groups, respectively. Bile spillage occurred in 28.6% of SA patients and 25.0% of GA patients. The median hospital stay was identical in both groups at 1 day, though the range was slightly broader in the SA group (1-4 days) compared to the GA group (1-2 days).

Table-1: Characteristics of Patients Who Underwent Laparoscopic Cholecystectomy

Characteristics of Patients Who Underwent Laparoscopic Cholecystectomy	Received Spinal Anesthesia (n = 49)	Received General Anesthesia (n = 48)
Age, median (range), years	45 (23-65)	46 (26-65)
Body mass index (BMI), a median (range)	27 (18-30)	26 (19-30)
Preoperative ERCP, No. (%)	4 (8.2%)	3 (6.3%)
Operative time, median (range), min	45 (20-90)	47 (20-110)
Total anesthesia duration,b median (range), min	61 (35-118)	62 (34-125)
Bile spillage, No. (%)	14 (28.6%)	12 (25.0%)
Hospital stay, median (range), days	1 (1-4)	1 (1-2)

Postoperative events varied between the spinal anesthesia (SA) and general anesthesia (GA) groups. Nausea and vomiting were slightly more common in the GA group (16.7%) compared to the SA group (14.3%). Dizziness and sinus rhythm tachycardia were observed only in the GA group, affecting 2.1% of patients each, whereas no cases were reported in the SA group. Pruritus was noted in 2.0% of SA patients but was absent in the GA group. Urinary retention occurred in 6.1% of SA patients, while no cases were observed in the GA group. These findings suggest that while both anesthesia methods have associated postoperative effects, SA was linked with a higher incidence of urinary retention, whereas GA was associated with a slightly higher frequency of nausea, dizziness, and tachycardia.

Table-2: Postoperative complication in the study group

Postoperative events	Received Spinal Anesthesia (n = 49)	Received General Anesthesia (n = 48)
Nausea/Vomiting	14.3%	16.7%
Dizziness	0.0%	2.1%
Pruritus	2.0%	0.0%
Urinary Retention	6.1%	0.0%
Sinus Rhythm Tachycardia	0.0%	2.1%

Pain scores at various postoperative time points were significantly lower in the spinal anesthesia (SA) group compared to the general anesthesia (GA) group (P < .001 for all comparisons). At 4 hours post-surgery, resting pain was minimal in the SA group (median 0, range 0-4) but higher in the GA group (median 3, range 0-8), while stress-induced pain was also lower in the SA group (median 2, range 0-8) compared to the GA group (median 5, range 1-10). Similar trends were observed at 8 hours, where resting pain remained at a median of 0 (range 0-6) in the SA group and was higher in the GA group (median 2, range 0-7), while stress-related pain followed the same pattern (median 2 vs. 5). By 12 hours, resting pain in the SA group remained minimal (median 0, range 0-2) compared to the GA group (median 2, range 0-7), and stress-induced pain was lower in SA patients (median 1, range 0-7) than in GA patients (median 4, range 0-7). At 24 hours, both resting and stress pain remained significantly lower in the SA group, with median scores of 0 (range 0-4) and 1 (range 0-7), respectively, compared to 1 (range 0-6) and 2.5 (range 0-7) in the GA group. These findings indicate that SA provides superior pain relief in both resting and stress conditions throughout the first 24 hours postoperatively.

Table-3: Pain Scores in study groups

Pain Scores in Patients Who Underwent Laparoscopic Cholecystectomy	Received Spinal Anesthesia (n = 49)	Received General Anesthesia (n = 48)	P value
At 4 hours			
Resting	0 (0-4)	3 (0-8)	<.001
Stress	2 (0-8)	5 (1-10)	<.001
At 8 hours			
Resting	0 (0-6)	2 (0-7)	<.001
Stress	2 (0-7)	5 (0-8)	<.001
At 12 hours			
Resting	0 (0-2)	2 (0-7)	<.001
Stress	1 (0-7)	4 (0-7)	<.001
At 24 hours			
Resting	0 (0-4)	1 (0-6)	<.001
Stress	1 (0-7)	2.5 (0-7)	<.001

DISCUSSION

Several studies have examined the outcomes of spinal anesthesia (SA) versus general anesthesia (GA) in laparoscopic cholecystectomy, revealing both similarities and differences with our findings [8]. Our study demonstrated that the baseline characteristics, including age, BMI, operative time, and total anesthesia duration, were comparable between the SA and GA groups. Similar findings were reported where both groups had no significant differences in demographic parameters and operative duration. This supports the notion that SA can be a viable alternative to GA in laparoscopic cholecystectomy without significantly impacting procedural time or patient selection criteria [9].

Postoperative events in our study revealed that nausea and vomiting were slightly more prevalent in the GA group (16.7%) compared to the SA group (14.3%), aligning with previous studies that reported a higher incidence of postoperative nausea and vomiting (PONV) in GA patients due to the use of volatile anesthetics and opioids [10]. Another studies similarly found that GA was associated with increased PONV rates compared to SA [11]. However, our study observed urinary retention exclusively in the SA group (6.1%), a finding that differs from certain studies where urinary retention was not a significant complication of SA. This discrepancy could be attributed to differences in fluid management, bladder catheterization protocols, or variations in patient populations.

Regarding postoperative pain, our study demonstrated significantly lower pain scores in the SA group at all time points compared to the GA group (P < .001). This finding is consistent with other studies which concluded that patients receiving SA experienced superior analgesia during the early postoperative period [12]. The prolonged analgesic effect of SA is likely due to the residual sensory blockade and reduced opioid requirement, which contribute to lower pain perception postoperatively.

A notable finding in our study was the absence of dizziness and sinus rhythm tachycardia in the SA group, while these were observed in 2.1% of GA patients. Previous research, including other studies has suggested that GA may predispose patients to hemodynamic instability, including tachycardia, due to stress responses induced by endotracheal intubation and volatile anesthetic use [13]. In contrast, SA has been reported to provide better cardiovascular stability, a trend reflected in our findings.

Overall, our study aligns with existing literature supporting the benefits of SA in reducing postoperative pain and PONV while maintaining similar operative and recovery profiles to GA. However, differences in urinary retention rates and the sustained analgesic advantage beyond 24 hours highlight potential areas for further investigation. Future studies with larger sample sizes and multicenter trials may provide more comprehensive insights into optimizing anesthesia strategies for laparoscopic cholecystectomy

CONCLUSION

Our study demonstrated that spinal anesthesia (SA) offers significant advantages over general anesthesia (GA) for laparoscopic cholecystectomy in terms of postoperative pain relief, with consistently lower pain scores at all time points up to 24 hours post-surgery ($P < .001$). While both anesthesia methods had comparable operative durations, total anesthesia times, and hospital stays, SA was associated with a higher incidence of urinary retention (6.1%), whereas GA led to a slightly higher occurrence of nausea (16.7%), dizziness (2.1%), and sinus rhythm tachycardia (2.1%). These findings suggest that SA is a viable alternative to GA, particularly for reducing postoperative pain and minimizing opioid use, though its risks, such as urinary retention, should be carefully considered.

REFERENCE

1. Gramatica L Jr, Brasesco OE, Mercado Luna A, *et al.*, Laparoscopic cholecystectomy performed under regional anesthesia in patients with obstructive pulmonary disease. Surg Endosc. 2002;16(3):472-475.
2. Pursnani KG, Bazza Y, Calleja M, Mughai MM. Laparoscopic cholecystectomy under epidural anesthesia in patients with chronic respiratory disease. Surg Endosc. 1998;12(8):1082-1084.
3. Luchetti M, Palomba R, Sica G, Massa G, Tufano R. Effectiveness and safety of combined epidural and general anesthesia for laparoscopic surgery. Reg Anesth. 1996;21(5):465-469.
4. Johnson A. Laparoscopic surgery. Lancet. 1997;349(9052):631-635.
5. Crabtree JH, Fishman A, Huen IT. Videolaparoscopic peritoneal dialysis catheter implant and rescue procedures under local anesthesia with nitrous oxide pneumoperitoneum. Adv Perit Dial. 1998;14:83-86.
6. Sharp JR, Pierson WP, Brady CE. Comparison of CO2 and N2O-induced discomfort during peritoneoscopy under local anesthesia. Gastroenterology. 1982; 82(3):453-456.
7. Hamad MA, Ibrahim El-Khattary OA. Laparoscopic cholecystectomy under spinal anesthesia with nitrous oxide pneumoperitoneum: a feasibility study. Surg Endosc. 2003;17(9):1426-1428.
8. Tzovaras G, Fafoulakis F, Pratsas K, Georgopoulou S, Stamatiou G, Hatzitheofilou C. Laparoscopic cholecystectomy under spinal anesthesia: a pilot study. Surg Endosc. 2006;20(4):580-582.
9. Aono H, Takeda A, Tarver S, Goto H. Stress responses in three different anesthetic techniques for carbon dioxide laparoscopic cholecystectomy. J Clin Anesth. 1998;10(7):546-550.
10. Boddy AP, Mehta S, Rhodes M. The effect of intraperitoneal local anesthesia in laparoscopic cholecystectomy: a systematic review and meta-analysis. Anesth Analg. 2006;103(3):682-688.
11. Alkhamesi NA, Peck DH, Lomax D, Darzi AW. Intraperitoneal aerosolization of bupivacaine reduces postoperative pain in laparoscopic surgery: a randomized prospective controlled double-blinded clinical trial [published online ahead of print December 16, 2006]. Surg Endosc. 2007;21(4):602-606.
12. Papadima A, Lagoudianakis EE, Antonakis PT, *et al.*, Parecoxib vs lornoxicam in the treatment of postoperative pain after laparoscopic cholecystectomy: a prospective randomized placebo-controlled trial. Eur J Anaesthesiol. 2007;24(2): 154-158.
13. Gupta A. Local anaesthesia for pain relief after laparoscopic cholecystectomy: a systematic review. Best Pract Res Clin Anaesthesiol. 2005;19(2):275-292.