Original Article ISSN (O):2395-2822; ISSN (P):2395-2814

A Prospective Randomised Study To Evaluate The Feasibility And Safety of Laparoscopic Cholecystectomy Under Spinal Anaesthesia.

Kartik Kaistha[1], Preetam Mehta[1], AJS Gulati[2], Atul Bhatnagar[3], Rajesh Ranjan[4], Rajeev Ranjan[5], Mitasha Singh[6]

[1]DNB General Surgery, Department of General Surgery, Mata Chanan Devi Hospital, Janakpuri, New Delhi.
[2]DNB General Surgery, Department of General Surgery, Mata Chanan Devi Hospital, Janakpuri, New Delhi.
[3]Senior Consultant, Department of General Surgery, Mata Chanan Devi Hospital, Janakpuri, New Delhi.
[4]Associate Professor, Department of Community Medicine, ESIC Medical College and Hospital, Faridabad, Haryana.
[5]Senior Resident, Department of General Surgery, UCMS, Delhi.
[6]Assistant Professor, Dept of Community Medicine, ESIC Medical College and Hospital, Faridabad.

Received: January 2018
Accepted: February 2018

ABSTRACT

Background: Laparoscopic cholecystectomy is the gold standard for the surgical treatment of symptomatic gall-stones The aim of this prospective randomized study was to compare the surgical outcome of LC performed with the patient under spinal anaesthesia with that of LC performed with the patient under general anaesthesia in the management of symptomatic uncomplicated gallstone disease. **Methods:** An Observational Descriptive Study was done on total 100 cases. Outcome Measures noted were a) Conversion rate of laparoscopic cholecystectomy under spinal anaesthesia to general anaesthesia, b) Hypotension and c) Bradycardia. **Results:** Spinal anaesthesia is a feasible, safe and effective alternative to general anaesthesia for laparoscopic cholecystectomy. Intraoperative hypotension, and bradycardia need to be addressed during laparoscopic cholecystectomy under spinal anaesthesia. Provided with good patient selection laparoscopic cholecystectomy under spinal anaesthesia can substitute that under general anaesthesia. **Conclusion:** Laparoscopic cholecystectomy under spinal anaesthesia is a better option for selected group of patients while anticipating fast track surgery or day care surgery.

Keywords: Laparoscopic cholecystectomy, Spinal anaesthesia, General anaesthesia.

INTRODUCTION

Laparoscopic cholecystectomy(LC) is the gold standard for the surgical treatment of symptomatic gall-stones.[1,2] This has been attributed to the minimally invasive nature of the procedure, which is associated with less post-operative pain, reduced hospital stay, and earlier return to daily activities.[1,2] The potential for LC to be performed as a day case has been recognized only a few years after the introduction of the procedure.[3] Several randomized studies comparing day-case and overnight-stay LC have confirmed that day-case LC in selected patients was feasible and safe and was associated with a high degree of patient satisfaction without an increase in the complications rate.[4-7]

Adequate pain relief is an important aspect of day-case surgery. Various methods have been attempted to decrease postoperative pain following LC such as peritoneal instillation of normal saline or local anaesthetic and wound infiltration with local anesthetic.[8,9] Spinal anaesthesia is a less invasive anaesthetic technique that has lower morbidity and mortality rates, compared with general anesthesia.[10] Furthermore, spinal anaesthesia offers several advantages over general anesthesia.[10]

First, the patient is awake and oriented at the end of the procedure. Second, the immediate postoperative period is viewed positively by patients because of the absence of general anaesthetic side effects (e.g., nausea and vomiting) and less pain experienced due to the effect of persistent neuraxial blockage. Third, patients who have received spinal anaesthesia tend to ambulate earlier than patients receiving general anesthesia.[10] Finally, pain related to intubation and/or extubation can be prevented by administering selective spinal anaesthesia to patients undergoing laparoscopic interventions.[11]

Several studies have demonstrated that LC with the patient under spinal anaesthesia was feasible and

Name & Address of Corresponding Author
Dr. Kartik Kaistha
DNB General Surgery, Department of General Surgery, Mata Chanan Devi Hospital, Janakpuri,
New Delhi.

safe and was associated with better postoperative pain control.[12–17]

The choice of anaesthesia for laparoscopic surgery has for long been general anaesthesia because of the following reasons: a) The patient's airway is under the control of the anaesthesiologist, b) Minimal chances of aspiration due to gastric regurgitation, c) No patient discomfort and shoulder pain due to pneumoperitoneum, d) Controlled ventilation to manage hypercarbia, e) No patient discomfort due to change in position, f) No complications due to decreased sympathetic outflow such as hypotension and bradycardias seen with regional anaesthesia, g) Better hemodynamic status.[9,11]

The aim of this prospective randomized study was to compare the surgical outcome of LC performed with the patient under spinal anaesthesia with that of LC performed with the patient under general anaesthesia in the management of symptomatic uncomplicated gallstone disease.

MATERIALS AND METHODS

The present study was carried out, after approval of ethical committee, at Department of General Surgery, MATA CHANAN DEVI HOSPITAL, NEW DELHI .From September 2012 to May 2014, all patients referred to our unit for elective laparoscopic cholecystectomy were considered eligible for the trial, provided that they fulfilled the following inclusion criteria: American Society of Anaesthesiologists' status I or II, between 20 and 65 years of age, either sex, normal coagulation profile and ultrasound suggestive of easy laparoscopic cholecystectomy. Exclusion criteria were acute cholecystitis, pancreatitis or cholangitis, previous open surgery in the upper abdomen, raised alkaline phosphatase or gamma glutamyl transferase, suspicion of gall bladder malignancy, contraindication for pneumoperitoneum, and contraindication for spinal anaesthesia owing to spinal deformity.

General and local examination was done, following investigations were done at the time of admission: haemogram, blood sugar, coagulation profile, liver function test, kidney function test, pulmonary function test. (if required),thyroid function test (if required),serum amylase, lipase, ultrasonography abdomen.

Informed consent was obtained from all patients and the trial protocol was approved by the institutional ethics committee.

Patients were randomized to have a laparoscopic cholecystectomy under either general or spinal anaesthesia. Randomization was created by a computer-generated list. Numbered and sealed envelopes were placed in the operating room and only opened at the patients' arrival there, so that both the patient and involved physicians were unaware of the randomization arm beforehand. With the reference of previous studies, we assumed that the difference of 2 in VAS at 1 hr is considered clinically significant, At 2-sided type 1 error of 0.05, 90% power and SD of 2 in each group, a sample size of 30 per group was required to detect a significant difference. But we took 50 patients per group.

We planned to perform an interim analysis after the 100 patients and the results of this analysis are discussed. Patients' preoperative evaluation and preparation were standardized. Both anaesthesia and surgery were performed in all cases by the same anaesthetic and surgical team.

On patients' arrival in the operating room, after establishing non-invasive monitoring (electrocardiogram, blood pressure and pulse oximetry) and 500 mL of Ringer solution was commenced intravenously. All patients were intravenously administered 4mg of odansetron and 40mg i.v pantoprazole before the induction of anesthesia. A nasogastric tube was also inserted (to be removed at the end of the procedure in both groups for methodological reasons) to decompress the stomach and avoid vomiting and aspiration; this is especially useful for the spinal group. After obtaining baseline vital signs, oxygen at 5 L/min was commenced through a face mask.

Patients randomized to spinal anesthesia were positioned at the right lateral decubitus position and a 25-gauge pencil-point spinal needle was introduced into the subarachnoid space at the L2-L3 intervertebral space under aseptic conditions. After free flow of cerebrospinal fluid was obtained, 3 to 3.5mL of hyperbaric bupivacaine hydrochloride was injected intrathecally. Then, the patient was placed in the supine position, staying in the Trendelenburg position. The level of sensory block was assessed (by pin prick test) every 30 seconds for 5 minutes and the patient's position was adjusted, so that the sensory level was fixed at T4 dermatome If the mean arterial blood pressure decreased by more than 20% below the preanesthetic value, an intermittent intravenous infusion of ephedrine 6mg solution was initiated and titrated to effect. Any patient complaining of right shoulder pain after the infiltration of diaphragm with 20ml of lignocaine by the surgeon was given 1 µg/kg body weight fentanyl and those still complaining of pain were converted to G.A

In patients randomized to receive general anesthesia, anesthesia was induced with propofol (1 – 2 mg/kg) and vecuronium (0.08 - .1 mg/kg). This will be followed by tracheal intubation and mechanical ventilation. Anaesthesia was maintained using isoflurane (1 MAC). After intubation of the trachea, the lungs were ventilated with 50% oxygen in air using a semiclosed circuit system. Ventilation was controlled with a tidal volume of 8 to 10 mL/kg and the ventilatory rate was adjusted to maintain a PaCO2value of 35 to 40mmHg. Residual neuromuscular block was antagonized with 25mg of

neostigmine methyl sulfate and 1 mg of atropine sulfate at the end of surgery.

All patients were monitored continuously during the operation. Both clinical observation and invasive hemodynamic monitoring (electrocardiogram, heart rate, arterial blood pressure, respiratory rate, pulse oximetry, arterial blood gas, and acid base balance) were recorded at 5-minute intervals. Intraoperative bradycardia (heart rate< 50) was reversed by .6mg i.v atropine sulphate. Intraoperative hypertension (b.pr> 160/95) was managed by i.v nitroglycerin 5µg/kg/min, it was titrated at 5µg/kg/min every 3 to 5 minutes after the dose exceeded 20 µg / kg /min it was incremented at 20µg/kg/min if required.

Laparoscopic cholecystectomy was performed by using the same technical principles for both groups, with the standard 4-trocar technique as previously described.

Pneumoperitoneum was established by using Veress needle with carbon dioxide at a maximum intra-abdominal pressure of 10 mm Hg, instead of the usual 14 mm Hg and the rate of insufflation was kept to 2l/min. Another modification of the technique was the minimal if any tilting of the operating table, i.e., head up and left tilt to minimize diaphragmatic irritation. Further diaphragm was infiltrated with local anaesthetic solution. A total of 10 mL of 2% lidocaine as a local anesthetic agent was applied through an aspiration needle inserted from the midclavicular trocar, and the right diaphragm was sprayed with that solution .Smoke collection during the procedure was discouraged as smoke leads to peritoneal and diaphragmatic irritation.

Operative time as well as any intraoperative events was recorded. Specifically, for patients having spinal anaesthesia, and thus being alert during the procedure, we recorded any symptoms related to either the anaesthetic approach or the pneumoperitoneum, such as shoulder pain, headache, nausea, and discomfort. Drainage of the sub hepatic space was done routinely.

Postoperatively, all patients were given standard intravenous fluids (1 L of Ringer solution and 1 L of dextrose, 5%) and intravenous analgesia (3ml of diclofenac 12 hourly, 1gm of acetaminophen for breakthrough pain). Postoperative pain was assessed by using the visual analogue scale at 3, 6, 9 hours after the completion of the procedure. Other postoperative events related either to surgical or anesthetic procedure, such as discomfort, nausea and vomiting, shoulder pain, urinary retention, headache, or other neurologic sequel, were also recorded. The patients were fed orally the morning after the operation and discharged next morning after the procedure, unless complications had occurred.

RESULTS

In the above table it was observed that there was no statically significant difference in ASA between the two groups [Table 1].

Table 1: Comparison of ASA between two groups.

ASA	General Anesthesia		Spinal Anesthesia		P Value
	Frequency	%	Frequency	%	
1	37	74.0 %	41	82.0 %	0.334
2	13	26.0 %	9	18.0 %	
Total	50	100%	50	100%	

Table 2: Comparison of Hypo/Hypertension between two groups.

Group	General Anesthesia (n-50)		Spinal Anesthesia (n=50)		P Value
	Frequency	%	Frequency	%	
Hypotension	0	0.0%	8	16.0%	0.006
Hypertension	3	6.0%	1	2.0%	0.617

In the above figure it is seen that there was statically significant difference in intraoperative hypotension* between the two groups (p value 0.006) but there was insignificant difference in hypertension between two groups [Table 2].

*Hypotension is defined as > 20% fall in MAP.

Table 3: Comparison of Operative difficulty between two groups.

Operative Difficulty	General Anesthesia		Spinal Anesthesia		P Value
	Frequency	%	Frequency	%	
No	50	100.0 %	46	92.0 %	0.117
Yes	0	0.0%	4	8.0%	
Total	50	100%	50	100 %	

Operative difficulty was noted in 0.0% of G.A cases and in 8% of cases under S.A the difference was statically insignificant [Table 3].

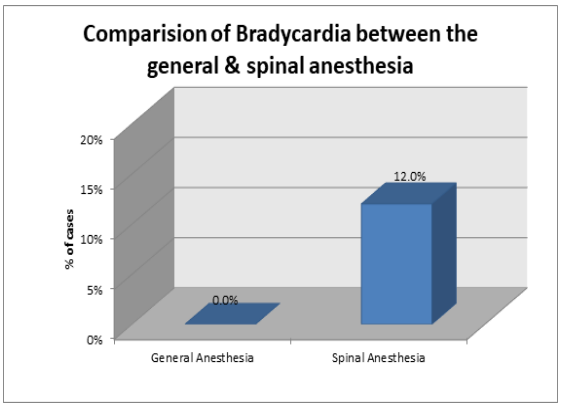

Figure 1: Comparison of Bradycardia between two groups.

In the above figure it was seen that intraoperative bradycardia was seen in 0.0% of G.A patients and 12.0% of S.A patients, the difference was statically significant (p value 0.027) [Figure 1].

DISCUSSION

Total number of cases in our study was 100 out of which 50 cases (50%) were included in G.A group and 50 cases (50%) were included in S.A group.

The comparison of ASA between the two groups showed: 74% of patients of G.A group fell into ASA 1 compared with 82% in S.A group.26% of patients of G.A group fell into ASA 2 compared with 18 % in S.A group. There was no statically significant difference in ASA between the two groups.

In our study intraoperative hypotension was recorded in none of the patients that received G.A and 16 % patients receiving S.A .The difference being statically significant (p value 0.006). Intra-operatively, intravenous phenylephrine was administered when mean arterial blood pressure drops of more than 20% from the pre-anesthetic values. In all these cases, mean arterial blood pressure was then normalized and the procedure was completed uneventfully.

In a study researcher observed hypotension in 4 % of G.A group patients as compared to 59 % patients from S.A group which was reversed by i.v phenylepherine.

In our study hypertension was recorded in 6 % of G.A patients and 2% of S.A group patients. The difference in incidence of intraoperative hypertension between the two groups was insignificant.

In our study operative difficulty was noted in 0.0 % (0) of G.A cases and in 8% (4) of cases under SAB the difference was statically insignificant (p value0.117). None of the patients of S.A group required conversion to G.A due to operative difficulty. None of our surgeons reported inadequate relaxation of abdominal wall leading to any sought of difficulty during the procedure in S.A group.

In our study it was seen that intraoperative bradycardia was seen in 0.0% of G.A patients and 12.0% (6) of S.A patients, the difference was statically significant (p value 0.027).To my knowledge, I found no previous studies comparing incidence of bradycardia between laparoscopic cholecystectomy in S.A vs G.A. SA induced hypotension, bradycardia, and improved venous drainage led to decrease in the surgical bed oozing.

In 2006 Tzovaras G, Fafoulakis F and Hatzitheofilou C performed laparoscopic cholecystectomy under spinal anaesthesia a controlled randomized trial. One hundred patients with symptomatic gallstone disease and American Society of Anaesthesiologists status I or II were randomized to have laparoscopic cholecystectomy under spinal (n = 50) or general (n = 50) anaesthesia. Intraoperative parameters, postoperative pain, complications, recovery, and patient satisfaction at follow-up were compared between the 2 .There were no conversions from spinal to general anaesthesia. Pain was significantly less at 4 hours (P < .001), 8 hours (P < .001), 12 hours (P < .001), and 24 hours (P = .02) after the procedure for the spinal anaesthesia group compared with those who received general anaesthesia. There was no difference between the 2 groups regarding complications, hospital stay, recovery, or degree of satisfaction at follow-up.[15]

In 2009 Sinha R, Gurwara AK, Gupta SC published there 12 year experience of Laparoscopic cholecystectomy under spinal anaesthesia, a study of 3492 patients, Eighteen (0.52%) patients required a conversion to GA. Hypotension requiring support was recorded in 700 (20.05%) patients, and 429 (12.29%) patients experienced neck and/or shoulder pain. Overall, 2.29% (80) patients had vomiting in the postoperative period, as compared to 30.30% (163 patients) in patients administered GA. In total, 34.36% (1200) patients required injectable diclofenac for their abdominal pain within 2 hours postoperatively after SA, and oral analgesic was required in 2150 (61.57%) patients within the first 24 hours. On the other hand, 91.45% patients operated on under GA required injectable analgesics in the immediate postoperative period. The conclusion was that LC done under spinal anesthesia does not require any change in technique and, at the same time, has a number of advantages, as compared to general anesthesia, and should be the anesthesia of choice.[16]

Yuksek YN et al in 2008; Twenty nine ASA I/II patients underwent surgery for laparoscopic cholecystectomy under spinal anaesthesia. All of the patients and surgeons were satisfied with LC under spinal anaesthesia. It was concluded that LC under spinal anaesthesia may be an appropriate treatment choice to increase the number of patients eligible for outpatient surgery.[14]

In 2009 Gautam B, performed laproscopic cholecystectomy on twelve American Society of Anaesthesiologists' physical status I or II patients received SA using 4 ml of 0.5% hyperbaric bupivacaine mixed with 0.15 mg Morphine. Results were spinal anaesthesia was adequate for surgery in all but one patient. Intraoperatively, two out of four patients who experienced right shoulder pain received fentanyl. Two patients were given midazolam for anxiety and one was given ephedrine for hypotension. Operative difficulty scores were minimal and surgery in one patient was converted to open cholecystectomy. Postoperatively, pain scores were minimal and no patient demanded opioid. One patient required antiemetic for vomiting and one patient each suffered headache and urinary retention. 11 patients were discharged within 48 hours of surgery and patient satisfaction scores were very good.[18]

CONCLUSION

Spinal anaesthesia is a feasible, safe and effective alternative to general anaesthesia for laparoscopic cholecystectomy. Intraoperative hypotension, and bradycardia need to be addressed during laparoscopic cholecystectomy under spinal anaesthesia. Provided with good patient selection laparoscopic cholecystectomy under spinal anaesthesia can substitute that under general anaesthesia.

REFERENCES

1. Lichten JB, Reid JJ, Zahalsky MP, Friedman RL. Laparoscopic cholecystectomy in the new millennium. Surg Endosc2001;15:867–872.
2. Grace PA, Quereshi A, Coleman J, Keane R, McEntee G, BroeP, Osborne H, Bouchier-Hayes D. Reduced postoperative hospitalization after laparoscopic cholecystectomy. Br J Surg1991;78:160–162.
3. Reddick EJ, Olsen DO. Outpatient laparoscopic laser cholecystectomy. Am J Surg 1990;160:485–487.
4. Ahmad NZ, Byrnes G, Naqvi SA. A metaanalysis of ambulatory versus inpatient laparoscopic cholecystectomy.Surg Endosc 2008;22:1928–1934.
5. Hollington P, Toogood GJ, Padbury RT. A prospective randomized trial of day-stay only versus overnight stay laparoscopic cholecystectomy. Aust N Z J Surg 1999; 69:841–843.
6. Curet MJ, Contreras M, Weber DM, Albrecht R. Laparoscopic cholecystectomy: Outpatient vs inpatient manage-ment. Surg Endosc 2002; 16:453–457.
7. Johansson M, Thune A, Nelvin L, Lundell L. Randomized clinical trial of day-care versus overnight-stay laparoscopic cholecystectomy. Br J Surg 2006;93:40–45.
8. Tsimoyiannis EC, Glantzounis G, Lekkas ET, Siakas P, Jabarin M, Tzourou H. Intraperitoneal normal saline and bupivacaine infusion for reduction of postoperative pain after laparoscopic cholecystectomy. Surg Laparosc Endosc 1998; 8:416–420.
9. Lepner U, Goroshina J, Samarutel J. Postoperative pain relief after laparoscopic cholecystectomy: A randomized prospective double-blind clinical trial. Scand J Surg 2003; 92:121–124.
10. Lennox PH, Vaghadia H, Henderson C, Martin L, Mitchell GW. Small-dose selective spinal anesthesia for short-duration outpatient laparoscopy: Recovery characteristics compared with desflurane anesthesia. Anesth Analg 2002;94:346–350.
11. Pursnani KG, Baza Y, Calleja M, Mughal MM. Laparoscopic cholecystectomy under epidural anesthesia in patients with chronic respiratory disease. Surg Endosc 1998; 12:1082–1084.
12. Hamad MA, Ibrahim El-Khattary OA. Laparoscopic cholecystectomy under spinal anesthesia with nitrous oxide pneumoperitoneum: A feasibility study. Surg Endosc 2003; 17:1426–1428.
13. Tzovaras G, Fafoulakis F, Pratsas K, Georgopouloun S,Stamatiou G, Hatzitheofilou C. Laparoscopic cholecystectomy under spinal anesthesia. A pilot study. Surg Endosc 2006;20:580–582.
14. Yuksek YN, Akat AZ, Gozalan U, Daglar G, Yasar Pala Y,Canturk M, Tutuncu T, Kama NA. Laparoscopic cholecystectomy under spinal anesthesia. Am J Surg 2008;195:533–536.
15. Tzovaras G, Fafoulakis F, Pratsas K, Georgopoulou S,Stamatiou G, Hatzitheofilou C. Spinal vs general anesthesia for laparoscopic cholecystectomy. Interim analysis of a controlled randomized trial. Arch Surg 2008; 143:497–501.
16. Sinha R, Gurwara AK, Gupta SC. Laparoscopic cholecystectomy under spinal anesthesia: A study of 3492 patients.J Laparoendosc Adv Surg Tech 2009;19:323–327.
17. Bessa SS, El-Sayes IA, El-Saiedi MK, Abdel-Baki NA, Abdel-Maksoud MM. Laparoscopic cholecystctomy under spinal versus general anesthesia. A prospective randomized study.J Laparoendosc Adv Surg Tech 2010; 20:515–520.
18. Gautam B. Spinal anaesthesia for laparoscopic cholecystectomy: A feasibility and safety study. Kathmandu Univ Med J (KUMJ) 2009;7:360–8

How to cite this article: Kaistha K, Mehta P, Gulati AJS, Bhatnagar A, Ranjan R, Ranjan R, Singh M. A Prospective Randomised Study To Evaluate The Feasibility And Safety of Laparoscopic Cholecystectomy Under Spinal Anaesthesia. Ann. Int. Med. Den. Res. 2018; 4(2):AN01-AN05.

Source of Support: Nil, **Conflict of Interest:** None declared