

# A prospective observational study to compare the efficacy and safety of spinal Vs general anesthesia for laparoscopic cholecystectomy

Subbiah V.<sup>1</sup>, Palaniappan S.K.<sup>2</sup>

<sup>1</sup>Dr. Venkatesh Subbiah, Assistant Professor. General Surgery, <sup>2</sup>Dr. Selva Kumar Palaniappan, Assistant Professor, Anaesthesia; both authors are affiliated with Velammal Medical College, Madurai, Tamil Nadu, India.

**Corresponding Author:** Dr. Selva kumar Palaniappan, Assistant Professor, Department of Anaesthesia, Velammal Medical College, Madurai. Velammal Village, Anuppanadi, Near Chinthamani Toll Gate, Madurai, Tamil Nadu, India, Email : selvakumarrevathy@gmail.com

## Abstract

**Background:** Laparoscopic cholecystectomy is usually performed under General anesthesia, but in recent times many studies have proposed spinal anesthesia as a cost-effective alternative mode of anesthesia, specially for resource poor settings with comparable efficacy, safety. But there is a scarcity of literature on the subject. Hence the current study was conducted with an objective of comparing the efficacy and safety of spinal anesthesia, as compared to general anesthesia.

**Materials and Methods:** The current study was prospective observational study, conducted in the department of general surgery and anesthesia, Velammal medical college, Madurai between April to December 2017. The study has included adult patients more than 18 years of age, with ASA grade I and II, posted for laparoscopic cholecystectomy. All the patients in the study period were administered with anesthesia as per their preference after explaining the pros and cons of each procedure. **Results:** A total of 73 subjects were included in the final analysis, with 28 subjects in spinal anesthesia group and 45 subjects in general anesthesia group. The median postoperative VAS score was statistically significantly lesser in spinal anesthesia group till 4-hour post-operative period, compared to general anesthesia group. After 4 hours the median VAS score was comparable between two groups. The ease of performing surgery score was similar in both the groups (2.63±0.62 in SA and 2.57±0.49 in GA, P value 0.647). The mean duration of surgery was also comparable between two groups (89.56±29.42 minutes in SA and 86.67±31.07minutes in GA, P value 0.694). Among the spinal anaesthesia group, 6(21.42%) had shoulder pain, 2(7.14%) had intraoperative nausea/vomiting, 9(32.14%) had hypertension. None of the GA group had intraoperative complications. The proportion of subjects with a post-operative headache was 25% and 17.78% in SA and GA group respectively (P value 0.61). The proportion of people with post-operative nausea and vomiting was 14.2% and 37.7% % in SA and GA groups respectively (P value 0.031). **Conclusions:** Spinalanaesthesia is a safe and effective alternative to general anaesthesia to perform laparoscopic cholecystectomy.

**Keywords:** Laparoscopic cholecystectomy, Spinal anaesthesia, Efficacy

## Introduction

Symptomatic gallstone disease is one of the most common disease encountered in surgical practice [1]. Hence cholecystectomy is one of the most common surgical procedures performed by surgeons globally and in India[2]. Considering the rapid rise in the prevalence of various risk factors for gallstonediseases like obesity, alcoholism, the incidence of the disease and number of surgeries has been on the rise in recent years[3]. Laparoscopic cholecystectomy has gradually replaced and emerged as the gold standard for surgical

management of symptomatic gallstone disease. As per reports as high as 98% of the cholecystectomies are being performed by this minimal access technique in some of the nations[4]. Various advantages like relatively lesser tissue dissection, lesser disruption of tissue planes, Lesser post-operative pain, Lower incidence of Intra and postoperative complications, early return to work and the Superior cosmetic outcome makes it an obvious choice over open cholecystectomy in the majority of the cases[5, 6].

Traditionally, the laparoscopic cholecystectomy has been performed under general anaesthesia [7]. But

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many studies in recent times have proposed spinal anaesthesia as a better alternative to general anaesthesia in terms of achieving better postoperative analgesia. Many studies have proposed it to be a more suitable alternative in resource poor settings like India, considering lower cost and possibility of shorter hospital stay[8-10] but there are some concerns regarding spinal anaesthesia including intraoperative shoulder pain, post spinal headache, post-operative nausea, and vomiting etc[11, 12]. Since the number of available studies on the subject is limited, clear evidence-based guidelines have not emerged in this regard. Hence there is a strong need for further studies on the subject, especially on the Indian population. In this background, the current study was conducted with the following objectives.

**Objectives**

1. To compare the efficacy of spinal anesthesia and general anesthesia in patients undergoing laparoscopic cholecystectomy
2. To compare the intra and postoperative complications between the two study groups

**Materials and methods**

**Study design:** Prospective observational study

**Study setting:** The study was conducted in the department of general surgery and department of anesthesia, Velammal medical college and Hospital, Madurai, which is a tertiary care teaching hospital.

**Study period:** The data collection for the study was done between April to December 2017.

**Study population:** The study population included patients, who were presenting to the department of general surgery OPD or emergency department subsequently posted for elective laparoscopic cholecystectomy.

**Inclusion criteria**

1. Adults aged more than 18 years
2. Both genders
3. ASA grade I and II
4. Clinically and radiologically confirmed cases

**Exclusion criteria-** Children below 18 years

All the patients were selected for the study by convenient sampling. The choice of anesthetic technique was based on the participants choice, after explaining the advantages and disadvantages of each

anesthetic technique and the cost. Any patient who had a prior contraindication for any of the anesthetic technique were excluded from the study.

**Ethical considerations:** The study was approved by Institutional Human ethics committee. Informed written consent was obtained from all the study participants after explaining the risks and benefits of participation in the study. Confidentiality of the personal data has been maintained throughout the study.

**Study procedure:** After obtaining the informed written consent, all the patients had detailed preoperative evaluation and preparation for surgery as per the standard hospital protocol. All the necessary hemodynamic parameters like Blood Pressure, SpO2 and heart rate were monitored in the pre-operative room and necessary medication was administered.

The spinal anesthesia was performed in sitting posture. Lumbar puncture was done with a 25 gauge spinal needle in the L2-L3 intervertebral space following infiltration with a local anaesthetic. Following this intrathecal injection of 0.5% bupivacaine (3ml) and 25 micrograms of Fentanyl was done. After putting the patient in supine position and achieving sensory block at the T4 level, the approval was given to perform surgery. If the patient did not achieve T4 level sensory block after 5 minutes of supine position, Trendelenburg position was attempted and if at the end of 20 min if adequate sensory block level was not achieved, the patient was converted to GA.

All necessary haemodynamic parameters were measured intra operatively for every 5 minutes and if the mean arterial blood pressure (MAP) declined more than 20% below the pre-anesthetic level, it was labeled as intraoperative hypotension and managed with intermittent incremental iv boluses of Ephedrine 5mg. If any patient complained of shoulder pain during the course of surgery, was managed with 25mcg fentanyl iv bolus repeated at every 5 minutes, till a maximum dose of 50mcg. GA was induced on the persistence of severe pain despite a maximum dose of fentanyl.

Following pre-oxygenation, the General anaesthesia group has received induction with Propofol (2mg/kg), Fentanyl (2mcg/kg,) and Atracurium (0.5mg/ kg). All subjects were intubated after 3min of ventilation and were maintained with air oxygen mixture enriched with Isoflurane (0.6-1.5%) and controlled mechanical ventilation. The surgery was performed by keeping the patients in a supine, reverse Trendelenburg position

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with the arms fully abducted minimal possible tilt to facilitate exposure of the gallbladder. Pneumoperitoneum was set at a pressure of 12mmHg, initial insufflation of Carbon Dioxide (CO<sub>2</sub>) was done at a low flow rate (2L/min) and gradually increased to 5L/min. The surgery was performed using standard four-trocar technique using a zero-degree optical scope. Gallbladder dissection was done as per standard protocol starting from Calot's triangle. Following surgical removal of the gallbladder, the subhepatic drain was placed, as per standard institutional protocol.

**Statistical methods:** The data were analyzed using IBM SPSS statistical software version 21. Descriptive analysis was done using mean and standard deviation

## Results

A total of 73 subjects were included in the final analysis, with 28 subjects in spinal anesthesia group and 45 subjects in general anesthesia group.

**Table-1: Comparison of baseline characteristics of the study population**

Parameter	Group 1 (Spinal) (N=28)	Group 2 (General) (N=45)	P value
Age	46.23±8.36	48.46±10.21	0.335
<b>Gender</b>			
Female	19(67.85%)	31(68.8%)	0.939
Male	9(32.15%)	14(31.11%)	
<b>BMI</b>	28.12±4.53	27.65±5.31	0.698
<b>Presenting Symptom</b>			
Pain abdomen	27(96.42%)	45(100%)	*
Vomiting	20(71.42%)	36(80%)	0.399
Fever	15(53.57%)	20(44.44%)	0.447
Jaundice	13(46.42%)	19(42.22%)	0.724
<b>Presence of co-morbidities</b>			
Diabetes mellitus	11(39.28%)	17(37.77%)	0.901
Hypertension	8(28.57%)	12(26.66%)	0.860
<b>ASA grade</b>			
ASA grade I	23(82.15%)	36(80%)	0.821
ASA Grade II	5(17.85%)	9(20%)	

\*No statistical test was applied- due to 0 subjects in the cells.

Among the study population, the mean age of spinal anaesthesia group was 46.23±8.36 and 48.46±10.21 in general anaesthesia group. The difference between age and study groups was statistically not significant (P value 0.335). In both, the study groups the proportion of females was almost double as that of males, but no statistically significant differences were found between two groups. No statistically significant differences were found between the two study groups, in terms of Anthropometric parameters, presenting symptoms, the presence of comorbidities and ASA grade (Table 1)

**Table-2: Comparison of baseline characteristics of the study population.**

Parameter	Group 1 (Spinal)(N=28)	Group 2 (General)(N=45)	P value
Ease of operating conditions	2.63±0.62	2.57±0.49	0.647
Duration of surgery in minutes	89.56±29.42	86.67±31.07	0.694
<b>Other Intraoperative events</b>			
Shoulder pain	6(21.42%)	0(0.00%)	*
Intraoperative nausea/Vomiting	2(7.14%)	0(0.00%)	*
Hypotension	9(32.14%)	0(0.00%)	*
Conversion to GA	0(0.00%)	NA	*

\*No statistical test was applied- due to 0 subjects in the cells.

Among the mean ease of operating conditions of spinal anaesthesia group was 2.63±0.62 and among the general anaesthesia group, 2.57±0.49. The difference between study groups and ease of operating conditions was statistically not significant (P value 0.647).

Among the mean duration of surgery of spinal anaesthesia group, was 89.56±29.42 and among the general anaesthesia group, 86.67±31.07. The difference between study groups and duration of surgery was statistically not significant (P value 0.694). Among the spinal anaesthesia group, 6(21.42%) had shoulder pain, 2(7.14%) had intraoperative nausea/vomiting, 9(32.14%) had hypertension. (Table 2)

**Table-3: Comparison of Post-operative analgesia and use of adjuvant analgesic between two study groups**

Postoperative analgesia (As assessed by VAS score)	Group 1 (Spinal) (N=30)	Group 2 (General) (N=30)	P value
Immediate post-operative period	0 (0, 1)	3(2, 6)	<0.001
30 minutes	0 (0, 1)	3 (2, 6)	<0.001
60 minutes	0 (0, 1)	4 (2, 7)	<0.001
90 minutes	0 (0, 1)	4.5 (2, 8)	<0.001
120 minutes	1 (1, 2)	4.5 (2, 8)	<0.001
4 hours	2 (1, 3)	4.5 (2, 8)	<0.001
8 hours	3.5 (2,5)	4 (2, 7)	0.326
10 hours	4 (2,6)	3.5(2, 6)	0.412
12hours	5 (2, 8)	4.5 (2,8)	0.512
24 hours	4.5 (2,8)	4.5 (2,8)	1

Among the spinal anaesthesia median VAS was 0(IQR0 to1) at immediate post-operative period, 0(IQR0 to 1) at 30 minutes, 0(IQR 0 to 1) Of 60 minutes, 0(IQR0 to 1) of 90 minutes, 1(IQR1 to 2) Of 120 minutes, 2(IQR 1 to30) of 4 hours, 3.5 (IQR 2 TO 5) OF 8 hours, 4 (IQR 2 to 6) Of 10 hours, 5(IQR 2 to 8) of 12 hours, 4.5(IQR 2 to 8) of 24 hours. Among the general anaesthesia median was 3(IQR 2 to 6) of immediate post-operative period, 3(IQR 2 to 6) of 30 minutes, 4(IQR 2 to 7) Of 60 minutes, 4.5(IQR 2 to 8) of 90 minutes, 4.5(IQR 2 to 8) of 120 minutes, 4.5(IQR 2 to 8) of 4 hours, 4 (IQR 2 to 7) of 8 hours, 3.5(IQR 2 to 6) of 10 hours, 4.5(IQR 2 to 8) of 12 hours, 4.5(2 to 8) Of 24 hours pre-operative analgesia.

The difference across study groups and immediate post-operative period,30,60,90,120 minutes,4 hours were statistically significant (P value <0.001),The difference across study groups and 8,10,12,24 hours' post-operative analgesia was statistically not significant (P value >0.05) (Table 3).

**Table-4: Incidence of various post-operative complications between two study groups.**

Post operative Complications	Group 1 (Spinal)(N=28)	Group 2 (General)(N=45)	P value
Post-operative headache	7(25%)	9(17.78%)	0.61
Post-operative nausea and vomiting	4(14.2%)	17(37.78%)	0.031
Post-operative wound sepsis	0(0.00%)	0(0.00%)	ND

\*ND+ not done as the data did not satisfy assumptions required to carry out chi square test/Fisher's exact test

Among the spinal anaesthesia group, 7 (25%) people had a post-operative headache, which was 9 (17.78%) in general anaesthesia group and the difference was statistically not significant (P value 0.61). The proportion of people with post-operative nausea and vomiting was 14.2% and 37.7% % in SA and GA groups respectively, with a statistically significant difference (0.031). None of the subjects in either of treatment groups had postoperative wound sepsis (Table 4).

## Discussion

Laparoscopic Cholecystectomy has emerged as the safe and effective choice over open cholecystectomy in recent years. Even in developing countries, a major portion of cholecystectomies is being performed laparoscopically [5].

In the current study, the operating time and ease of operating conditions and duration of hospital stay etc were comparable between both spinal and general anaesthesia groups. These findings were in line with the majority of the published literature on the subject. None of the subjects in spinal anaesthesia group required conversion to general anaesthesia. Tzouvaras, G., et al.[13] In one of the first pilot study on the feasibility of spinal anaesthesia for Laparoscopic cholecystectomy have reported 100% successful execution. Yuksek, Y. N., et al.[12], have reported a conversion rate of 11.53% of cases to general anaesthesia due to severe right shoulder pain. Developed during spinal anaesthesia. Gautam, B et al[8] have reported the failure very minimal operative difficulty. In a study by Sinha, R., et al[10] among laparoscopic cholecystectomy cases done under spinal anaesthesia, 0.52% patients required a conversion to GA. There were no differences between two study groups in operating time and other operative parameters.

In the current study, The spinal anaesthesia had resulted in better postoperative analgesia, especially in the first 4-hour post-operative period. The overall analgesic requirement was also lesser in this group, as compared to general anaesthesia. Tzouvaras, G., et al.[13] have reported a postoperative median pain scores ranging from 1 to 1.5, with no major complications with spinal anaesthesia.

Similar to current study findings, Tzouvaras, G., et al. [14] in another study have reported that significantly

lower pain until 4 hours. But in contrast to the current study, the superior pain relief with spinal anaesthesia had continued till 24 hours. In a study by Sinha, R., et al.[10] the overall post-operative injectable analgesic requirement was 34.36% and 91.45% in SA and GA groups respectively, indicating superior pain relief with SA. Bessa, S. S., et al.[15] have also reported similar findings to the current study, where for the first 2 to 4 hours, the mean pain scores were significantly lesser with spinal anaesthesia, as compared to general anaesthesia. The analgesic requirement in the first postoperative day was also significantly lower in SA group. Imbelloni, L. E., et al. [16] have reported significantly lower pain with spinal anaesthesia in the first 6 hours following surgery.

In the current study, among the spinal anaesthesia group, 6(21.42%) had shoulder pain, 2(7.14%) had intraoperative nausea/vomiting and 9(32.14%) had hypertension. None of the subjects in general anaesthesia group had the above-mentioned complications. In a study by Yuksek, Y. N., et al.[12], out of 26 patients attempted for laparoscopic cholecystectomy under SA, 3 patients needed conversion to general anaesthesia due to severe right shoulder pain. No major cardiopulmonary problems were reported by this study except transient hypotension Intra operatively. But almost 50% of the subjects had reported severe right shoulder pain, needing treatment by fentanyl, local washing of the right diaphragm with 2% lidocaine solution. As per a study by Gautam, B et al [8] the problems reported in the spinal anaesthesia group were shoulder pain intraoperatively requiring treatment with by Fentanyl and anxiety treated by midazolam. In a study by Sinha, R., et al[10] among laparoscopic cholecystectomy cases done under spinal anaesthesia, the most common issues occurred during the intraoperative period were hypotension requiring



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treatment in 20.05% of patients and, neck and/or shoulder pain in 12.29% of patients. Which was similar to current study findings. In a study by Kumar, A et al[9] commonest complaint reported was a pain in right shoulder and anxiety at the beginning of operation/pneumoperitoneum. In the current study Among the spinal anaesthesia group, 7(25%) people had a post-operative headache, which was 9 (17.78%) in general anaesthesia group and the difference was statistically not significant (P value 0.61). The proportion of people with post-operative nausea and vomiting was 14.2% and 37.7% in SA and GA groups respectively, with a statistically significant difference (0.031). None of the subjects in either of treatment groups had postoperative wound sepsis. Tzovaras, G., et al[14] in contrast to current study have reported comparable post-operative complication rate between spinal and general anaesthesia. In a study by Sinha, R., et al[10] post-operative nausea and vomiting were present in 2.29% in SA group against 30.30% in GA. A postural headache was reported in 5.9% of patients following SA.

A randomized controlled trial by Bessa, S. S., et al[17] have reported higher proportion (8.8 % Vs 0%) of subjects in GA group requiring anovernight post-operative stay, as they had nausea and vomiting, inadequate pain control and unexplained hypotension.

Imbelloni, L. E., et al[16] have reported significantly lower pain with spinal anaesthesia in the first 6 hours following surgery. They have also specified the cost of spinal anaesthesia to be considerably lower as compared to GA and proposed it to be a more suitable option in resource-limited settings.

**Conclusions**

1. The spinal anaesthesia had resulted in better postoperative analgesia, especially in the first 4-hour post-operative period. The overall analgesic requirement was also lesser in this group, as compared to general anaesthesia.
2. The incidence of some of the intraoperative complications like shoulder pain and intraoperative hypotension, nausea, and vomiting were slightly higher in spinal anaesthesia group. A post-operative headache also was slightly higher in spinal anaesthesia group.
3. The incidence of postoperative nausea and vomiting was higher in general anaesthesia group.
4. The operating time, operating conditions and post-operative stay were comparable between two groups.

**Limitations:** Since the study participant selection was not randomly done, the role of selection bias and the effect of potential unknown confounding factors and the magnitude and direction of their effect could not be estimated

**Recommendations:** There is a need for large-scale randomized controlled trials on the subject to generate more evidence on the subject to guide informed clinical decision making. Till such time the choice of anaesthesia should be made by carefully weighing the risks, benefits, cost of the procedure and patient preferences into consideration.

**What this study adds to existing knowledge:** The study further strengthens the evidence existing regarding the comparative efficacy and safety of spinal anaesthesia in patients undergoing laparotomy.

The study findings prove that the spinal anaesthesia can be used safely for laparoscopic cholecystectomy and achieve comparative efficacy, without any undue adverse effects. The study findings assume greater importance due to scarcity of studies on the subject in Indian population.

**Author Contribution**

**Author 1:** The first author has conceptualized the study, participated in developing appropriate study protocol, involved in all stages of the study from the design, data collection, data analysis, preparation and review of the drafts to submission of the manuscript for publication.

**Author 2:** The second author had provided a supportive role data collection, data entry. He had contributed to the preparation of the draft manuscript, editing of the drafts and also was involved in doing necessary modifications to the drafts as per reviewer's inputs.

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