

A Hospital Based Randomized Comparative Assessment of Laparoscopic Cholecystectomy under Spinal Anaesthesia vs General AnaesthesiaAmrit Kumar¹, Vikram Nath²¹Senior Resident, Department of Anaesthesia, Shri Krishna Medical College, Muzaffarpur, Bihar²Senior Resident, Department of Anaesthesia, Shri Krishna Medical College, Muzaffarpur, Bihar

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Conflict of interest: Nil

Abstract**Aim:** The aim of the present study was to evaluate the efficacy, safety and advantages of conducting LC under SA in comparison to GA.**Methods:** The study was conducted in the Department of Anaesthesia for 8 months . Informed consent was obtained from all the patients who had agreed to participate in the study. A detailed explanation of the procedure and risks involved was given. A total number of 70 patients were included in the study.**Results:** Both the groups had similar demographic profile. In the SA group, 45 patients were females and 25 patients were males. The mean age was 46 ± 12.68 years and 48.82 ± 10.45 in SA and GA groups respectively. The duration of surgery was 82.98 ± 21.99 min and 98.2 ± 36.04 min in the GA and SA groups which was not statistically significant. For each procedure the surgeon was asked to give a score of 1-3, regarding the surgical conditions and muscle relaxation; 1 was bad, 2 good and 3 being excellent. In the SA group, 8 patients complained of shoulder pain, 3 patients required conversion to GA as the pain did not subside with Fentanyl and they were excluded from further analysis. All the patients (100%) in the GA group had pain at operated site immediately after completion of operation and their pain score ranged from 4-7, all patients received rescue analgesic before shifting to the ward. In the first 24h tramadol required as rescue in the GA group was 84 ± 26 mg which was significantly higher than the SA group requiring only 31 ± 32.18 mg. Although, the GA group had more patients experiencing postoperative nausea & vomiting it was not statistically significant.**Conclusion:** We concluded that laparoscopic cholecystectomy can be safely performed under spinal anaesthesia using bupivacaine and clonidine as an adjuvant. Spinal anaesthesia provides stable intra-operative haemodynamic and respiratory parameters, requires less postoperative analgesics with extended duration of analgesia, with no major complications and has better patient satisfaction.**Keywords:** Cholecystectomy, Gallstone disease, Laparoscopic cholecystectomy, Laparoscopy, Regional anaesthesia, Spinal anaesthesia.

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Introduction

Laparoscopic cholecystectomy (LC) has become the gold standard for the surgical treatment of symptomatic cholelithiasis and has gained worldwide acceptance. [1] It is a minimally invasive procedure with a significantly shorter hospital stay and a quicker convalescence compared with the classical open cholecystectomy. [2] LC is conventionally done under general anaesthesia (GA) and may be associated with postoperative pain and nausea and vomiting (PONV). Rodgers et al., published a meta-analysis showing that the use of neuraxial techniques for a variety of surgical procedures resulted in a decrease in mortality, venous thromboembolism, myocardial infarction, and several other complications. [3] Spinal anaesthesia (SA) is a commonly used

anaesthetic technique that has a very good safety profile. SA has several advantages over GA. These advantages include the patients' being awake and oriented at the end of the procedure, less postoperative pain, and the ability to ambulate earlier than patients receiving general anaesthesia. Moreover, the incidences of nausea and vomiting are less with selective spinal anaesthesia than with general anaesthesia. [4] SA is more effective than GA in blunting the neuroendocrine stress and adverse responses to surgery. [5]

Laparoscopic cholecystectomies are usually performed under the general anaesthesia (GA) with endotracheal intubation and controlled ventilation. By this way secondary aspiration, abdominal discomfort and respiratory distress due to carbon

dioxide pneumoperitoneum could be prevented and avoided from hypercapnia. [6-9] Recent studies about spinal and epidural anesthesia for laparoscopic cholecystectomies verified the safety and availability of this procedure. Regional anesthesia demonstrated less postoperative pain and less neuroendocrine stress response comparing with GA. [10-12]

It was thought that laparoscopy cholecystectomy necessitates endotracheal intubation. This was to prevent aspiration, abdominal discomfort and hypercarbia which was expected secondary to induction of CO₂ pneumoperitoneum. [13] Recent studies demonstrate that laparoscopic cholecystectomy with low-pressure CO₂ pneumoperitoneum can indeed be safely performed under spinal anaesthesia (SA). [14] In spite of the emerging evidence that laparoscopic cholecystectomy can be performed safely under regional anaesthesia, it has not gained widespread acceptance.

The aim of the present study was to evaluate the efficacy, safety and advantages of conducting LC under SA in comparison to GA.

Materials and Methods

The study was conducted in the Department of Anaesthesia, Shri Krishna Medical College, Muzaffarpur, Bihar for 8 months. Informed consent was obtained from all the patients who had agreed to participate in the study. A detailed explanation of the procedure and risks involved was given. A total number of 70 patients were included in the study.

The inclusion criteria were: American Society of Anaesthesiologists Grade I and II patients belonging to the age groups of 20-70 y of either sex, admitted with uncomplicated symptomatic cholelithiasis. Exclusion criteria were patients with acute cholecystitis, gallbladder malignancy, previous upper abdominal surgeries, pregnancy and patient unfit or refusing SA.

After detailed preoperative evaluation and preparation for surgery, patients were randomly allocated to either the SA group or the GA group using a table of computer-generated random numbers. All patients were premedicated with oral 150 mg of Ranitidine on the night before and morning of surgery. On arrival in the preoperative room the patient's non-invasive blood pressure(NIBP), oxygen saturation(SpO₂), and heart rate(HR) were recorded. Intravenous(iv) cannulation was done with an 18 G catheter inserted in the forearm and patients received 500ml of Ringer lactate solution, 1mg Midazolam IV and 4mg Ondansetron IV. A 14F nasogastric tube was inserted routinely in all patients and they received

prophylactic preoperative intravenous antibiotic ceftriaxone 1 gm/v.

In the SA group SA was performed with the patient in sitting position. After infiltration with 1% xylocaine, a 25 gauge lumbar puncture was done in the L2-L3 intervertebral space. Three ml of hyperbaric bupivacaine (0.5%) and 25 micrograms (mcg) of Fentanyl was injected intrathecally. The patient was then placed in the supine position for 5min. The sensory level of T4 dermatome level was accepted as to allow LC. A Trendelenburg position was given in patients who did not achieve a level of T4 at 5 minutes and sensory level was checked every minute till T4 level was achieved. At the end of 20min if adequate level was not achieved, GA was administered and the patient excluded from the study. As soon as the sensory block level reached T4 dermatome level, the surgery was started. HR, NIBP, and SpO₂ were measured and recorded at five minute intervals during the surgery. A decrease in the mean arterial blood pressure(MAP) by more than 20% below the pre-anaesthetic level was managed by intermittent incremental iv boluses of Ephedrine 5mg. Intraoperative shoulder pain was treated with fentanyl 25mcg iv bolus repeated at five minute intervals, with a maximum of 50mcg. GA was induced on persistence of severe pain despite maximum dose of fentanyl.

In the GA group, after pre-oxygenation, induction was done with Propofol (2mg/kg), Fentanyl (2mcg/kg,) and Atracurium (0.5mg/ kg).An appropriate size endotracheal tube was inserted after 3min of ventilation. Maintenance of anaesthesia was done with air oxygen mixture enriched with Isoflurane (0.6-1.5%) and controlled mechanical ventilation.

The patients were then placed in the supine, reverse Trendelenburg position with the arms fully abducted and a right up lateral tilt was given. A minimal possible tilt to facilitate exposure of the gallbladder of the patient was used (i.e. minimal use of both reverse Trendelenburg positioning and right shoulder elevation).Pneumoperitoneum was set at a pressure of 12mmHg, initial insufflation of Carbon Dioxide (CO₂)was done at a low flow rate (2L/min) and gradually increased to 5L/min. A standard four-trocar technique of LC was followed. Open technique was used for the placement of the umbilical port for the creation of pneumoperitoneum. A zero-degree optical scope was used for the surgery. Dissection of the gallbladder was started at the triangle of Calot with the identification and clipping of both the cystic duct and artery. Mobilization of the gallbladder from the liver bed started at the triangle of Calot. Following removal of the gallbladder, a subhepatic drain was placed, as per our institutional practice.

The operation time was recorded and intraoperative incidents like right shoulder pain, hypotension, nausea and/or vomiting were recorded. Postoperative pain was assessed regularly using a visual analog scale from 0 to 10, with 10 being most severe, for 24h. Intramuscular Tramadol 50mg was used as rescue analgesic and the total dose administered during the first 24h postoperatively was recorded. If the pain did not reduce to a VAS < 4 in 45min, 1gm Paracetamol iv. infusion was given and repeated every six hours. The sub hepatic drain was removed at the end of 24h. Patients were for discharge after 48h. Follow

up of the patients was performed at the end of the first and fourth postoperative week.

Statistical Analysis

Statistical analysis was done by student t-test. ANOVA and Chi-square test were performed for nonparametric values and corresponding p-value was computed using SPSS (Statistical Package for the Social Sciences (software version 17) for windows and p-value <0.05 was considered statistically significant.

Results

Table 1: Demographics of patients in both groups studied

| | SA Group | GA Group | p-value |
|---------------------------|------------------|-------------------|---------|
| Age (years) Mean \pm SD | 46 \pm 12.68 | 48.82 \pm 10.45 | 0.360 |
| Gender | | | |
| Male (N %) | 15 (42.86) | 10 (28.58) | 0.384 |
| Female (N %) | 20 (57.15) | 25 (71.42) | |
| Age in years | 61.95 \pm 7.78 | 64.44 \pm 10.22 | 0.364 |

Both the groups had similar demographic profile. In the SA group, 45 patients were females and 25 patients were males. The mean age was 46 \pm 12.68 years and 48.82 \pm 10.45 in SA and GA groups respectively.

Table 2: Surgery duration & Surgeon score of operating conditions

| Surgery duration | SA Group(n=35) | GA Group(n=35) | p-value |
|---------------------------------------|------------------|-------------------|---------|
| Duration of surgery | 98.2 \pm 36.04 | 82.98 \pm 21.99 | 0.096 |
| Surgeon score of operating conditions | 2.42 \pm 0.58 | 2.46 \pm 0.54 | 0.844 |
| Surgeon score | | | |
| Grade 1 | 2 | 3 | 0.786 |
| Grade 2 | 30 | 31 | |
| Grade 3 | 3 | 1 | |

The duration of surgery was 82.98 \pm 21.99 min and 98.2 \pm 36.04 min in the GA and SA groups which was not statistically significant. For each procedure the surgeon was asked to give a score of 1-3, regarding the surgical conditions and muscle relaxation; 1 was bad, 2 good and 3 being excellent.

Table 3: Spinal Anaesthesia group intraoperative events

| | N |
|-------------------------|----|
| Shoulder pain | 8 |
| Conversion to GA | 3 |
| Hypotension | 10 |
| Nausea intraoperatively | 2 |
| Vomiting | 0 |
| Immediate Post op pain | 0 |

In the SA group, 8 patients complained of shoulder pain, 3 patients required conversion to GA as the pain did not subside with Fentanyl and they were excluded from further analysis. None of the patients in the SA group had immediate postoperative pain at operated site.

Table 4: Pain scores and tramadol usage

| VAS \pm SD | SA group(n=35) | GA group(n=35) | p-value |
|--|-----------------|-----------------|---------|
| Immediate postoperative period | 0 | 6 \pm 1.17 | < 0.001 |
| 1 hour post op | 0 | 4.44 \pm 1.36 | < 0.001 |
| 2 hour post op | 0 | 3.79 \pm 1.31 | < 0.001 |
| 4 hour post op | 0.47 \pm 1.33 | 4.18 \pm 1.22 | < 0.001 |
| 8 hour post op | 3.58 \pm 0.92 | 4.94 \pm 1.36 | < 0.001 |
| 24 hour post op | 3.79 \pm 0.91 | 3.46 \pm 0.94 | 0.22 |
| Total Tramadol used on first post op day (mg \pm sd) | 31 \pm 32.18 | 84 \pm 26 | < 0.001 |

All the patients (100%) in the GA group had pain at operated site immediately after completion of operation and their pain score ranged from 4-7, all patients received rescue analgesic before shifting to the ward. In the first 24h tramadol required as rescue in the GA group was 84 \pm 26 mg which was significantly higher than the SA group requiring only 31 \pm 32.18 mg.

Table 5: Postoperative complication

| VAS±SD | SA group(n=35) | GA group(n=35) | p- value |
|---------------------------------|----------------|----------------|----------|
| Postoperative nausea & vomiting | 5 | 8 | 0.44 |
| Postoperative spinal headache | 0 | 0 | - |
| Urinary retention | 2 | 0 | 0.44 |
| Wound sepsis | 0 | 0 | - |

Although, the GA group had more patients experiencing postoperative nausea & vomiting it was not statistically significant. 3 patients in the SA group needed catheterisation. None of the patients had postoperative infections or headache.

Discussion

Laparoscopic cholecystectomy is the gold standard for surgical treatment of symptomatic gallstones due to the minimally invasive nature of the procedure, less postoperative pain, reduced hospital stay and early return of daily activities. [14] Until recently the choice of anaesthetic technique for laparoscopic cholecystectomy had been limited to general anaesthesia with muscle relaxation, tracheal intubation and positive pressure ventilation. [15] Spinal anaesthesia is a less invasive and has lower morbidity and mortality rates as compared to general anaesthesia. Under spinal anaesthesia patient is awake, there is no airway instrumentation, less postoperative pain and absence of nausea and vomiting. [16] Also the cost effectiveness of spinal anaesthesia makes it an attractive choice. The limiting factor for use of spinal anaesthesia in laparoscopic cholecystectomy was the patient discomfort because of respiratory embarrassment associated with pneumoperitoneum and the shoulder tip pain. [17]

Both the groups had similar demographic profile. In the SA group, 45 patients were females and 25 patients were males. The mean age was 46 ± 12.68 years and 48.82 ± 10.45 in SA and GA groups respectively. The duration of surgery was 82.98 ± 21.99 min and 98.2 ± 36.04 min in the GA and SA groups which was not statistically significant. For each procedure the surgeon was asked to give a score of 1-3, regarding the surgical conditions and muscle relaxation; 1 was bad, 2 good and 3 being excellent. In the SA group, 8 patients complained of shoulder pain, 3 patients required conversion to GA as the pain did not subside with Fentanyl and they were excluded from further analysis. None of the patients in the SA group had immediate postoperative pain at operated site. Referred pain to right shoulder is a well described phenomena and is thought to occur due to irritation of subdiaphragmatic surface by the CO₂ pneumoperitoneum. [19] The postoperative VASs could be influenced by intraperitoneal pressure, use of local anesthetics, peritoneal irrigation, psychological factors and type of incision. [20-22]

All the patients (100%) in the GA group had pain at operated site immediately after completion of operation and their pain score ranged from 4-7, all patients received rescue analgesic before shifting to the ward. In the first 24h tramadol required as rescue in the GA group was 84 ± 26 mg which was significantly higher than the SA group requiring only 31 ± 32.18 mg. Although, the GA group had more patients experiencing postoperative nausea & vomiting it was not statistically significant. 3 patients in the SA group needed catheterisation. None of the patients had postoperative infections or headache. The post-operative 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. [23,24] 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 immediate post-operative period but by the time of discharge the level of post-operative pain/discomfort was same for both groups. The reduced pain in the SA group may be due to a persistent neuraxial blockade by SA and also the use of a low-pressure pneumoperitoneum. A recent meta-analysis concluded that the use of a low-pressure pneumoperitoneum appears effective in decreasing pain after LC. [25]

Conclusion

We concluded that laparoscopic cholecystectomy can be safely performed under spinal anaesthesia using bupivacaine and clonidine as an adjuvant. Spinal anaesthesia provides stable intra-operative haemodynamic and respiratory parameters, requires less postoperative analgesics with extended duration of analgesia, with no major complications and has better patient satisfaction.

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