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# A COMPARATIVE STUDY BETWEEN SPINAL VS GENERAL ANESTHESIA FOR LAPAROSCOPIC CHOLECYSTECTOMY A RANDOMIZED CONTROLLED TRIAL

**Kumar Sushil** — MD, PDCC , Senior Resident , Deptt. Of anaesthesiology , JLN Medical College and Hospital , Bhagalpur , Bihar , India

**Horo Veena*** — M.D. , Associate Professor , Deptt. Of anaesthesiology , JLN Medical College and Hospital , Bhagalpur, Bihar , India *Corresponding Author

## ABSTRACT

Cholecystectomy is one of the most commonly performed surgery in modern day surgical practice. While laparoscopic cholecystectomy has been well established as a gold standard for cholecystectomy surgery, there is ambiguity about the best method of anesthesia for laparoscopic cholecystectomy surgery. While General anesthesia is the preferred and accepted method for laparoscopic cholecystectomy surgery , spinal anesthesia with supplemental sedation is being very widely tried and found to be at least as satisfactory if not better than General Anesthesia . Plus the added advantages of cost effectiveness and better postoperative analgesia makes spinal anesthesia a very acceptable alternative to GA for lap cholecystectomy. We designed a staudy to compare spinal vs. General anesthesia in a controlled study and found spinal anesthesia to be better than GA for lap cholecystectomy.

**Objectives of study :** To compare spinal anesthesia with the currently accepted gold standard technique i.e. general anesthesia for elective laparoscopic cholecystectomy.

**Setting:** Medical College Hospital

**Design:** Controlled randomized trial.

**Settings and Study design:** One hundred patients with symptomatic gallstone disease and American Society of Anesthesiologists status I or II were randomized to have laparoscopic cholecystectomy under spinal (n=50) or general (n=50) anesthesia.

**Materials and Methods:** Patients meeting inclusion criteria were randomised into two groups. Group A and Group B received general and spinal anaesthesia by standardised techniques. Both groups underwent standard four port laparoscopic cholecystectomy. Mean anaesthesia time and surgery time defined primary outcome measures. Intraoperative events and post operative pain score were secondary outcome measure. Intraoperative parameters, postoperative pain, complications, recovery, and patient satisfaction at follow up were compared between the 2 groups.

**Statistical Analysis Used :** Student t test and chi square test

**Results :** All the procedures were completed by the allocated method of anesthesia, as there were no conversions from spinal to general anesthesia. 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 anesthesia group compared with those who received general anesthesia. There was no difference between the 2 groups regarding complications, hospital stay, recovery, or degree of satisfaction at follow-up.

**Conclusions :** Spinal anesthesia is adequate and safe for laparoscopic cholecystectomy in otherwise healthy patients and offers better postoperative pain control than general anesthesia with similar recovery times and better patient satisfaction to some extent. Also, all the complications associated with general anesthesia can be avoided and conduct of anesthesia becomes safer.

## KEYWORDS :

## INTRODUCTION

Laparoscopic cholecystectomy under regional anesthesia alone has been reported only occasionally in the past; these reports included patients unfit to receive general anesthesia, i.e. ASA III and IV patients and those with moderate to severe chronic obstructive airway disease.[1,2]

Though recently , there has been an increase in interest towards regional anesthesia especially spinal anesthesia for laparoscopic cholecytectomy . Recent studies have demonstrated spinal anesthesia to be at least as effective and satisfactory as general anesthesia . Also, spinal anesthesia alone or in combination with i.v. sedation is more cost effective than general anesthesia in patients undergoing the procedure. Apart from this , all the complications associated with general anesthesia can be avoided and thus conduct of anesthesia becomes safer.

Regional anesthesia has been used for laparoscopy in healthy patients in the past almost exclusively in combination with general anesthesia to extend the analgesic effect during the early postoperative period. In a randomized trial, epidurals combined with general anesthesia have been found to be more effective in lessening postoperative pain in healthy patients compared with general anesthesia alone.[3]

Over the last few years , in the era of minimally invasive medicine, regional anesthesia is gaining popularity and is gaining more utility as a sole method of anesthesia in laparoscopic procedures.

Johnson[4] noted that "all laparoscopic procedures are merely a change in access and still require general anesthetic; hence the difference from conventional surgery is likely to be small." This statement is predominantly based on the assumption that laparoscopy necessitates endotracheal intubation to prevent aspiration and respiratory compromise secondary to the induction of carbon dioxide pneumoperitoneum,[2] which is not well tolerated in a patient who is awake during the procedure.[5,6] However, it is surprising that regional anesthesia has been successfully used for laparoscopic cholecystectomy in patients unfit to have the procedure under general anesthesia but has not been tested in healthy patients in whom any presumed risk would be theoretically much lower.

Hamad and Ibrahim El-Khattary[7] used spinal anesthesia for laparoscopic cholecystectomy for the first time in a small series of healthy patients. In their study, however, nitrous oxide pneumoperitoneum was applied instead of the standard carbon dioxide.

Many studies have recently shown the feasibility of successfully and safely performing laparoscopic cholecystectomy with low-pressure carbon dioxide pneumoperitoneum under spinal anesthesia alone in healthy patients with symptomatic gallstone disease.[8] We have also noticed that spinal anesthesia results in less postoperative pain . As such a controlled randomized trial was designed to compare spinal anesthesia with the currently accepted gold standard i.e. general anesthesia for elective laparoscopic cholecystectomy in healthy patients.

From January 2016 to December 2016 , 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 Anesthesiologists' status I or II, between 18 and 65 years of age, body mass index (calculated as weight in kilograms divided by height in meters squared) of 30 or less, and normal coagulation profile.

Exclusion criteria were , pancreatitis or cholangitis, CBD stones, previous open surgery in the upper abdomen, contraindication for pneumoperitoneum, and contraindication for spinal anesthesia owing to spinal deformity. 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 anesthesia. Randomization was created by a computer-generated list in blocks of 50 patients with sex stratification. 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.

The primary end point of the trial was any difference in postoperative pain between the 2 groups, and the secondary end points were differences in complication rate, hospital stay, recovery, and patient satisfaction. A sample size of 50 patients per randomization arm was calculated on an expected 20% difference in the postoperative pain assessed by the visual analog scale between the 2 groups, with a power of 80% at detecting this difference at the 5% level. We planned to perform an interim analysis after the first 100 patients and the results of this analysis are discussed.

Patients' preoperative evaluation and preparation were standardized.

All patients received deep venous thrombosis prophylaxis (2.5 mg of fondaparinux subcutaneously once a day) during hospitalization. Both anesthesia and surgery were performed in all cases by the same anesthetic and surgical team.

On patients' arrival in the operating room, after establishing noninvasive monitoring (electrocardiogram, non invasive blood pressure, and pulse oximetry), 500 mL of Ringer solution was commenced intravenously. All patients were intravenously administered 1 mg of midazolam hydrochloride, 4 mg of ondansatron hydrochloride, and 50 mg of ranitidine hydrochloride 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.[8] After obtaining baseline vital signs, oxygen at 5 L/min was commenced through a face mask.

Patients randomized to spinal anesthesia were positioned in sitting position and a 27-gauge pencilpoint 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, 3.5 ml i.e. 17.5 mg of hyperbaric bupivacaine hydrochloride, and 20 µg of fentanyl citrate were injected intrathecally.

Then, the patient was placed in the supine position, staying in 30 degrees Trendelenburg position for 4 minutes. 5 mg boluses of ephedrine hydrochloride was used to manage incidents of hypotension. Intramascular sedation with 1 mg butorphanol and fentanyl with propofol i.v. was used and titrated to get adequate analgesia and sedation.

In patients randomized to receive general anesthesia, anesthesia was induced with propofol (2-3 mg/kg), fentanyl citrate (5 µg/kg), and Vecuronium bromide (0.1 mg/kg). Balanced anesthesia was continued with Isoflurane , 0.5% to 1% and 20 mg boluses of propofol when required . After endotracheal intubation was done , the lungs were ventilated with 50% oxygen in air using a semiclosed circle system. Ventilation was controlled with a tidal volume of 10 mL/kg and the ventilatory rate was adjusted to maintain a $PaCO_2$ value of 35 to 40mmHg. Residual neuromuscular block was antagonized with 0.06 mg/kg of neostigmine sulfate and 0.2 mg of glycopyrrolate for each mg of neostigmine at the end of surgery.

All patients were monitored continuously during the operation. Both clinical observation and non invasive hemodynamic monitoring (electrocardiogram, heart rate, noninvasive blood pressure, respiratory rate and pulse oximetry, ) were recorded . A capnogram was continuously recorded in all the cases. Laparoscopic cholecystectomy was performed by using the same technical principles for both groups, with the standard 4-trocar technique as previously described.[4] Pneumoperitoneum was established by using the open (Hasson) technique with carbon dioxide at a maximum intra-abdominal pressure of 10 -12 mm Hg, instead of the usual 14 mm Hg. Another modification of the technique was the minimal—if any—tilting of the operating table, ie, head up and left tilt to minimize diaphragmatic irritation.

Operative time as well as any intraoperative events were recorded. Specifically, for patients having spinal anesthesia, and thus being alert during the procedure. We recorded any symptoms related to either the anesthetic approach or pneumoperitoneum, such as shoulder pain, headache, nausea, and discomfort. Drainage of the subhepatic space was not used.

Postoperatively, all patients were given standard intravenous fluids (1 L of Ringer solution and 1 L of 5% DNS , for the next 24 hours) and intravenous analgesia (50 mg of diclofenac sodium every 12 hours, 500 mg of acetaminophen every 6 hours, and supplementary opioids on demand). Postoperative pain was assessed at both relaxed and stressed (ie, after coughing) conditions by using the visual analog scale at 4, 8, 12, and 24 hours after the completion of the procedure. Other postoperative events related either to surgical or (especially) anesthetic procedure, such as discomfort, nausea and vomiting, shoulder pain, urinary retention, pruritus, headache, and other neurologic sequelae, were also recorded. The patients were fed orally the morning after the operation and discharged 24 hours after the procedure, unless complications had occurred.

All patients were followed up 10 to 15 days after the operation as outpatients by an independent physician who was not involved in the procedure and was blinded to patients' type of anesthesia to assess their recovery and degree of satisfaction with the procedure by using a standardized questionnaire.[8] This included a questionnaire, tailored to the relevant procedure, regarding quality of life assessment during the first 2 weeks after the operation. Questions targeted the severity of pain during patients' recovery period; how this influenced their daily activities; the type, amount, and duration of analgesia required; the degree of satisfaction from the anaesthetic procedure and the whole process; as well as their final impressions compared with their initial expectations. The answers were scored, with a total score ranging from 0 to 26. Another telephone contact was performed at 1 month postoperatively to detect late complications.

Statistical analysis was performed using the SPSS for windows . The Mann-Whitney *U* and Fisher exact tests were used as appropriate to detect differences between the 2 groups. Differences were considered significant at *P*_.05 (2- tailed test).

Between January 2016 and December 2016 , 100 patients entered our ongoing trial. They were randomized to have laparoscopic cholecystectomy under spinal (n=50) or general (n=50) anesthesia. One patient from the spinal anesthesia arm withdrew informed

consent, and in 2 patients from the general anesthesia arm, the laparoscopic procedure was converted to an open approach. These 3 patients were therefore excluded from further analysis, leaving 49 patients in the spinal and 48 patients in the general anesthesia groups for analysis .

**Table 1 : Charactaristics of patients who underwent laparoscopic cholecystectomy**

| Charactaristic | GA group (n=50) | Spinal group (n=50) | P value |
|---|---|---|---|
| Age (in years) | 41.12 ± 11.23 | 42 ± 06 | 0.20 |
| Gender (M/F) | 16/34 | 18/32 | 0.16 |

Chi square test : P < 0.05 considered as significant.

The two study groups were very similar in charactaristics including age and gender composition.

The 2 groups were similar regarding demographics (**Table 1**). All the procedures were completed by the allocated method of anesthesia, as there were no conversions from spinal anesthesia to general anesthesia. Intraoperatively, intravenous ephedrine was administered in 29 (59%) patients from the spinal anesthes group compared with 2 (4%) patients from the general anesthesia group owing to mean arterial blood pressure drops of more than 20% from the preanesthetic values. In all these cases, mean arterial blood pressure was then normalized and the procedure was completed uneventfully. Discomfort and/or right shoulder pain in some degree was present after the introduction of pneumoperitoneum in 21 patients (43%) who received spinal anesthesia. However, the pain was severe enough to require intravenous fentanyl administration in only 10 cases. The remaining patients did not require any additional medication or other intervention, and procedures were completed uneventfully in all cases.

**Table 2: Postoperative adverse events in the two groups**

| Event | No. Of patients |
|---|---|
| Abdominal discomfort | 9 |
| Referred shoulder pain | 8 |
| Hypotension | 5 |
| Nausea/ Vomiting | 3 |
| Anxiety | 2 |

Discharge from the hospital at 24 hours after surgery was possible for 48 (98%) patients from the spinal anesthesia group and 47 (98%) patients from the general anesthesia group. We had no mortality in either group and essentially no major morbidity. One patient from the regional anesthesia group who required catheterization for urinary retention developed a urinary tract infection and was treated with antibiotics.

Postoperative events related to surgical and/or anesthetic procedures, like nausea, vomiting, or urinary retention, are presented in Table 2. As presented in Table 3,

**Table 3: Median Visual Analogue Score**

| | GA Group (n=50) | SA Group (n=50) | P value |
|---|---|---|---|
| 06 hrs postop | 4 | 1 (0-3) | <0.002 |
| 12 hrs postop | 3 | 1 (0-4) | 0.002 |
| 24 hrs postop | 2 | 0 (0-4) | 0.010 |

**Table 4**

| Charactaristic | GA GROUP | SA GROUP | P value* |
|---|---|---|---|
| Duration of anesthesia (min) | 49.45 ± 6.73 | 40.64 ± 5.55 | 0.02 |
| Duration of pneumoperitoneum (min) | 32.42 ± 5.72 | 34.47 ± 5.01 | 0.18 |
| Duration of Surgery (min) | 34.22 ± 5.83 | 36.11 ± 4.98 | 0.15 |

*: Chi square test . P < 0.05 i.e. significant

pain assessed by the visual analog scale was significantly less for the spinal anesthesia group at 4, 8, 12, and 24 hours postoperatively, including both relaxed and stressed conditions. Supplementary postoperative opioid analgesia was administered in only 1 of the 49 (2%) patients who received spinal anesthesia compared with 12 of the 48 (25%) patients who received general anesthesia (*P*_.001, Fisher exact test).

At 2 weeks' follow-up, the quality of life and patient satisfaction scores were similar in the 2 groups: patients who received spinal anesthesia had a median score of 19 (range, 4-26) compared with a median score of 20 (range, 6-26) for patients who received general anesthesia (*P*=.2, Mann-Whitney *U* test). Overall, 96% of the spinal anesthesia group and 94% of the general anesthesia group were highly or fairly satisfied with the anesthetic procedure they had. No late complications were reported at week 4 through telephone contact in any of the patients.

The interim analysis of our study not only confirmed the feasibility of safely performing laparoscopic cholecystectomy under spinal anesthesia as the sole anesthetic procedure but also showed the superiority of spinal anesthesia in postoperative pain control compared with the standard general anesthesia. Pain assessed at both relaxed and stressed conditions was significantly lower at any time during the postoperative hospital stay in patients having spinal anesthesia compared with those having general anesthesia. Furthermore, supplementary opioids were administered in significantly fewer patients having spinal anesthesia compared with those having general anesthesia. This difference could be attributed to a combination of several factors: the avoidance of endotracheal intubation–related discomfort; the presence of adequate levels of analgesia for the first few hours after the completion of the surgical procedure owing to the existing activity of the analgesia injected in the subarachnoid space; and the potentially minimal stress response associated with a minimal invasive anesthetic procedure, such as spinal anesthesia.,[9] Pain following laparoscopic cholecystectomy is not a major problem, but it has been a matter of interest in several studies during the last few years. Minimal invasive surgery has dominated because of the rapid and smooth recovery it offers, and postoperative pain control is probably the main factor that characterizes smooth recovery. Several researchers have tested intraperitoneal instillation or aerolization of local anesthetic agents (eg, bupivacaine), use of the newer anti-inflammatory COX-2 inhibitors (ie, parecoxib, which was used in this study), addition of epidural analgesia, and oral or epidural administration of steroids, finding some effect on postoperative pain, which varies between studies.3,10-14 When we designed this trial comparing the 2 methods of anesthesia on several aspects of the intraoperative and postoperative course, we defined postoperative pain control as our primary end point based on the initial experience gained from our pilot study,8 in which the exceptionally good postoperative pain control became obvious very quickly. Our data presented herein confirm the superiority of spinal over general anesthesia in postoperative pain control.

Intraoperative events of note in the spinal anesthesia group included a decrease of the mean arterial blood pressure of more than 20% below the preanesthetic value as well as right shoulder pain. With regards to the former, this is a well known adverse effect of spinal anesthesia and is easily overcome after administration of phenylephrine, and therefore it does not essentially affect the planned procedure. Regarding the latter, 43% of the patients who received spinal anesthesia experienced some degree of shoulder pain or discomfort; however, less than half of those patients required treatment.

Laparoscopy-related right shoulder pain has been reported in previous studies and attributed to diaphragmatic irritation from carbon dioxide pneumoperitoneum.

5-7 At times, this symptom could be severe enough to result in conversion of the anesthetic approach.7 However, the pain was mild in most cases in our study and it did not result in conversion from spinal anesthesia in any of our patients. Even when present,

shoulder pain was easily dealt with; reassurance and no medical treatment were used in most patients who experienced this symptom. This could be attributed to our lower cutoff pressure for pneumoperitoneum (12 mm Hg instead of the usual 14 mm Hg) combined with minimal tilting of the operating table; we have, thus, minimized the diaphragmatic irritation.

The use of low-pressure pneumoperitoneum did not jeopardize the adequacy of space and subsequently the view and virtually all the procedures were completed without any technical difficulty. This was especially true for the spinal anesthesia group, because this type of anesthesia offers sensory, motor, and sympathetic blockade at a high level and thus obviates the need for abdominal wall muscle relaxants, which sometimes are necessary when general anesthesia is used. To avoid technical problems with obese patients in whom a potentially higher intra-abdominal pressure is required, we designed the trial with a body mass index cutoff of 30. It is possible, however, that carefully selected patients with higher body mass indexes could have laparoscopic cholecystectomy under regional anesthesia, as our limited anecdotal experience with such obese patients outside the trial suggests.

With regards to the early (in-hospital) postoperative course, the only essential event detected in the spinal anesthesia group was urinary retention; again, this is known to be related to regional anesthesia with rates of up to 20% in some series.15 Postoperative urinary retention developed in 3 (6%) patients from the spinal anesthesia group (1 female and 2 male patients). Instant catheterization was the only treatment required in 2 patients and did not affect their recovery or time of discharge. However, the third patient developed a postcatheterization urinary tract infection requiring antibiotics and prolonged hospitalization. At 2 weeks' follow-up, the vast majority of patients from both groups reported being satisfied with the anesthetic approach and experienced equally good recovery.

On the other hand, postdischarge patients' recovery after laparoscopic cholecystectomy under spinal anesthesia was reported to be equally good compared with the present standard method of anesthesia.

From these preliminary data, it appears that spinal anesthesia is a promising method of anesthesia for laparoscopic procedures, and with proper refinements, it could potentially evolve as the new gold standard anesthetic approach for elective laparoscopic cholecystectomy in healthy patients.

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