Section: Medicine

Research

COMPARATIVE STUDY OF GENERAL ANAESTHESIA VERSUS SPINAL ANAESTHESIA IN TERMS OF EFFICACY AND HEMODYNAMIC STABILITY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY

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Abstract

Background: Spinal anaesthesia has been reported as an alternative to general anaesthesia for performing laparoscopic cholecystectomy (LC). The aim is to evaluate efficacy, and safety of conducting laparoscopic cholecystectomy under spinal anaesthesia (SA) in comparison to general anaesthesia(GA). Settings and design: a prospective, randomised study conducted at an urban, teaching hospital. **Materials and Methods:** Patients meeting inclusion criteria were randomised into two groups. Group A received general anaesthesia and Group B received spinal anaesthesia by standardised techniques. Both groups underwent standard four port laparoscopic cholecystectomy. Mean anaesthesia time, pneumoperitoneum time and surgery time defined primary outcome measures. Intra operative events and post-operative pain score were secondary outcome measures. Statistical analysis used- the Student t test, Pearson′s chi-square test and Fisher exact test. **Result:** Out of 100 cases enrolled in the study, 50 cases in Group A and 50 in Group B were analysed. Mean anaesthesia time appeared to be more in the GA group (40.35 vs. 31.64, P = 0.02) while the total surgery time was slightly longer in the SA group which was statistically insignificant. 3/50 cases who received SA experienced intraoperative events. No postoperative complications were noted in either group. Pain relief was significantly more in SA group in immediate post operative period (06 and 12 hours) but same as GA group at time of discharge (24 hours). No late postoperative complication or readmissions were noted in either group. **Conclusion:** Laparoscopic cholecystectomy done under spinal anaesthesia as a routine anaesthesia of choice is feasible and safe. Spinal anaesthesia can be recommended to be the anaesthesia technique of choice for conducting laparoscopic cholecystectomy in hospital setups in developing countries where cost factor is a major factor.

INTRODUCTION

Laproscopic choleystectomy has become very popular after it was described in 1987 by Phillipe Mouret in France. Endotracheal general anaesthesia (GA) is the anaesthetic technique of choice for laparoscopic cholecystectomy (LC). Laparoscopic cholecystectomy under regional anaesthesia alone has been reported only occasionally in the past; these reports included patients unfit to receive general anaesthesia. Recent studies demonstrate that laparoscopic cholecystectomy with low pressure CO2 pneumoperitoneum can indeed be safely performed under spinal anaesthesia. In spite of emerging evidence that LC can be performed safely under spinal anaesthesia, it has not gained widespread acceptance. This study was thus designed to compare the efficacy and safety of spinal anaesthesia and general anaesthesia in laparoscopic cholecystectomy.

MATERIALS AND METHODS

Study Design

This prospective, single blind, two-armed, randomised parallel group study was conducted at secondary health care centre catering to a primarily urban population.

Patient Selection

100 incident cases of cholelithiasis who reported to surgical out patient department during the study period were included after considering the following criteria.

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Inclusion Criteria

- Individuals aged between 18-60years.
- Individuals found to be American Society of Anaesthesiologist's (ASA) physical status grade I and II.

Exclusion Criteria

- Acute inflammatory process (cholecystitis, pancreatitis, cholangitis).
- Suspected /confirmed common bile duct stone.
- Anxiety prone patient.
- Bleeding diathesis.
- Local spinal deformity.
- Previous open surgery in upper abdomen.
- Any cardiovascular disorders, respiratory disorders, renal disease and liver disease.
- Circulatory instability.
- Patients with known sensitivity to local anaesthetics.

Methodology

Ethical clearance for the study was obtained from the Institutional Ethical Committee, Government Hospital Gandhi Nagar, Jammu before commencement of study. Informed written consent was taken from all the patients who fit the inclusion criteria before enrolling them into the study.

Pre-Anesthetic Evaluation

All patients were interviewed by the anesthesiologist in a pre-operative visit who specifically instructed them about possible intra-operative events while under SA, like vomiting, shoulder pain, and anxiety. It was instructed to them that in eventuality of these events occurring, intravenous medications would be administered and, if required, conversion to GA would be done. Detailed history was recorded regarding current medical illness, drug history, and previous exposure with general or regional anaesthesia if any, and a thorough clinical examination was done. Review of baseline investigations including CBC, RFTs, LFTs, blood sugar fasting, serum electrolytes, PTI, ECG, Chest X-ray and other specific investigations necessary for the patient were undertaken.

Randomization

Using an online random sequence generator, the 100 study subjects were randomly divided equally into one of the following two groups:

Group A: Laparoscopic Cholecystectomy under GA.

Group B: Laparoscopic Cholecystectomy under SA.

The randomization was carried out by a resident who was not further involved in the surgery or in the post operative follow-up.The surgery was performed by the same set of consultant surgeons and anesthesiologists for patients in both the study groups. The post-operative monitoring and data collection was done by an independent observer who had not been involved in either pre-operative or intra-operative course of events.

Clinical Procedure: All the patients scheduled for the procedure were advised to remain nil per oral for at least 8 hours before the surgical procedure. Before beginning, they were all explained, once again, about the procedure, risk involved, and chances of conversion to GA.The following criteria were established for conversion of the anaesthesia from SA to GA:

- Patient anxiety.
- Pain which was not relieved by addition of Inj ketamine 50 mg.
- Bleeding which could not be controlled by routine manoeuvres.

On arrival into the OT ECG, NIBP, SPO2, Pulse, RR were recorded. An IV line was secured using 18G/20Gauge cannula and patient was preloaded with 15ml/kg of Ringer Lactate solution over 30 mins. All patients were premedicated with Inj. Glycopyrrolate 4mcg/kg, Inj. Ondansetron 0.08mg/kg, Inj. Pantop 40mg, and Inj. Voveron 1.5mg/kg im stat.

In Group A, anaesthesia was induced with 2.5mg/kg of propofol and 0.5mg/kg of Inj Atracurium. Inj. tramadol 1.5mg/kg was given for analgesia. Maintenance of anaesthesia was done with 02, N2O, and Isoflurane. The respiratory rate was adjusted to maintain EtCO2 between 32-36mmHg. Residual neuromuscular blockade was antagonized with 2.5mg of Inj Neostigmine and 0.4mg of Glycopyrolate [given in 0.1mg/kg] at the end of surgery.

In Group B, the patients were placed in sitting or left lateral decubitus position based on comfort of patient. A 26G spinal needle was introduced into L3-L4 interspace under all aseptic precautions. After confirming free flow of CSF 3.5-4ml of hyperbaric Bupivacaine 0.5% was injected intrathecally in cephalad direction. Afterwards, patients were placed in the supine position with head-down tilt. Approximately 10 minutes after intrathecal injection, the level of analgesia was checked. After the confirmation of T4 level by pin prick, surgery was started. If the mean arterial pressure dropped below 60mmHg, 6 mg of Inj Mephenteramine was administered. During the procedure, anxiety was treated by 0.03mg/kg midazolam and pain with ketamine 1.5mg/kg.

Surgical Procedure: Laparoscopic Cholecystecomy was performed using the same techniques in both the groups with standard 4 trocar insertion. Pneumoperitoneum was established by using the open (HASSEN) technique with carbon-dioxide (CO2) at maximum(max.) intra-abdominal pressure of 12mmHg.

Intraoperative monitoring: Continuous monitoring of hemodynamic parameters was 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:

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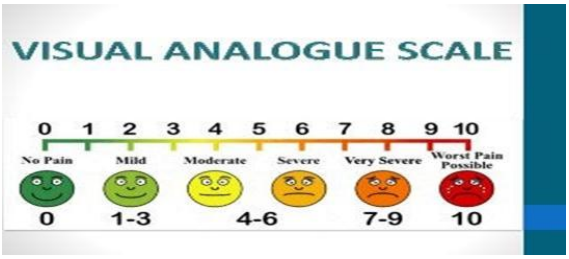
- Anaesthesia time: It was defined as time taken from spinal puncture to final dressing of patient in SA group while it was the time taken from induction to extubation for the GA group.
- Surgery time: This was defined as time from first incision to final suture in both the groups.
- Pneumoperitoneum time: This was defined as time from CO2 insuffulation through veres needle till 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.
- Post-operative management: Patient was shifted to general ward after surgery and maintained on IV fluids for 4 hours post-surgery. Pain relief was maintained by Inj. Paracetamol 1gm by intravenous infusion 8hrly. Inj. Tramadol 50mg was supplemented as a second rescue analgesia if patient persisted to have pain. Thereafter, operating surgeon along with anaesthesiologist 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 anaesthesia, 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 complication warranted further stay. Mean anaesthesia time, pneumoperitoneum time and surgery time defined primary outcome measures. Intraoperative events and post operative pain score were secondary outcome measures.

Statistical Analysis

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

RESULTS

During the study period, 100 patients were equally divided into two study groups. [Table 1] depicts the distribution of the subjects in the two groups according to age and gender. The two groups were found to be evenly matched in this respect.

[Table 2] summarises the mean anaesthesia, pneumoperitoneum and total surgery time in both the groups.

Intraoperatively only 3 patients experienced hypotension which was treated with saline infusion and 3mg mephentermine [Table 3]. Post-operative events were noticed in 3 patients [Table 4]. Two patients with urinary retention were catheterised. One patient had back pain. There were no late post-operative complications noted.

[Table 5] summarises the visual analogue score for pain measured in both the groups at 06, 12 and 24 hours after completion of surgery.

Table 1: Demographic characteristics of study subjects

Characteristic	Group A (N=50)	Group B (N=50)	P value
Age (Yrs)	43.23±10.6	45.65±12.7	0.18
Gender(M/F)	6/44	8/42	0.15

Table 2: Mean anaesthesia and surgery time

	GROUP A	GROUP B	P Value
Duration of anaesthesia	40.35±7.2	31.64±5.25	0.02
Duration of surgery	23.56±5.72	25.46±5.01	0.18
Duration of pneumoperitoneum	25.22±5.35	23.11±4.98	0.14

SA Group: Mean anaesthesia time appeared to be more in the GA group (40.35 vs. 31.64, P = 0.02). It must be noted that this was the anaesthesia time in the operation theatre and did not include persistence of anaesthesia in post-operative room for the SA group. Though the pneumoperitoneum time and corresponding the total surgery time was slightly longer in the SA group, it was not statistically significant. Among the 50 cases who were randomised to receive SA, the level of anaesthesia was adequate in all to commence laparoscopic surgery.

Table 3: Intraoperative Events in Spinal Anesthesia Group B

Event	Frequency
Abdominal discomfort	0
Referred shoulder pain	0
Hypotension	3
Nausea/Vomitting	0
Anxiety	0

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Table 4: Post operative Events

Event	Group A	Group B
Pain abdomen	3	Nil
Nausea/Vomitting	3	Nil
Urinary retention	Nil	2
Hypotension	Nil	Nil
Headache	Nil	Nil
Pain back	Nil	1
Sore throat	2	Nil

GA Group: Among the 50 cases that were randomised to receive GA, successful laparoscopic surgery was accomplished. Post operative events were noticed in 8 patients [Table 4]. Commonest complaint noticed was pain abdomen (2) and nausea/vomiting (2), these patients received Inj tramadol 50mg i.m in addition to the standard Inj Paracetamol. The patients complaining of nausea/vomiting received additional Inj Ondasteron 8 mg IV. 2 patients had sore throat which was treated with steam inhalation.

Table 5: Post operative Pain Score

Median Visual Analogue Score			
Post-operative time	**Group A**	**Group B**	**P Value**
06 hrs	6(1-7)	0(0-4)	<0.001
12 hrs	4(1-5)	2(0-4)	0.02
24 hrs	1(0-4)	0(0-2)	0.13

The pain was less in SA group in immediate operative period (up to 12 hours) but was similar to the other group at 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.

DISCUSSION

Though regional anaesthesia for laparoscopic cholecystectomy has been shown to be safe and associated with better post operative pain control, it has not become the anaesthesia procedure of choice. There may be multiple reasons for this. It is assumed that pneumoperitoneum induces rise in intraabdominal 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, is believed to decrease venous return to the heart.[3,4,5,6,7,8,9,10] Spinal anaesthesia itself induces peripheral vasodilatation. Hence, there is a fear that laparoscopic procedure done under spinal anaesthesia may result in hypotension. Indeed, effects of CO2 pneumoperitoneum on intra-operative haemodynamics under SA is not a well-studied scenario. In our study, we noticed that liberal preanaesthetic hydration prevents occurrence of hypotension. Sinha et al.[4] noted an incidence of hypotension as 20.5% in their series. While we did have hypotension in three cases (6%), it could be corrected with saline infusion and selective alpha blocker agent (Inj Mephenteramine). The negative effects of the pneumoperitoneum with CO2 on the respiratory function have been widely investigated. Initially, absorption of CO2 increases its elimination in the expired air, in the arterial and venous blood.[11,12] This carboxemia induces metabolic and respiratory acidosis which decreases arterial and mixed venous pH and arterial pO2.[13,14] In our series we noticed that the SpO2 remained within normal limits for the patients undergoing LC under SA. Retention of CO2 and hypoxemia were not observed in the spinal anaesthesia group during the procedure. This experience is similar to that noted by other series and confirms safety of creating CO2 pneumoperitoneum under SA.[11,12] None of the patients under SA were converted to GA. This is similar to experience of other authors too where the incidence of conversion from SA to GA was noted to range from nil to 2.8%.[3,4,6] Incidence of referred pain to the right shoulder, while doing LC under regional anaesthesia, has been described as ranging from 25%–43%.[3,4,6,15] Referred pain to right shoulder is a well described phenomena and is thought to occur due to irritation of subdiaphgramatic surface by the CO2 pneumoperitoneum.[16] None of our patients experienced referred pain in right shoulder. This is also helped by the fact we used low pressure pneumoperitoneum.[17] The significant advantage of this is in terms of reduced post-operative pain, less use of analgesics, preservation of pulmonary function, and reduced hospital stay.[18] The post-operative recovery of patients was normal in all patients of both the groups.[19] It is described that SA is associated with lower frequency of serious peri-operative morbidities and an improved outcome when compared to GA.[20,21] In our series the incidence of post-operative events which required intervention was 16% in GA group compared to 6% in the SA group. Surgical procedure related pain 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

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lesser pain in 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,[22] in a similar study, too confirm that LC done under SA results in significantly less early post-operative pain, compared to that performed under general anaesthesia. It may be argued that GA permits true "day care" anaesthesia with the patient being discharged to home the same evening while SA would entail an overnight stay. Based on own experience, we would agree that GA would permit "day care LC" even in healthcare setups of developing countries. But it is imperative to understand that true day care anaesthesia on an universal basis is less likely to be feasible in a developing country like ours where there are inherent limitation of availability of reliable transport, facility for home nursing, and the fact that 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 GA or SA. Though the surgery done under spinal anaesthesia shows longer operating time, but this was not statistically significant and there were no late complications noted in our series. However, it would be pertinent to mention that this endeavour should be undertaken by surgeons with adequate skills and experience in laparoscopic surgery. 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 anaesthesia 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 anaesthesia. This study did not include a cost analysis, but other studies indicate that laparoscopic cholecystectomy under SA is more cost effective than under GA. This makes SA an attractive option as the anaesthesia of choice especially in developing countries.

CONCLUSION

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

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