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A Prospective Randomized Study of Laparoscopic Cholecystectomy Performed Under Spinal Anesthesia

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Abstract

Background: When performing a laparoscopic cholecystectomy, spinal anesthesia has proven to be more affordable than general anesthesia.

Aim: The purpose of the study was to compare the effectiveness, safety, and cost-benefit of performing a laparoscopic cholecystectomy under spinal anesthesia (SA) against general anesthesia (GA).

Settings And Design: An urban non-teaching hospital carried out a thirteen-month prospective randomized research. Supplies and Procedures: Intraoperative events and postoperative pain scores were the secondary outcome measures, while mean anesthesia time, pneumoperitoneum time, and surgery time defined the primary outcome measure for patients meeting inclusion criteria and randomly assigned to groups A and B, respectively, to receive standard techniques for SA and GA, respectively, during a three-port laparoscopic cholecystectomy. The student t-test, Pearson's chi-square test, and the Fisher exact test were the statistical analyses employed.

Results: The analysis of 298 patients—196 instances in group A and 102 cases in group B—showed that the GA group had a slightly longer mean anesthetic time, whereas the SA group had a slightly longer pneumoperitoneum time and, consequently, a slightly longer total operation time. In both groups, there were no reported postoperative complications. At the time of discharge after 24 hours, pain alleviation was comparable in the SA group and much greater in the postoperative period (06 and 12 hours). In neither group were readmissions or late postoperative complications reported.

Conclusion: Spinal anesthesia was used during the laparoscopic cholecystectomy procedure since it is a practical and secure regular anesthesia. It is suggested that spinal anesthesia be used as the anesthetic method for laparoscopic cholecystectomy in hospital settings in underdeveloped nations where cost is a primary consideration.

Introduction

Anesthetic approach of choice for laparoscopic cholecystectomy is endotracheal general anesthesia. It has been claimed that the only method available for performing laparoscopic cholecystectomy as a substitute for GA is regional anesthesia[1-3]. At first, it was only mentioned in relation to high-risk GA candidates. It has been reported as a standard procedure for healthy patients in more recent times. The difficult part was that endotracheal intubation was required during the laproscopy cholecystectomy in order to prevent aspiration, which was expected to cause abdominal discomfort and hypercarbia due to the induction of CO2 pneumoperitoneum[3]. It is safe to conduct laparoscopic cholecystectomy under spinal anesthesia using low-pressure CO2 pneumoperitoneum, as recent investigations have shown[4-6]. We planned a randomized controlled research to determine whether spinal anesthesia—rather than general anesthetic—could be utilized as

a standard in clinical practice, despite the growing body of information suggesting that laparoscopic cholecystectomy may be performed safely under this type of anesthesia.

MATERIALS AND METHODS

STUDY DESIGN

Over the course of thirteen months, this prospective, randomized trial was carried out in an urban secondary level hospital.

PATIENT SELECTION:

Enrollment in the study was open to newly diagnosed patients of cholelithiasis who reported to the hospital's surgery department and who satisfied the following requirements. Physical state of the American Society of Anesthesiologists 1, 2, 3. between the ages of 18 and 80.

Acute inflammatory process (cholecystitis, pancreatitis, or cholangitis) is the exclusive criterion. suspected or verified stones in the bile duct. individuals with a history of anxiety or psychiatric illness. Diathesis bleeding. localized spinal abnormalities that made safe spinal anesthesia impossible. when someone has long-term obstructive pulmonary illness.

METHODOLOGY: Consent was acquired after explaining the technique to each subject. During a preoperative visit, the anaesthesiologist interviewed each patient and provided them with detailed instructions regarding potential intraoperative occurrences such as vomiting, shoulder pain, and anxiety while under SA.They were told that in the unlikely event that this happened, intravenous medicine would be given, and if necessary, conversion to GA would take place. The size of the research groups was not determined by a separate analysis because there could be several different outcomes.

RANDOMISATION: For the cholecystectomy, patients were randomized to receive either spinal or general anesthesia. Neither the surgery nor the post-operative follow-up involved the resident who was in charge of randomization. The same consultant surgeon administered anesthesia to both research groups and carried out the surgery. An impartial observer who was not involved in the pre-operative or intraoperative course of events conducted the post-operative monitoring and data gathering.

ANESTHETIC MANAGEMENT:

All patients received the same pre-anesthetic medicine, and pre-anesthetic measurements of heart rate, mean arterial pressure, respiratory rate, and pulse oximetry were documented.

In the general anesthesia group, scoline and 2.5 mg/kg of propofol were used to produce anesthesia. O2, N2O, and sevoflurane were used to maintain the anesthesia, and the respiratory rate was changed to keep the PCO2 between 32 and 36 mm of Hg. An automated gas analyzer was used to continually monitor the expired concentrations of CO2, O2, and sevoflurane. At the conclusion of the procedure, 2.5 mg of neostigmine and 0.4 mg of glycopyrrolate were used to antagonize residual neuromuscular blockade.

Patients in the spinal anesthetic group were positioned in either a sitting or left lateral decubitus posture, depending on what was comfortable for them. After performing a subarachnoid space puncture between the L3 AND L4 apophysis, 2.5 to 4 milliliters of hyperbaric 0.5% bupivacaine were administered. The patient was positioned head down in a supine position. The all-clear was given when the surgeon used a pinprick to confirm anesthesia at the T4 level. Mephentermine was given during the procedure if the mean arterial pressure fell below 60 mm Hg. Fentanyl intravenous boluses were used to treat pain and anxiety, respectively, while 2 mg of midazolam was used for anxiety.

Table 1: Causes of failure of successful laproscopic cholecystectomy under spinal anaesthesia.

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:

A three-port laparoscopic cholecystectomy was carried out. The following were some key components of the method that both the GA and SA groups used: Following the second trocar, 30 milliliters of a solution containing 10 milliliters of 2% lignocaine and 0.5% bupivacaine dissolved in 10 milliliters of saline were applied to the liver's subdiaphragmatic surface. CO2 was used to maintain the pneumoperitoneum at 8–10 mmHg. The nasogastric tube was not frequently inserted. If the surgeon wanted to decompress the stomach, it was done. Following the removal of the gall bladder, the liver of the gall bladder fossa was submerged in a 20 ml solution containing 5 ml of 2% lignocaine and 0.5% bupivacaine diluted in 10 ml of saline.

Intraoperative monitoring:

Using a non-invasive multiparameter monitor, all patients in both groups had their hemodynamic parameters continuously monitored. Additionally, the following criteria were recorded in each instance for both groups: Anaesthesia time was defined as the amount of time that passed between the spinal puncture and the patient's final dressing in the SA group and the induction and extubation in the GA group. Surgery time: For both groups, this was the amount of time between the initial incision and the last suture. Pneumoperitoneum time: The interval between CO2 and this time was defined. Insufflation using a Veress needle until all CO2 is expelled at the conclusion of the process. The following conditions were considered intraoperatively significant events: headache, nausea, vomiting, right shoulder pain, anxiety, and stomach discomfort.

Postoperative management: Following surgery, the patient was moved to the general ward and kept on IV fluids for four hours. Using inj dynapar 1 amp in with ns 08 hourly, pain alleviation was sustained. In the event that the patient's discomfort persisted, 30 mg of injectable pentazocin was added as a second line of defense. The patient was then assessed for pain, nausea, vomiting, degree of consciousness, and vital signs (oxygen saturation) by the anesthesiologist and the operating surgeon. The Visual Analogue Scale-8 was used to measure post-operative pain in both groups six, twelve, and twenty-four hours following the conclusion of the procedure. Any other neurologic complaint, discomfort, nausea, vomiting, shoulder pain, urine retention, headache, or any post-operative symptoms connected to the anesthetic or surgery were also noted. Generally speaking, patients were sent home the following day, unless there were circumstances that called for an extended stay. The major outcome variables that were defined were mean anesthetic time, pneumoperitoneum time, and surgery time. A secondary outcome measure included postoperative pain levels and intraoperative events.

Followups

Patients are recommended to follow up three and six months after the sutures are removed.

Statistical analysis

The Pearson's chi-square test or the Fisher exact test were used to compare means and percentages using the Student's t-test. When $P<0.05$, differences were deemed significant.

RESULTS

298 cases of cholelithiasis were reported to the Surgery outpatient department (OPD) throughout the research period. Each of these qualifies for study enrollment. A summary of the study's development is provided for the 149 cases that were enrolled. When it came time for per-protocol analysis, 196 cases from the SA group and 102 cases from the GA group were available. Both the gender and age distribution of these groups was evenly distributed. summarizes the two groups' mean anesthetic, pneumoperitoneum, and overall surgical time. Ninety-nine cases of mean anesthesia were enrolled in the study, and the study's progress is summarized. When it came time for per-protocol analysis, 196 cases from the SA group and 102 cases from the GA group were available.

Both the gender and age distribution of these groups was evenly distributed. summarizes the two groups' mean anesthetic, pneumoperitoneum, and overall surgical time. The average duration of anesthesia seemed to be longer in the GA than in the OR, and it did not account for the SA group's continued anesthesia in the recovery area. Despite the fact that the SA group's pneumoperitoneum time and related overall operation time were marginally longer, this difference was not statistically significant. Mean time for surgery and anesthesia SA Group In all 196 of the randomized

instances that received SA, the degree of anesthesia was sufficient to start laparoscopic surgery. As the procedure went on, there were no instances of intraoperative occurrences that called for more assistance.

Intraoperative Events in Spinal Anesthesia Group:

In 12 of 196 patients, post-operative occurrences were noted. Catheterization was used for patients with urine retention. Four hypotensive patients were managed. Saline infusion was the only treatment used for four hypotensive instances. There was no need for further medication. Pentazocin injection (30 mg IM) relieved the characteristic post-dural puncture headache that had occurred in six of the instances. Two patients reported experiencing soreness at the lumbar puncture site. Tramadol (50 mg) intravenous injection was used to treat these. Next day, all patients were released. Following up with them in the OPD, they had their sutures taken out 8–10 days later. No late post-operative problems were seen. GA Group postoperative events: Of the 102 instances that were randomized to get GA, 102 of them underwent successful laparoscopic surgery.

The most often reported symptom was abdominal ache. In addition to conventional intravenous tramadol, all patients got 30 mg of pentazocin intramuscularly. Extra injections of Ondasteron (8 mg IV) were given to the patients of nausea and vomiting. summarizes the visual analog pain score obtained six, twelve, and twenty-four hours following the end of surgery for both groups. In the first 12 hours following surgery, the SA group experienced less pain than the other group, but at the time of discharge (24 hours), the pain was comparable. Like the SA group, all patients were released the next day. In neither group were readmissions or late postoperative problems reported.

Table 2: Postoperative Pain on visual analogue scale and requirement for analgesia

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	102	92	84	20
1	14	10	4	2
2	2	10	2	0
3	0	4	2	0
4	0	4	2	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

Regional anesthesia has not taken over as the preferred anesthetic technique for laparoscopic cholecystectomy, despite evidence that it is safer and improves postoperative pain control. This could be due to a number of factors. Pneumoperitoneum is thought to cause increase. An increase in intra-abdominal pressure is caused by pneumoperitoneum[7-10]. This could cause the stomach contents to regurgitate, in which case endotracheal intubation would be required to avoid aspiration. It is thought that the head-up tilt utilized during upper abdominal laparoscopies and the increased intraperitoneal pressure during pneumoperitoneum reduce the amount of blood returning to the heart from veins. Peripheral vasodilatation is induced by spinal anesthesia alone. Therefore, there is concern that hypotension could arise from a laparoscopic procedure performed under spinal anesthetic[11].

In fact, there is a paucity of research on the impact of CO2 pneumoperitoneum on intraoperative hemodynamics in SA. According to our research, a liberal pre-anesthetic hydration regimen can prevent hypotension, which is observed to occur in 20.5% of cases. Although there were three instances of hypotension, it was manageable with saline infusion and a selective alpha-blocker medication

(Inj Mephenataramine). There was one instance where the patient's nausea and vomiting were so bad that they needed to be intubated right away. Numerous studies have been conducted on the detrimental effects of pneumoperitoneum with CO2 on respiratory performance. At first, when CO2 is absorbed, it is eliminated more quickly from the bloodstream—both venous and arterial[12-15].

Because of the metabolic and respiratory acidosis caused by this carboxemia, arterial and mixed venous pH as well as arterial pO2 are decreased. We observed in our series that the SpO2 for the individuals receiving SA stayed within normal bounds. During the surgery, no hypoxemia nor retention of CO2 were noted in the group under spinal anesthetic. This experience supports the safety of CO2 pneumoperitoneum under SA and is consistent with previous series8, 9. When performing LC regional anesthesia, the incidence of referred pain to the right shoulder has been reported to range from 25% to 43% overall. Referred pain to the right shoulder is a well-documented phenomenon that is believed to be caused by the CO2 and pneumoperitoneum irritating the subdiaphragmatic surface. In our series, the incidence of the same was 06/98 instances[16-18].

None of these needed to be converted to GA because they were all controlled by intravenous fentanyl.

We credit the widespread application of local anesthetics (bupivacaine plus lidocaine) to the subdiaphramatic area right after pneumoperitoneum creation for the low prevalence of referred shoulder pain. The fact that we performed the surgery using low pressure pneumoperitoneum (<10 mmHg) also helps with this. Pneumoperitoneum pressures between 12 and 14 mmHg are required for normal LC; however, it has been demonstrated that lower pneumoperitoneum pressures are linked to decreased shoulder and stomach pain. In our situations, low-pressure pneumoperitoneum increased the dissection's technical complexity. When dissecting tissue, the surgeon had to go more slowly and carefully[19].

Furthermore, the patient occasionally complained of discomfort, necessitating the interruption of the treatment and the intervention of the anesthesiologist with additional medicine. This explains why the SA group had a longer pneumoperitoneum and, thus, a longer surgery. The technical challenges a surgeon faces when working in a small field made possible by low pressure pneumoperitoneum have also been reported in other research. This has a major benefit in terms of decreased pain following surgery, less need for analgesics, preservation of lung function, and shorter hospital stay. Every patient in both groups recovered normally from their surgeries[19,20].

When compared to GA, SA is linked to a lower incidence of significant peri-operative morbidities and better results. In our series, the GA group saw a 21% higher incidence of post-operative occurrences requiring intervention than the SA group. However, we do not think that comparing the two groups on this basis is warranted. Whereas the occurrences in one group were unique to SA, they were unique to GA in the other. Maybe the only occurrence that would be shared by both would be discomfort from the surgical procedure; individuals who had the surgery under SA consistently reported much less pain than those who had it under GA.

We think that the sensory blocking that lasts for a while throughout the recovery phase is what caused this. Although the patients in the SA group appeared to experience less pain during the first few days following surgery, both groups' levels of post-operative pain and discomfort were the similar at the time of discharge. Similar research by Bessa et al. also confirms that LC conducted under A causes far less early post-operative pain than LC performed under general anesthesia. We concur that GA would allow "day care LC" even in underdeveloped nations' healthcare systems based on personal experience.

However, it is crucial to realize that universal day care anesthesia is unlikely to be possible in a developing nation like ours due to inherent limitations in home nursing facilities, reliable transportation, and the fact that most cases that come to our urban hospitals come from remote rural areas. Therefore, whether they are treated under SA or GA, the majority of patients must be in for at least one night. Despite the technically more difficult procedure performed under spinal anesthetic requiring a longer operating duration, no late problems were observed in our series, easing

concerns that a surgical technical challenge might jeopardize patient safety.

It is important to note that this project should only be carried out by surgeons who possess the necessary training and expertise in laparoscopic surgery. The lack of a sample size calculation or pre-research power analysis may be a legitimate critique of the current study. Therefore, it might not be possible to draw the right conclusions, as has already been noted in relation to research that are comparable to the current one. Studies such as this one are nonetheless limited by the fact that they consider several different kinds of outcome measurements. With a single sample size, it might not be able to verify that the sample size calculation was accurate or to offer the power and significance level for each test.[20]

However, the current study offers a sizable sample size that can serve as the foundation for a bigger, more targeted investigation. The safety and viability of using spinal anesthesia as the only anesthetic approach for performing elective laparoscopic cholecystectomy (LC) are confirmed by this study. Similar results are seen in patients when the surgery is performed under general anesthesia. Although a cost analysis was not conducted for this study, research suggests that laparoscopic cholecystectomy performed under SA is less expensive than GA. Because of this, SA is a desirable alternative for anesthesia, particularly in developing nations.

CONCLUSION

Because spinal anesthesia is a routine anesthesia of choice that is both safe and feasible, a laparoscopic cholecystectomy was performed under it. In developing nations where cost is a key concern, spinal anesthesia is the recommended anesthetic technique for performing laparoscopic cholecystectomy in hospitals.

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