Original Research Article

Laparoscopic cholecystectomy under spinal anesthesia: A prospective randomized study

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Abstract

Context: Spinal anesthesia has been cost-effective to general anesthesia for performing laparoscopic cholecystectomy. **Aim:** Study aimed to evaluate the efficacy, safety, and cost-benefit of conducting laparoscopic cholecystectomy under spinal(SA) in comparison to general anaesthesia(GA). **Settings And Design:** A prospective randomized study was conducted over a thirteen-month at an urban non-teaching hospital. **Materials And Methods:** Patients meeting inclusion criteria and randomized into two categories group A receive SA and group B receive GA by standard techniques, three-port laparoscopic cholecystectomy, mean anesthesia time, pneumoperitoneum time, and surgery time defined primary outcome measure intraoperative events and postoperative pain scores were secondary outcome measures. **Statistical Analysis Used:** The student t-test, Pearson's chi-square test, and Fisher exact test. **Results:** Out of 149 cases enrolled in the study 98 cases for group A and 51 cases in group B analyzed mean anesthesia time appeared to be more in the GA group while pneumoperitoneum time and corresponding the total surgery time was slightly longer in the SA group. No postoperative complication was noted in either group. Pain relief was significantly more in the SA group in the immediate postoperative period (06 and 12 hrs) but the same as the GA group at the time of discharge 24 hrs. No late postoperative complication or readmission was noted in either group. **Conclusion**: Laparoscopic cholecystectomy was done under spinal anesthesia as a routine anesthesia of choice is feasible and safe. Spinal anesthesia can be recommended to be the anaesthesia technique for conducting laparoscopic cholecystectomy in hospital setups in developing countries where cost factor is a major concern.

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INTRODUCTION

Endotracheal general anesthesia is the anesthetic technique of choice for laparoscopic cholecystectomy. Regional anesthesia to has been reported as the sole technique for performing laparoscopic cholecystectomy as an alternative to GA. Initially, it was reported only for cases that were high-risk candidates for GA. More recently it has been noted as a routine technique for the healthy patients. It was tough that laproscopy cholecystectomy necessitates endotracheal intubation this was to prevent aspiration abdominal discomfort and hypercarbia which was expected to be secondary to induction of CO2 pneumoperitoneum. Recent studies demonstrate that laparoscopic cholecystectomy with low-pressure CO2 pneumoperitoneum can indeed be safely performed under spinal anesthesia. Inspite of the emerging evidence that laparoscopic cholecystectomy can be safely perform under regional anesthesia, we designed a randomized controlled study to assess if spinal anesthesia, instead of general anesthesia, can be used as a routine in clinical practice.

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MATERIALS AND METHODS

STUDY DESIGN

This prospective, randomized study was conducted in an urban secondary level hospital in a period of thirteen-month from March 2021 to March 2022.

PATIENT SELECTION:

Inclusive criteria: Newly diagnosed cases of cholelithiasis who reported to the department of surgery of the hospital and who met the following criteria were enrolled in the study. American society of anesthesiologists physical status 1,2,3. Age between 18 to 80.

Exclusive criteria: Acute inflammatory process (cholecystitis, pancreatitis or cholangitis). Suspected /confirmed bile duct stones. Anxiety-prone patients/diagnosed with psychological morbidity. Bleeding diathesis. Local spinal deformities which precluded safe spinal anesthesia. In cases of chronic obstructive pulmonary disease.

METHODOLOGY: All patients were explained the procedure and consent was obtained. All patients were interviewed by the anesthesiologist in a pre operative visit who in turn specifically instructed them about possible intraoperative events while under SA like vomiting, shoulder pain and anxiety .it was instructed to them that in eventuality of this events occurring intravenous medication would be administered and if required conversion to GA would be done. As there would be multiple outcomes possible, no separate analysis was undertaken to determine the size of the study groups.

RANDOMISATION: Patients were randomized to undergo spinal anesthesia or general anesthesia for the cholecystectomy. The individual resident responsible for randomization was not subsequently involved in the surgery or in the post-operative follow-up.

The surgery was performed by the same consultant surgeon and anesthesia for both study groups. The post-operative monitoring and the data collection
was done by an independent observer who had been not been involved in either pre-operative or intraoperative course of events.

ANESTHETIC MANAGEMENT:

Pre-anesthetic medication was standard for all patients, pre anesthetic values of heart rate, mean arterial pressure, respiratory rate and pulse oximetry were recorded.

In the general anesthesia group, anesthesia was induced with 2.5mg/kg of propofol and scoline maintenance of anesthesia was done with **O2, N2O** and sevoflurane, the respiratory rate was adjusted to maintain PCO2 between 32 to 36 mm of Hg. Expired concentrations CO2, O2, and sevoflurane were monitored continuously by a gas analyzer. Residual neuromuscular blockade was antagonized with 2.5mg of neostigmine and 0.4 mg of glycopyrrolate at the end of the surgery.

In the spinal anesthesia group, the patients were placed in sitting or left laterals decubitus position as deemed comfortable. The subarachnoid space puncture was performed between the L3 AND L4 apophysis and 2.5 to 4 ml of hyperbaric 0.5 % bupivacaine were injected afterward. Patient were placed in a supine position with a head down position. After the surgeon confirms anesthesia at T4 level by pinprick, go-ahead was given. If the mean arterial pressure dropped below 60 mm of Hg, mephentermine was administered during the procedure, anxiety was treated with 2 mg midazolam and pain with fentanyl in intravenous boluses.

Causes of failure of successful laproscopic cholecystectomy under spinal anaesthesia.

Table 1

causes	anaesthesia	surgery
Hypoxemia and respiratory difficulty	Spinal converted to general anaesthesia	Laproscopic cholecystectomy
Failure of neuraxial blockade	Spinal converted to general anaesthesia	Laproscopic cholecystectomy
Dense adhesions and frozen calots triangle	Spinal anaesthesia	Laproscopic converted to open cholecystectomy
Densely adherent gall bladder to duodenum	Spinal converted to general anaesthesia	Laproscopic converted to open cholecystectomy

SURGICAL TECHNIQUE:

Laparoscopic cholecystectomy was performed with three ports certain salient features of the technique practiced for both the groups, GA as well as SA, were as: After the second trocar, the subdiaphragmatic surface of the liver was bathed with 30 ml of a solution which contained 10 ml each of 2% Lignocaine and 0.5% Bupivacaine dissolved in 10 ml of saline. The pneumoperitoneum was maintained with CO2 at 8-10 mmHg. Nasogastric tube was not introduced routinely. It was done if the surgeon desired decompression of the stomach. After the gall bladder had been extracted, the gall bladder fossa liver was bathed with 20 ml of solution with 5 ml each of 2% Lignocaine and 0.5% Bupivacaine dissolved in 10 ml of saline.

Intraoperative monitoring:

Continuous monitoring of hemodynamic parameters were maintained for all patients in both the groups with non invasive multiparameter monitor

Following parameters were also noted in all cases in both the groups: **Anaesthesia time:** It was defined as time taken from a spinal puncture to final dressing of patient in SA group while it was the time taken from induction to extubation for the GA group. **Surgery time:** This was defined as time from the first incision to final suture in both groups. **Pneumoperitoneum time:** This was defined as the time from CO2. Insufflation through Veress needle till the expulsion of all CO2 at end of the procedure. Intraoperative significant events were defined as pain in the right shoulder, anxiety, headache, nausea, vomiting, and abdominal discomfort.

Postoperative management:

Patient was shifted to the general ward after surgery and maintained on IV fluids for 4 hours post-surgery. Pain relief was maintained by inj dynapar 1 amp in with ns 08 hourly. InjPentazocin 30 mg was supplemented as a second rescue analgesia if patient persisted to have pain. Thereafter, the operating surgeon along with anesthesiologist evaluated the patient for pain, nausea, and vomiting, consciousness level, and vital parameters (including oxygen saturation). Post-operative pain was evaluated, in both groups, by the Visual Analogue Scale[8] at 6, 12 and 24 hours after the end of the surgery. Other post-operative events related to the surgery or anesthesia, such as discomfort, nausea, vomiting, shoulder pain, urinary retention, headache, or any other neurologic complaint were also recorded. Patients were routinely discharged to home the next day, unless some complications warranted further stay. Mean anesthesia time, pneumoperitoneum time and surgery time defined primary outcome measures. Intraoperative events and postoperative pain scores was a secondary outcome measure.

Followups

After removal of sutures patient are advised for followup after 3 month and 6 month.

Statistical analysis

The Student's t-test was used to compare means and percentages by the Pearson's chi-square test or Fisher exact test. Differences were considered significant when P< 0.05.

RESULTS

During the study period, 149 cases of cholelithiasis reported to the Surgery outpatient department (OPD). Out of these all eligible to be enrolled in the study. One hundred forty-nine cases were enrolled in the study and the progress of the study is summarised. Ninety-eight cases in the SA group and 51 cases in the GA group were finally available for per-protocol analyses. These groups were evenly matched as per age and gender distribution. summarises the mean anesthesia, pneumoperitoneum, and total surgery time in both the groups. Mean anesthesia hundred and forty-nine cases were enrolled in the study and the progress of the study is summarised.

Ninety-eight cases in the SA group and 51 cases in the GA group were finally available for per-protocol analyses. These groups were evenly matched as per age and gender distribution. summarises the mean anesthesia, pneumoperitoneum, and total surgery time in both the groups. Mean anaesthesia time appeared to be more in the GA. the operating theatre and did not include persistence of anaesthesia in post- operative room for the SA group. Though the pneumoperitoneum time and corresponding total surgery time was slightly longer in the SA group, it was not statistically significant. Mean anesthesia and surgery time SA Group Among the 98 cases that were randomized to receive SA, the level of anaesthesia was adequate in all to commence laparoscopic surgery. However, as the surgery proceeded, there were no cases of intraoperative events which required some intervention.

Intraoperative Events in Spinal Anesthesia Group: Post-operative events were noticed in 06/98 cases . Patients with urinary retention were catheterized. The two cases of hypotension were treated two cases of hypotension were treated with saline infusion only. No additional medication was required. Three cases developed typical post-dural puncture headache which subsided with Injection Pentazocin 30 mg IM. Two cases complained of pain at the site of the lumbar puncture. These were treated with Injection Tramadol (50 mg) IV. All patients were discharged the next day. They were followed up in OPD till sutures were removed 8-10 days later. There were no late post-operative complications noted.

Postoperative events GA Group: Among the 51 cases that were randomised to receive GA, successful laparoscopic surgery was accomplished in 51 cases. Commonest complaint noticed was pain abdomen. All patients received Inj Pentazocin 30 mg IM in addition to the standard Inj Tramadol. The cases of nausea/vomiting received additional Inj Ondasteron 8 mg IV. summarises the visual analogue score for pain measured in both the groups at 06, 12 and 24 hours after completion of surgery. The pain was less in the SA group in immediate operative period (up to 12 hours) but was similar to the other group at the time of discharge (24 hours), Similar to the SA group, all patients were discharged the next day. There were no late post-operative complications or readmissions noted in either group.

Postoperative Pain on visual analogue scale and requirement for analgesia

Table 2

Pain on visual analogue	Post 1 hour of surgery	Post 6 hours of surgery	Post 12 hours of surgery	Post 24 hours of surgery
0	51	46	42	10
1	7	5	2	1
2	1	5	1	0
3	0	2	1	0
4	0	2	1	0
5 and above	0	0	0	0
Median score	0	0	0	0
mode	0	0	0	0
Percentage of patient requiring analgesic medication	1.60%	15%	6.67%	10%

DISCUSSION

Though regional anesthesia for laparoscopic cholecystectomy has been shown to be safe, and associated with better postoperative pain control, it has not become the anesthesia procedure of choice. There may be multiple reasons for this. It is assumed that pneumoperitoneum induces rise pneumoperitoneum induces rise in intra-abdominal pressure. This may result in regurgitation of gastric content thus necessitating the use of endotracheal intubation to prevent aspiration in such an eventuality.[1,2] The increased intra abdominal pressure during pneumoperitoneum, together with the head-up tilt used in upper abdominal laparoscopies, are believed to decrease venous return to the heart.[9,10] Spinal anesthesia itself induces peripheral vasodilatation. Hence, there is a fear that laparoscopic procedure done under spinal anesthesia may result in hypotension. Indeed, the effects of CO2 pneumoperitoneum on intra-operative hemodynamics under SA is not a well-studied scenario. In our study, we notice that liberal pre-anesthetic hydration prevents occurrence of hypotension noted an incidence of hypotension as 20.5% in their series. While we did have hypotension in three cases, it could be corrected with saline infusion and selective alpha-blocker agent (Inj Mephenataramine). We did have one case whose nausea and vomiting were severe enough to warrant immediate intubation. The negative effects of the pneumoperitoneum with CO2 on the respiratory function has been widely investigated. Initially, absorption of CO2 increases its elimination in the expired air, in the arterial and venous blood.[8,9] This carboxemia induces metabolic and respiratory acidosis which decreases arterial and mixed venous pH and arterial pO2-[9,10] In our series we noticed that the SpO2 remained within normal limits for the patients undergoing SA. Retention of CO2 and hypoxemia were not observed in the spinal anesthesia group during the procedure. This experience is similar to that noted by other series[8,9] and confirms the safety of CO2 pneumoperitoneum under SA. Overall, Incidence of referred pain to the right shoulder, while doing LC under regional anaesthesia, has been described as ranging from 25%-43%.[3,4,12] Referred pain to the right shoulder is a well-described phenomena and is thought to occur due to irritation of subdiaphragmatic surface by the CO2, pneumoperitoneum.[16] The incidence of the same in our series was 06/98 cases. All of these were managed by Intravenous fentanyl and none required conversion to GA. We attribute this low incidence of referred shoulder pain to liberal use of local anaesthetic agents (Lignocaine plus Bupivacaine) to bathe the subdiaphgramatic surface immediately after creating pneumoperitoneum. This is also helped by the fact we used low pressure pneumoperitoneum (<10 mmHg) during the surgical procedure. While standard LC entails a pneumoperitoneum at 12-14mmHg, pneumoperitoneum pressure below 10 mmHg has been shown to be associated with lesser abdominal/shoulder pain.[14] Low-pressure pneumoperitoneum in our cases added to the technical complexity of the dissection process. The surgeon had to be slower and gentler in tissue dissection. Additionally, on occasions, it became necessary to interrupt the procedure when the patient complained of discomfort and then the anaesthesiologist had to intervene with additional medication. This explains the fact that the pneumoperitoneum time and correspondingly the surgery time was more in the SA group. Other studies[15,16] too have documented the technical difficulty faced by the surgeon when operating in a limited field permitted by low pressure pneumoperitoneum. The significant advantage of this is in terms of reduced postoperative pain, less use of analgesics, preservation of pulmonary function, and reduced hospital stay. The postoperative recovery of patients was normal in all patients of both the groups. It is described that SA is associated with lower frequency of serious peri-operative morbidities and an improved outcome when compared to GA.[19,18] In our series the incidence of post-operative events that required intervention was 21% in GA group compared to in the SA group. But in our opinion, it is not justified to

compare the two groups on this basis. While in one group the events were peculiar to SA, in the other they were peculiar to GA. Perhaps the only event which would be common to both would be surgical procedure-related pain which was consistently reported significantly less by the patients who had undergone the surgery under SA as compared to those who had undergone it under GA. We believe this was due to the sensory blockade which persists for some time in the post-operative period. The patients in SA group seemed to have lesser pain in the immediate post-operative period but by the time of discharge the level of post-operative pain/discomfort was same for both groups. Bessa *et al.*,[16] in as similar study, too confirm that LC done under A results in significantly less early post-operative pain, compared to that performed under general anesthesia. Based on own experience, we would agree that GA would permit "day care LC" even in healthcare setups of developing countries.[20] But it is imperative to understand that true day care anesthesia on a universal basis is less likely to be feasible in a developing a country like ours where there are inherent limitation of availability of reliable transport, facility for home nursing, and the fact that the majority of the cases reporting to our urban hospitals do so from far off rural areas. Hence, most patients have to be admitted at least for an overnight period whether they are done under SA or GA. Though the surgery done under spinal anesthesia was technically more demanding and resulted in longer operating time, there were no late complications noted in our series which would allay the fear that technical difficulty in surgery would result in compromise in patient safety. However, it would be pertinent to mention that this endeavour should be undertaken by surgeons with adequate skills and experience in laparoscopic surgery. A valid criticism to the present study may emanate from the fact that no pre-study power analysis or sample size calculation was done. Hence, as has been pointed out earlier in respect to similar studies like the present one, it may not be feasible to draw correct conclusions. This remains a limitation to studies like this because they take into account multiple outcomes measures of varied types. It may not be possible to confirm the correctness of sample size calculation or provide the power and level of significance for each test with a singular sample size. Nevertheless, the present study provides a large sample size based on which a larger, more focused studies can be designed. This study confirms the feasibility and safety of spinal anesthesia as the sole anaesthesia technique for conduct of elective laparoscopic cholecystectomy (LC). The patient outcomes are similar to that observed if the surgery is done under general anesthesia. This study did not include a cost analysis, but other studies[25] indicate that laparoscopic cholecystectomy under SA is more cost effective than under GA. This makes SA an attractive option as the anesthesia of choice especially in developing countries.

CONCLUSION

Laparoscopic cholecystectomy was done under spinal anaesthesia as a routine anaesthesia of choice is feasible and safe. Spinal anesthesia can be recommended to be the anesthesia technique of choice for conducting laparoscopic cholecystectomy in hospital setups in developing countries where cost factor is a major concern.

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