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## Original Research Article

# Laparoscopic cholecystectomy under spinal anesthesia with intravenous sedation, its feasibility, safety, cost effectiveness and outcome: A prospective observational study

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### Abstract

**Introduction:** Gallstones disease is one of the most common problems seen in surgical OPD requiring laparoscopic cholecystectomy in symptomatic patients. Routinely all laparoscopic surgeries are performed safely under general anesthesia, and practice of using spinal anesthesia is very less as most of patients experience shoulder discomfort. To alleviate the shoulder discomfort use of intravenous sedation can be implemented.

**Aims and Objectives:** To perform Laparoscopic cholecystectomy safely under spinal anesthesia with i.v sedation for symptomatic gallstones diseases, and to assess the analgesic effect of the procedure in the early post-operative period, Safe completion of surgery and operative time and inoperative events.

**Materials and Methodology:** It is a prospective observational study where in 50 patients who presented with biliary colic meeting the inclusion criteria were enrolled. All patients underwent hematological and biochemical investigations, appropriate investigation (LFT, USG, and chest x ray, CT scan / MRCP if needed) were performed based on clinical suspicion. All patients underwent pre-anesthetic evaluation and patients belonging to ASA grade 1 and 2 were taken up for surgery under standard lumbar spinal anesthesia technique with additional intravenous ketamine as sedation.

**Results:** Spinal anesthesia with i.v sedation was adequate for surgery in all the 50 patients (100%) with none of patients requiring to convert to general anesthesia (100%) Intraoperatively two out of fifty (4%) patients experienced right shoulder pain. Two patients (4%) were given Midazolam for anxiety and one (2%) was given Ephedrine for hypo tension. One patient (2%) had desaturation for which high oxygen was given. Operative difficulty scores were minimal and none of them requiring to convert for open cholecystectomy (100%). Post operatively pain scores were minimal and four patients demanded opioid (20%). One patient (2%) required anti-emetic for vomiting and no patient suffered headache (0%) and urinary retention (0%). 34 patients (68%) were discharged within 24 hours of surgery and patient satisfaction scores were very good.

**Conclusion:** This study suggest that laparoscopic cholecystectomy can be performed safely under spinal anesthesia with intravenous sedation in ASA grade 1&2 patients providing good analgesia and muscle relaxation in intra operative period and post-operative analgesia and helps in early recovery.

**Keywords:** Laparoscopic cholecystectomy, spinal anesthesia, ketamine

### Introduction

In 1985, Professor Dr. Eric Muhe of Germany performed the first laparoscopic cholecystectomy and hence opened a new horizon in the management of cholelithiasis. He selected a fairly well preserved with no comorbidity patient for the procedure. However, as experience gained, even the high risk category patients otherwise candidates for conventional cholecystectomy were subjected for laparoscopic cholecystectomy under general anesthesia<sup>[1]</sup>. Until recently the choice of anesthetic technique for laparoscopic cholecystectomy was mostly limited to general anesthesia with muscle paralysis, tracheal intubation and intermittent positive pressure ventilation.<sup>1</sup> Laparoscopic cholecystectomy under spinal anesthesia alone has been reported only occasionally in the past; which included patients unfit to receive general anesthesia, mainly patients with severe chronic obstructive airway disease<sup>[2, 3]</sup>. Hamad and Ibrahim El-Khattary used spinal anesthesia for laparoscopic cholecystectomy for the first time in a small series of healthy patients but they used nitrous oxide as a pneumo peritoneum instead of standard carbon dioxide<sup>[4]</sup>.

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Recently it has been shown that laparoscopic cholecystectomy can be performed successfully under spinal anesthesia in healthy patients with symptomatic gall stone disease using carbon dioxide pneumo peritoneum. Even many researchers have observed that performing laparoscopic surgery under spinal anesthesia carries many advantages. The reduction of surgical stress response is considered as one of its major advantages. This is achieved successfully through two aspects, the laparoscopic technique, itself reduces the degree of tissue trauma and consequently the injury response and the spinal analgesia itself provides pain relief by blocking afferent neural block together with block of various humoral mediator cascade systems. Avoidance of airway instrumentation and lower incidence of deep vein thrombosis are other important advantages of this technique<sup>[4]</sup>. Most of these studies used intra operative perihepatic infiltration as a post-operative analgesic effect and to prevent intra operative shoulder discomfort. However, none of them used intravenous sedation for the same. The objective of the study is to prove that spinal anesthesia with intravenous sedation has the advantage of providing good analgesia and muscle relaxation and rapid postoperative recovery in laparoscopic cholecystectomy. In addition, there is a protection against the intubation related complications of general anesthesia.

### Aims and Objectives

#### Aim

To perform Laparoscopic cholecystectomy safely under spinal anesthesia with intravenous sedation.

#### Objectives of study

##### Primary

1. Safe completion of surgery
2. Analgesic effect of the procedure in the early post-operative period.
3. 3) Surgery time and intra operative events

##### Secondary

1. Intra operative and post-operative complications
2. Duration of hospital stay
3. Cost effectiveness

### Materials and Methods

This is a prospective observational study conducted in the department of general surgery, Tertiary teaching hospital, Shivamogga, Karnataka.

### Study population

The study population consists of 50 patients aged between 18 to 70 years of either sex with ASA physical status 1 & 2 posted for elective laparoscopic cholecystectomy.

### Sample size estimation

Sample size was estimated by using the incidence of shoulder pain (Most common complication) in patients undergoing laparoscopic cholecystectomy under spinal anesthesia with intravenous sedation as 12.29% from the study by Sinha R *et al.*<sup>5</sup> using the formula

$$\text{Sample size} = Z_{1-\alpha/2}^2 p(1-p) / d^2$$

Here  $Z_{1-\alpha/2}$  is standard normal variant (at 5% type 1) error ( $P < 0.05$ ) It is 1.96 and at 1% type 1 error ( $P < 0.01$ ) It is 2.58) as in majority of studies P values are considered significant

below 0.05 hence 1.96 is used in formula

P= Expected proportion in population

D= Absolute error or precision- Has to be decided by researcher

P = 12.29

q = 87.71

d = 10%

Using the above values at 95% Confidence level a sample size of 42 subjects undergoing spinal anesthesia with sedation for Laparoscopic cholecystectomy will be included in the study. Considering 20% Non-responsive a sample size of  $42 + 8.4 = 50$  subjects will be included in the study.

### Study duration

24 months

### Inclusion criteria

#### Patients with

1. American Society of Anesthesiologists physical status 1, 2
2. symptomatic gall stone disease
3. Age between 18 and 70 years of age.
4. Passed out CBD stones with symptomatic gall stones.
5. Resolved biliary pancreatitis
6. Patient who underwent ERCP for CBD stones
7. Patients with above disease with controlled diabetes, hypertension and mild COPD

### Exclusion criteria

#### Patients with

1. Ongoing complications like acute cholecystitis /biliary pancreatitis/empyema/perforated gall bladder/collection.
2. Anxiety prone patient
3. Bleeding diathesis and platelet count less than 1,00,000.
4. Local spinal deformity which precluded safe spinal anesthesia
5. Post per cutaneous cholecystectomy.
6. Uncontrolled diabetes mellitus, cardio respiratory compromise.
7. Patients who underwent previous laparotomy.
8. Obesity with BMI > // 30

### Methodology

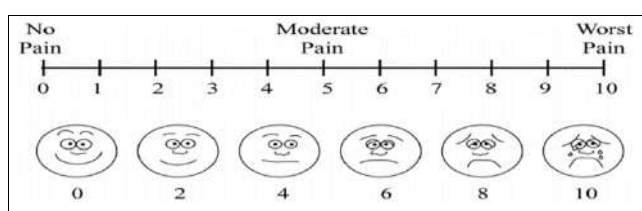
This study consists of 50 patients, with symptomatic gall stone disease with satisfied inclusion criteria included. History and physical examination was performed in all patients and recorded in the questionnaire. Complete hemogram, Liver function test and ultrasound abdomen were done in all cases. CT scan and MRCP were performed in selected patients according to suspected disease. Later patients were subjected for laparoscopic cholecystectomy under spinal anesthesia with intravenous ketamine (1mg/kg) sedation after getting fitness from the anesthetist. An informed consent was taken. All patients were nil per orally for 6 hours for solids and 2 hours for clear liquids prior to surgery. On receiving the patient to operating room, an intravenous line was secured with 18 gauge (G) canula, inj. Glycopyrrolate (4 mcg/kg), inj. Ondansetron(0.1mg/kg), inj. Ranitidine (1mg/kg) was given to all patients intravenously on arrival to the operation theater prior to induction. The patient was placed in the right lateral decubitus position. Under strict aseptic precautions lumbar puncture was performed at L3-L4 inter vertebral space with 26G quincke needle using the median approach<sup>[6]</sup>. After free flow of clear cerebrospinal fluid, Inj. 0.5% hyperbaric bupivacaine 3.2ml was injected at 0.2ml/sec<sup>[7]</sup>. Patient was made to lie down supine, pneumo peritoneum with

CO<sub>2</sub> was created in a standard technique. During creation of pneumo peritoneum anesthetist was asked to administer intravenous ketamine (1mg/kg) and was repeated if patient was having discomfort in the intra operative time.

Ketamine is a dissociative anesthetic agent that has analgesic properties in sub anesthetic doses [8, 9]. Ketamine is the most potent NMDA-receptor-channel blocker available for clinical use, binding to the phencyclidine site when the channels are in the open activated state [10].

In a standard manner laparoscopic cholecystectomy was performed and intra operative findings were monitored. Intra operative drainage of gall bladder fossa for those needy patients was monitored. Hemodynamic changes like Blood pressure, respiratory rate (RR), Heart rate (HR), SPO<sub>2</sub> was monitored at 15 min, 30min and 1 hour. Post operatively patients pain score was monitored using visual analogue score (VAS) at 2, 4, 8, 12, 24 hours and as a standard practice. I.V Paracetamol (dose 1000mg) 8<sup>th</sup> hourly and I.V Diclofenac sodium 75mg 12<sup>th</sup> hourly was administered to all the patients along with required antibiotics. Use of narcotics like I.V Tramadol was restricted on demand basis and was noted. Any post-operative complications during hospital stay were noted.

**0-10 VAS Numeric Pain Distress Scale [11]**

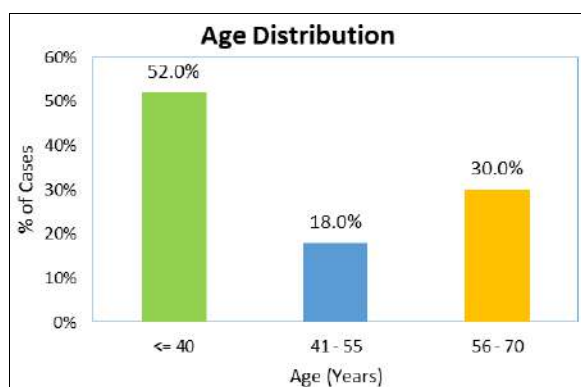


- Score 0-2 no pain
- Score 2-4 mild pain
- Score 4-6 moderate pain
- Score 6-8 severe pain

**Statistical analysis**

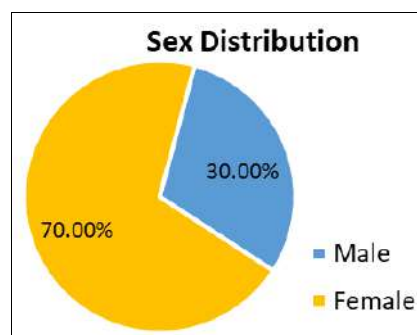
Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Chi-square test was used as a test of significance for qualitative data. Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram and pie diagram. Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

**Observation and Results**

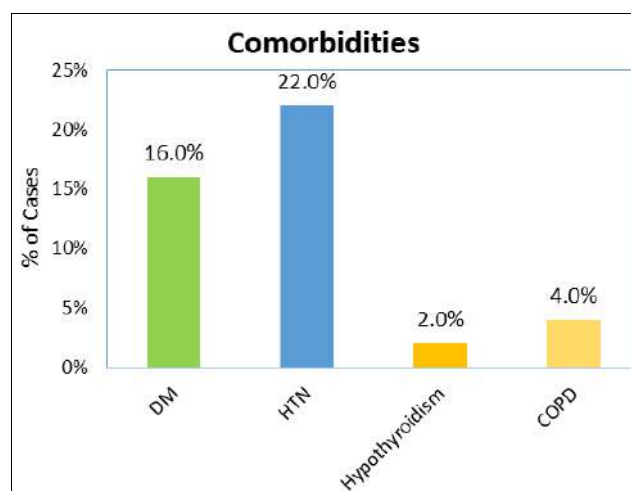


**Fig 1:** Bar diagram showing age distribution

Above diagram shows percentage of study population under 40yrs are 52%, between 40 and 55 are 18% and between 56 to 70 are 30%.



**Fig 2:** Pie diagram showing gender wise distribution

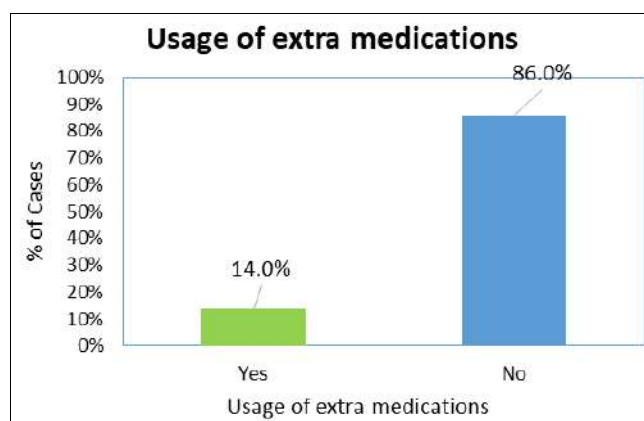


**Fig 3:** Percentage of patients with co-morbidities

This bar diagram shows 16% of study population had diabetes mellitus, 22% had hypertension and 2% had COPD.

**Table 1:** Percentage of population with altered LFT

Liver Function Test	No. of Subjects	Percentage
Altered	6	12.0%
Normal	44	88.0%
Total	50	



**Fig 4:** Bar diagram showing usage of extra medications

This bar diagram represents the number of percentage of study population requiring extra medications like Inj. Ephedrine and Inj. Phenylephrine for hypo tension intra operatively and 25% dextrose for hypoglycemia along with spinal anesthesia and I.V

sedation. Only 14% of study population received extra medications.

**Table 2:** Intra operative anesthetic complications

Anesthetic Complications	No. of Subjects	Percentage
Yes	6	12.0%
No	44	88.0%
Total	50	

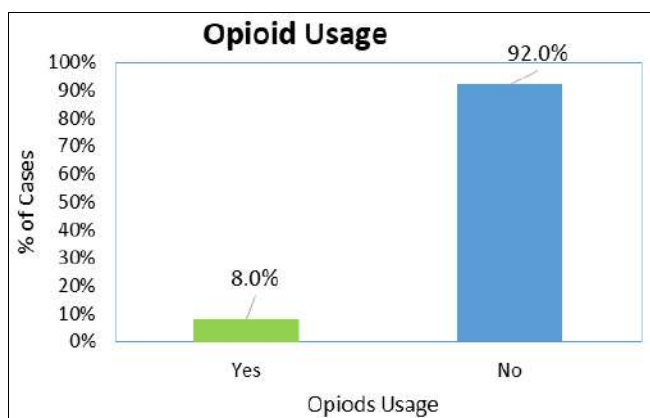
Above table represent only 12% developed intra operative anesthetic complications like bradycardia, hypo tension, desaturation, however 88% of patients did not have any Intra operative anesthetic complications

Our study shows only 2 patients (4% of study population) required intra operative drain placement in the gallbladder fossa. Study also shows only 1 patient (2% of population) had nausea and vomiting post operatively and 98% had no such complication. Urinary retention is one of the postoperative complications in spinal anesthesia, however in our study none of the patient had urinary retention.



**Fig 5:** Pie diagram showing % of study population with shoulder pain

This pie diagram represents that only 4% patients suffered shoulder discomfort and 96% had no shoulder discomfort which was statistically significant.



**Fig 6:** Bar diagram showing opioid usage

This bar diagram shows only 8% of study population required opioid (Tramadol) usage and remaining 92% of study population

did not require any opioid in postoperative period. The below table shows mean age in years is 43.64, mean duration of surgery is 61.90 minutes and mean day of discharge is 1.38

**Table 3:** Showing mean age in years, duration of surgery and day of discharge

		Age (Years)	Duration of Surgery (Mins)	Post-Operative Day of Discharge
N	Valid	50	50	50
	Missing	0	0	0
Mean		43.64	61.90	1.38
Std. Error of Mean		2.262	2.338	.099
Median		39.00	60.00	1.00
Std. Deviation		15.997	16.534	.697
Minimum		18	40	1
Maximum		70	120	4

We monitored variations in blood pressure intra operatively both systolic and diastolic at every 15min, 30 min and 1 hour, which showed mean systolic blood pressure are 129.58, 113.92 and 115.76 respectively (which was not statistically significant) and diastolic pressure are 79, 68.36 and 67.9 respectively. As p value is <0.001 there is significant difference in diastolic blood pressure intra operatively.

**Table 4:** Showing mean diastolic blood pressure

DBP	Mean	Std. Deviation
15Mins	79	10.204
30Mins	68.36	11.883
1Hr	67.9	8.774

P Value <0.001

Similarly monitoring of heart rate done at every 15 min, 30min and 1 hr interval shows mean heart rate is 84.06, 80.62 and 78.92 respectively which showed some differences but not statistically significant (As p value is 0.006).

Even oxygen saturation when monitored did not reveal any significant differences (As p value is < 0.322) throughout intra operative period, similarly respiratory rate did not reveal any significant differences (As p value is < 0.291) intra operatively.

**Visual Analogue Scale (VAS)**

**Table 5:** Showing VAS score in study population in postoperative period

VAS	Mean	Std. Deviation
2Hr	0.9	1.474
4Hr	2.52	1.313
6Hr	3.12	0.689
12Hr	3.04	0.533
24Hr	2.18	1.38

P Value <0.001

Above table shows mean VAS score at 2 hrs of post operative period was 0.9, 4hr was 2.52, 6hr was 3.12, 12hr was 3.04 and 24hr was 2.18 with p value <0.001 showing significant postoperative analgesia in early post operative period.



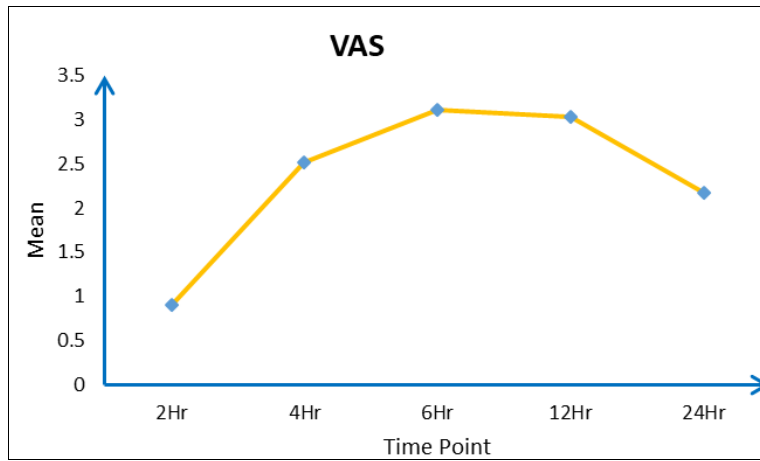


Fig 7: Graphical representation of VAS score

Table 6: Showing drugs and materials used in spinal anesthesia and its charges

Drugs and materials	Cost (in rupees)
0.5% Hyperbaric Bupivacaine	27.50
Inj. Glycopyrolate	13.70
Inj. Ondansetron	13.12
Inj. Ranitidine	5.44
Ephedrine	33
Ketamine	45
Atropine	4
Spinal needle 26G quincke	170
Total cost	372

Table 7: Showing drugs used in general anesthesia and its charges

Drugs	Cost (in rupees)
0.25% Bupivacaine{ Local Infiltration}	54
Isoflurane	656
Midazolam	16
Neostigmine	9
Atropine	4
Ephedrine	30
Glycopyrolate	99
Propofol	344
Suxamethonium chloride	50
Vecuronium	181
Endotracheal tube	200
Breathing circuit	980
Total cost	2623

According to above tables the approximate cost of drugs and materials used in most of the patients for spinal anesthesia and general anesthesia are 372/- and 2623/- respectively showing significant differences.

Table 8: Mean hospital stay in post-operative period

no of patients	Hospital stay	Percentage
34	24hrs	68
14	48hrs	28
2	84hrs	4

Mean hospital stay is 1.38 days

The above table shows in the post operative period out of 50 patients 68% of study population are discharged with in 24hours, 28% in 48hours and 4% in 84hrs.

**Discussion**

Following the advent of laparoscopic surgery with its

accompanying smaller incisions, less pain and shorter hospitalization, surgeons have performed an increasing number of laparoscopic cholecystectomies. Most of the cholecystectomies are performed for biliary colic. Laparoscopic cholecystectomies are conventionally performed under general anesthesia. But now a days spinal anesthesia is given in patients who are not only contraindicated for general surgery but also for patients with ASA grade I and grade II with minimal complications. The advantages are uniform like total muscle relaxation, relatively uneventful recovery and post operative analgesic effect after spinal anesthesia on the one hand and the protection from potential complications of general anesthesia on the other, were the main reasons for selecting spinal anesthesia as the first choice [12, 13, 14, 15].

In our study we present our experience using spinal anesthesia with intravenous sedation with ketamine as the first choice for laparoscopic cholecystectomies with the intention that it is a good alternative to general anesthesia. Spinal anesthesia for laparoscopic cholecystectomies was used in 50 patients who satisfied the inclusion criteria over the last 2 years. There was no modification in the technique of laparoscopic cholecystectomy and the intra-abdominal pressure was kept between 13 to 15mm Hg. Intra venous sedation with ketamine (1mg/kg body weight) was given in all the patients. Conversion to general anesthesia was not needed in any of our patients and conversion to open surgery was also not needed in any patient. Perioperative events were monitored. Blood pressure, heart rate, respiratory rate, saturation noted at 15min, 30min and 1 hr. Patients in which operative time exceeded 1hour, hemodynamic parameters were monitored at 30 min interval till the completion of surgery. Anesthetic and surgical complications like hypo-tension, Brady or tachycardia, desaturation, hypoglycemia, shoulder pain, nausea and vomiting were noted. Usage of rescue fentanyl and other medications were monitored.

Post-operative events were also monitored for pain using visual analogue scores at 2, 4, 8, 12, 24 hours and usage of narcotics in required patients were noted. Spinal anesthesia complications like nausea, vomiting, shoulder discomfort and urinary retention were monitored. In our study none of the patient were converted to general anesthesia (100% success) and none of them were converted to open surgery (100% success rate). 14% of study group required extra medications like ephedrine, phenylephrine, atropine, dextrose. 12% of patient experienced anesthetic complications like transient hypo tension, bradycardia. For hypo tension inj. ephedrine i.v was given in the incremental bolus dose of 5mg. Out of it one patient experienced desaturation for which 100% oxygen along with bag and mask ventilation given

for 5 minutes and recovered hence not required to convert for general anesthesia. Only 4% of study group had Perioperative shoulder discomfort for which inj.fentanyl 1mcg/kg i.v was given. Mean Systolic & diastolic BP, heart rate, respiratory rate and saturation when monitored at 15min, 30min and 1 hr did not show any significant differences. 2% of population had post-operative nausea and vomiting which was treated with Inj. Ondansetron 0.1mg/kg i.v. None of the patient had urinary retention in post operative period. 8% of patients required opioid (Inj. Tramadol 50mg i.v) usage in the post operative period

### Shoulder discomfort

In our study, all the patients were given spinal anesthesia with i.v sedation using ketamine, most of the patients did not experience shoulder discomfort/pain. Only 4% (2 patient) of the study population had intra operative shoulder discomfort for which they received inj. Fentanyl (1mcg/kg) intra-operatively. Kumar A *et al.*,<sup>[16]</sup> conducted a study with the title Laparoscopic cholecystectomy under spinal anesthesia only, a prospective study to evaluate the efficacy, safety and cost benefit. In their study, all patients underwent laparoscopic cholecystectomy without any major complications. None had to be converted to general anesthesia. However the commonest complaint was pain in the right shoulder (up to 40%) and anxiety at the beginning of operation/pneumo peritoneum. All patients were highly or well satisfied during follow up. They concluded that Laparoscopic cholecystectomy can be performed under spinal anesthesia which can be used as a routine anesthesia of choice, which will be feasible, safe, was cost-effective, with minimal postoperative pain and smooth recovery; the disadvantage being right shoulder pain following pneumo-peritoneum (40%).

In the above mentioned study 40% of study population had right shoulder pain but in our study only 4% of study population had shoulder pain which may be due to our usage of intravenous ketamine intra operatively along with spinal anesthesia.

### Post operative analgesia, vomiting and urinary retention

In the post operative period of our study group, Visual analogue score (VAS) in 2, 4, 8, 12, 24 hrs are 0.9, 2.52, 3.12, 3.04 and 2.18 respectively with p value < 0.001 indicating significant analgesia in the early postoperative period. Goutham *et al.*<sup>[17]</sup> conducted a study with the title "feasibility and safety of SA for conducting LC". Spinal anesthesia was adequate for surgery in all but one patient. Intraoperatively, two out of four patients who experienced right shoulder pain received Fentanyl. Operative difficulty scores were minimal and surgery in one patient was converted to open cholecystectomy. Post operatively, pain scores were minimal and no patient demanded opioid. One patient required anti emetic for vomiting and one patient each suffered headache and urinary retention. 11 patients were discharged within 48 hours of surgery and patient satisfaction scores were very good. The study concluded that Spinal anesthesia is adequate and safe for elective LC in otherwise healthy patients and minimizes postoperative pain because of post operative analgesia and opioid use.

In above mentioned study many patients post operative analgesia score were good, one patient had vomiting and urinary retention. In our study also patient had significant post operative analgesia, one patient had nausea and vomiting however none of our patient experienced urinary retention.

### Cost effectiveness

In our study, we observed the cost of drugs and materials administered in spinal anesthesia was around 7 times lower than

general anesthesia. Added to that 68% of study population were discharged with in 24 hours of surgery and 28% were discharged in 48 hours of surgery showing less hospital stay and less ward charges. Sangeetha tiwari, Ashutosh Chauhan conducted similar study in 2009 with the title "laparoscopic cholecystectomy under spinal anesthesia a randomized control study"<sup>[12]</sup>. They concluded that mean anesthesia time appeared to be more in the general anesthesia group and they concluded that laparoscopic cholecystectomy done under spinal anesthesia as a routine anesthesia of choice is feasible and safe, in hospital setups in developing countries where cost factor is a major concern.

### Conclusion

Our study concludes that laparoscopic cholecystectomy can be done safely under spinal anesthesia with intra venous sedation which is a cost effective and gives good analgesia, muscle relaxation with no hemodynamic instability. It gives good post operative analgesia with decreased incidence of post operative nausea and vomiting and helps in smooth recovery, early ambulation and decrease in duration of hospital stay. Addition of intravenous sedation with Ketamine to spinal anesthesia reduces the incidence of intra-operative shoulder pain/discomfort compared to traditional spinal anesthesia alone.

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