

SPINAL ANAESTHESIA VERSUS GENERAL ANAESTHESIA FOR LAPAROSCOPIC CHOLECYSTECTOMY - A PROSPECTIVE RANDOMIZED CONTROLLED STUDYPrasad C. G. S¹, Prashant P. Mannur², Suresh G³**HOW TO CITE THIS ARTICLE:**

Prasad C.G.S, Prashant P. Mannur, Suresh G. "Spinal Anesthesia versus General Anesthesia for Laparoscopic Cholecystectomy - A Prospective Randomized Controlled Study". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 06, February 10; Page: 1361-1368, DOI: 10.14260/jemds/2014/1992

ABSTRACT: INTRODUCTION: Combining minimal invasive surgical and lesser invasive anesthesia technique reduces morbidity and mortality. The aim of the study is to compare spinal anesthesia with the gold standard general anesthesia for elective laparoscopic cholecystectomy. **MATERIALS & METHODS:** 60 healthy patients were randomized under spinal anesthesia (n=30) & General Anesthesia (n=30). Hyperbaric 3ml bupivacaine plus 25mcg fentanyl was administered for spinal group and conventional general anesthesia for GA group. Intraoperative parameters and post-operative pain and recovery were noted. Under spinal group any intraoperative discomfort were taken care by reassurance, drugs or converted to GA. Questionnaire forms were provided for patients and surgeons to comment about the operation. **RESULTS:** None of the patients had significant hemodynamic and respiratory disturbance except for transient hypotension and bradycardia. Operative time was comparable. 6 patients under spinal anesthesia had right shoulder pain, 2 patients were converted to GA and 4 patients were managed by injection midazolam and infiltration of lignocaine over the diaphragm. There was significant post-operative pain relief in spinal group. All the patients were comfortable and surgeons satisfied. **CONCLUSION:** Spinal anesthesia is adequate and safe for laparoscopic cholecystectomy in otherwise healthy patients and offers better postoperative pain control than general anesthesia without limiting recovery, but require cooperative patient, skilled surgeon, a gentle surgical technique and an enthusiastic anesthesiologist.

KEYWORDS: Spinal Anesthesia, Laparoscopic Cholecystectomy, General Anesthesia.

INTRODUCTION: Laparoscopic Cholecystectomy has become the treatment of choice for cholelithiasis owing to its advantage over the open cholecystectomy like minimally invasiveness of the procedure which is associated with less postoperative pain, reduced hospital stay & early return to daily activities.^{1,2} Laparoscopic Cholecystectomy is conventionally performed under General Anesthesia.

Spinal anesthesia is a less invasive technique that has lower morbidity & mortality rates as compared to General Anesthesia. Under spinal anesthesia, the patient is awake & oriented throughout the procedure, less pain in the immediate post-operative period due to the effect of persistent neurological blockade, associated with absence of General anesthesia side effects like nausea & vomiting, pain related to intubation & or extubation and patients who receive spinal anesthesia tend to ambulate earlier than patients with GA.³

Therefore combining minimal invasive surgical procedure with a lesser invasive anesthesia technique theoretically further enhances the advantage of laparoscopic cholecystectomy. Despite the obvious advantage of regional anesthesia for Laparoscopic Cholecystectomy regional anesthesia has been given to patients unfit to receive General anesthesia mainly in patients with severe COPD.^{4,5}

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Recently reports have been published regarding the use of spinal anesthesia for Laparoscopic Cholecystectomy in patients fit for GA. The aim of the study is to compare spinal anesthesia technique with gold standard General Anesthesia technique for elective laparoscopic cholecystectomy in healthy patients.

MATERIALS & METHODS: This prospective randomized controlled study was conducted between January 2012 to December 2012 at ESIC Medical College Hospital PGIMSR, Rajaji Nagar, Bangalore. This study was undertaken after obtaining approval from institutional ethical committee. Written informed consent was taken from the patient after fully explaining the procedure. 60 patients of both sexes posted for elective laparoscopic cholecystectomy with symptomatic gall stone disease were randomized under spinal anesthesia (n=30) & General Anesthesia (n=30) with the following inclusion and exclusion criteria.

Inclusion criteria:

- a) ASA Grade I or II
- b) Age 18-65 years
- c) BMI < 30
- d) Normal coagulation profile.

Exclusion criteria:

- a) Acute cholecystitis / cholangitis / pancreatitis.
- b) Previous open surgery in the upper abdomen.
- c) Known Contraindications for pneumoperitoneum.
- d) Known Contraindications for spinal anesthesia.

Patients are randomly divided into 2 group's namely spinal group and general anesthesia group by a computer-generated list. 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.

During preoperative visit the patients were clearly explained about the procedure. Patient posted under spinal anesthesia were explained that any pain, discomfort or anxiety will be dealt with administration of medication or converted to General anesthesia if required. Similarly surgeons were informed to ask for general anesthesia if there was any technical difficulty during procedure.

On the day of surgery all patients were monitored for non-invasive blood pressure, oxygen saturation and heart rate just before the operation and baseline readings were noted. Intravenous access was obtained with 18G vasofix on the left hand. 500ml of Ringer Lactate was infused for all the patients. Injection ondansetron 4mg and injection midazolam 1mg was given i.v. Nasogastric tube was inserted and bladder was catheterized in all the patients.

Patients in the spinal group were positioned in right lateral position. Spinal anesthesia was given with 26G quincke spinal needle between L₂-L₃ intervertebral space. After free and clear flow of CSF 3ml of 0.5% heavy bupivacaine with 25ug fentanyl was injected intrathecally. Patient positioned back to supine position and table was tilted to trendelenberg position. Pin prick test was performed to evaluate the sensory block level. As soon as the sensory block level reached T₄ dermatome level the surgeons were allowed to proceed with the surgery. Blood pressure, oxygen saturation, heart

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rate, respiratory rate were recorded every 5 minutes to all the patients. If mean blood pressure was lower than 60mmHg injection ephedrine 6mg was administered i.v. and heart rate less than 50 beats per minute injection glycopyrrolate 0.02mg administered i.v. Patients who experienced intraoperative discomfort like right shoulder pain were initially reassured, when persisted were given additional drugs midazolam 1mg + fentanyl 25ug and in patients in whom fentanyl failed to stop right shoulder pain, surgeons were asked to spray the right dome of diaphragm with 10ml of 2% lignocaine. All the local anesthetic solutions were dispersed homogeneously over the diaphragmatic surface. In spite of above measures if patient had discomfort and / or surgeons not comfortable it was converted to General Anesthesia.

In patients randomized to receive general anesthesia, anesthesia was induced with injection propofol 2mg/kg, injection fentanyl 2ug/kg and injection Vecuronium 0.1mg/kg. After intubation, anesthesia was maintained with oxygen, nitrous oxide and Sevoflurane with IPPV using closed circuit. Intraoperatively all patients were monitored continuously. Pulse, blood pressure, saturation, ETCO₂ were noted every 5minutes. At the end of surgery patient was reversed with neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg.

Operation time was recorded for all patients in both the groups. Post operatively were monitored for vitals, pain using VAS score, time for first rescue analgesia and any complication/side effects were noted and treated. Post operatively pain was managed by injection tramadol 50mg i.v. and injection paracetamol 1g i.v. infusion.

Simplified questionnaire forms were developed for patients whose operation was completed with spinal anesthesia (Appendix I) and for surgeons to evaluate comments about the operation. (Appendix II) Surgeons completed the questionnaire forms immediately after the operation. The patients were asked to complete the questionnaire on 2nd post-operative day.

APPENDIX I

QUESTIONNAIRE FORM FOR PATIENTS³

1. How was the operation comfort?
 - a. Very well
 - b. Well
 - c. Moderate
 - d. Poor

2. Are you happy after this operation?
 - a. Yes
 - b. No

3. Do you advise this operation to your friends?
 - a. Yes
 - b. No

APPENDIX II

QUESTIONNAIRE FORM FOR SURGEONS³

1. How was abdominal relaxation of patient?
 - a. Well
 - b. Moderate
 - c. Poor

2. Was there any technical problem?
 - a. A lot
 - b. Little
 - c. None

3. Was there any difference with general anaesthesia?
 - a. Yes
 - b. No

STATISTICAL ANALYSIS: In the present study to calculate the sample size, with 80% power (β error = 20%), 95% confidence (α error = 5%) difference in the post-operative pain assessed by visual analogue scale in the two groups required a minimum of 28 subjects. Data was analyzed using Statistical Package for Social Science SPSS V18 software. p- Value < 0.05 was considered for statistical significance. Descriptive statistics of SPO₂, Blood Pressure, Respiratory Rate, Heart Rate, Etc. were analyzed and presented with mean and standard deviation. Independent t test was used to compare the average Blood Pressure, SPO₂, Respiratory Rate, Heart Rate, Etc. between the groups at different time. Chi-square test was used to compare proportion of complications between the groups. Continuous covariates will be compared using analysis of variance (ANOVA).

RESULTS: Between January 2012 to December 2012, 60 patients who fulfilled our criteria entered our ongoing trial. They were randomized into spinal group (n = 30) and general anesthesia group (n = 30).

All the 60 patients, both in GA and Spinal group, operation were completed laparoscopically and there was no need for open surgery. Average time of surgery was 60minutes in GA group and 70 minutes in spinal group, which is not statistically significant with p value of >0.05.

Demographic Profile

Demographic profile	Spinal Group	GA Group
Gender (M: F)	17:13	25:5
Age (years)	35.06 (7.50 Std Deviation)	38.5 (9.83 Std Deviation)
Weight (kgs)	48 (6.96 Std Deviation)	48.83 (4.57 Std Deviation)
Height (cms)	144.66(4.71 Std Deviation)	144.133 (4.9)
BMI (kg/m ²)	22.96 (2.98 Std Deviation)	23.5 (1.98 Std Deviation)
ASA grade (I: II: III: IV)	22:8:0:0	23:7:0:0

Table no. 1: Showing demographic data between two groups

The two groups were similar regarding demographics.

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Intra operative event	No. of patients	Percentage
Shoulder Pain	6	20%
Operative difficulty	2	6.66%
Hypotension	3	10%
Hypertension		NIL
Bradycardia	3	10%
Conversion to GA	2	6.66%
Anesthesia related	1	3.33%
Surgical related	1	3.33%

Table 2: Showing intraoperative events in the spinal group

In the spinal group out of 30 patients, 6 (20%) patients had right shoulder pain. 2 patients were given injection midazolam 1mg + fentanyl 25 mcg. 4 patients along with this medication also required spraying of the diaphragm with lignocaine 10 ml. 1 out of these 4 patients was converted to GA due to persistent shoulder pain. Operative difficulty was experienced in 2 (6.66%) patients, 1 patient was converted to GA because of the prolongation due to technical difficulty and other patient was given injection midazolam 1mg and fentanyl 25mcg.

In our study 3 patients (10%) had hypotension which was managed by giving infusion of crystalloids and injection ephedrine 6mg iv. Bradycardia was encountered in 3 patients (10%) and injection glycopyrrolate 0.02mg iv was given. All the above results were not statistically significant with a p value of >0.05.

Post-Operative Events	Spinal Anesthesia (n=30)	General Anesthesia (n=30)
Nausea / Vomiting	4	5
Respiratory Depression	0	1
Pruritus	1	0
Time for first rescue analgesia	160.13± 15.518 minutes	90±10minutes

Table 3: Showing post-operative events between two groups

Post operatively all the patients were monitored in the recovery room. Vitals like ECG, SPO₂, and NIBP were monitored. All the patients in both the groups were hemodynamically stable. Adverse/side effects were minimal in both the groups. 4 patients in spinal group experienced nausea and vomiting and 5 in general anesthesia, injection ondansetron 4mg were given i.v. 1 patient in GA group had respiratory depression and supplemental oxygen was given. All these above results were not statistically significant with p value > 0.05.

The time for first rescue analgesia was 160.13±15.518 minutes in spinal group and 90±10minutes in GA group which was statistically significant with p value of <0.01.

As for the questionnaire given to the patients in the spinal group on 2nd post-operative day, all the 30 patients responded. Regarding the comfort during the procedure 15 patients answered the question as very well, 9 patients answered the question as well, 4 patients answered the question as

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moderate and 2 patients answered the question as poor. 24 patients were happy with the procedure. 28 patients were satisfied about the technique and would recommend this to their friends.

All surgeons agreed that there was no problem with abdominal relaxation. Surgeons encountered little technical difficulty in 2 patients. They all stated there was no difference between spinal and GA for laparoscopic cholecystectomy.

DISCUSSION: Laparoscopic Cholecystectomy & regional anesthesia is relatively recent phenomenon with lot of work going in this direction. Laparoscopic Cholecystectomy traditionally has been performed under GA & regional anesthesia for Laparoscopic Cholecystectomy was performed in patients unfit to receive GA (mainly in patients with severe COPD).⁴⁻⁶ Regional Anesthesia has been used for Laparoscopy in healthy patients almost exclusively in combination with GA to extend the analgesic effect during early post-operative period. Luchetti et al in a randomized trial have found epidural combined with GA to be more effective in lessening post-operative pain in healthy patients compared to GA alone.⁷ Hamad et al used spinal anesthesia for Laparoscopic Cholecystectomy for the first time in a small series of healthy patients. In their study Nitrous Oxide was used instead of CO₂ for pneumoperitoneum.⁸ Van Zundert et al have described segmental thoracic spinal anaesthesia for Laparoscopic Cholecystectomy. This constitutes an even more specific method of anaesthesia for Laparoscopic Cholecystectomy.⁹

In the era of minimally invasive medicine regional anaesthesia have not gained popularity as the sole method of anaesthesia for laparoscopic procedures. Johnson noted that "all laparoscopic procedures are merely a change in axis & still requires GA, hence the difference from conventional surgery is likely to be small"¹⁰ This statement is based on assumption that laparoscopy necessitates endotracheal intubation to prevent aspiration, respiratory embarrassment secondary to the insufflations of Carbon Dioxide which is not well tolerated in patient who is awake during the procedure.⁵ Tzovaras G et al have shown the feasibility of performing safe & successful Laparoscopic Cholecystectomy with low pressure CO₂ pneumoperitoneum under spinal anaesthesia alone in healthy patients in symptomatic gall stone disease. They noted exceptionally minimal postoperative pain.^{11,12} Surprisingly with all this, regional anaesthesia for laparoscopy is used more commonly in patients unfit for GA & has not been much tested in healthy patients in whom any presumed risk would be theoretically much lower.^{4,5}

One of the major problems of laparoscopic cholecystectomy is severe right shoulder pain during operations.¹³ In our study out of 30 patients in the spinal group, 6 (20%) patients had right shoulder pain. 2 patients were given injection midazolam 1mg + fentanyl 25 mcg. 4 patients along with this medication also required spraying of the diaphragm with lignocaine 10 ml. 1 out of these 4 patients was converted to GA due to persistent shoulder pain. In the study conducted by Arati S et al¹⁴ 9(18%) patients experienced right shoulder pain, 2 patients were converted to GA and 4 patients were managed by giving injection tramadol. In a study conducted by Tzovaras et al²¹ (43%) patients experienced discomfort / right shoulder pain they were managed by giving injection fentanyl iv in 10 patients and remaining patients were managed without any intervention.¹²

Operative difficulty was experienced in 2 (6.66%) patients, 1 patient was converted to GA because of the prolongation due to technical difficulty and other patient was given injection midazolam 1mg and fentanyl 25mcg. Similar results were found in the studies of Arati S et al and Yusek Y N et al.^{3,13}

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Intraoperative hypotension and bradycardia is a common problem for patients undergoing laparoscopic cholecystectomy under spinal anaesthesia which can be managed effectively.^{9,14,15} In our study 3 patients (10%) in spinal group had hypotension which was managed by giving infusion of crystalloids and injection ephedrine 6mg iv. Bradycardia was encountered in 3 patients (10%) and injection glycopyrrolate 0.02mg iv was given.

Post-operative nausea and vomiting are relatively common after laparoscopic cholecystectomy under GA.¹⁶ In our study 4 patients in spinal group experienced nausea and vomiting and 5 in general anaesthesia, injection ondansetron 4mg were given i.v.

Post operatively pain was monitored by using VAS scale. In our study the time for first rescue analgesia was 160.13± 15.518 minutes in spinal group and 90±10minutes in GA group. It was managed by injection tramadol 50mg i.v. and injection paracetamol 1g iv infusion. Prolonged duration of analgesia was also found in studies of Sinha R et al and Bessa S S et al in the spinal group.^{6,15}

The answer to the questionnaire regarding the comfort during the procedure almost all patients were well satisfied and happy and would recommend the technique to their friends.

All surgeons agreed that there was no problem with abdominal relaxation. They all stated there was no difference between spinal and GA for laparoscopic cholecystectomy.

CONCLUSION: The results of our study encourages for further studies with a broader spectrum of patients. It appears that spinal anaesthesia is a reasonable alternate method for Laparoscopic cholecystectomy, which is feasible, safe and its associated with less post-operative pain without limiting recovery compared to general anaesthesia. However this approach requires co-operative patients, a skilled surgeon, a gentle surgical technique and an enthusiastic anesthesiologist. With proper refinements spinal anaesthesia could potentially evolve as a promising anaesthesia technique for elective laparoscopic cholecystectomy for healthy patients.

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