

Comparison of Different Concentrations of Isobaric Ropivacaine with Dexmedetomidine versus Isobaric Ropivacaine for Patients Undergoing Laparoscopic Cholecystectomy under Segmental Spinal Anaesthesia: A Randomised Control Pilot Study

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ABSTRACT

Introduction: Segmental Spinal Anaesthesia (SSA) refers to blocking of the required dermatomes essential for the proposed surgical procedure with very low effective local anaesthetic drug dose. Thoracic SSA offers a safer alternative to General Anaesthesia (GA) with fewer cardiorespiratory complications especially for American Society of Anaesthesiologists (ASA) 2 and 3 patients.

Aim: To compare the different concentrations of isobaric ropivacaine with dexmedetomidine versus isobaric ropivacaine for patients undergoing laparoscopic cholecystectomy under SSA.

Materials and Methods: The present randomised control study was done in the Department of Anaesthesia at Gautam Buddha Chikitsa Mahavidyalaya, a tertiary care centre from November 2024 to July 2025. In the present study, 32 patients were randomly divided into two groups, Group R+D and Group R using the fish bowl method of randomisation. Subjects in Group R+D were administered 1.8 mL ropivacaine 0.5% +5 micrograms dexmedetomidine whereas subjects in Group R were administered 2 mL of 0.75% ropivacaine. Haemodynamic parameters like Heart Rate (HR), Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) were compared in all the groups. The patient and surgeon satisfaction scores and the need for rescue analgesic was also assessed. Repeated measure Analysis of Variance (ANOVA) was applied for comparing the means of one group in different time

intervals. For comparing the means between two independent groups, independent t-test was used. A p-value less than 0.05 was considered statistically significant.

Results: Age was comparable in both the groups ($p=0.07$). Mean HR recorded was found to be significant at 25, 30, 40, 50 minutes. ($p=0.04$ at 25, 30, 40 minutes and $p=0.01$ at 50 minutes). At 60 minutes, the mean HR recorded to be statistically significant ($p=0.01$). The recording in SBP was noted to be significant at a time interval of 5 minutes intraoperatively ($p=0.04$). Within the Group, the p-value was significant for the SBP in Group R+D ($p=0.03$) and the value was significant for DBP in Group R ($p=0.04$). So, there was significant hypotension produced in the groups but the difference was not significant while comparing with each other. The intraoperative incidence of side effects was comparable in both the groups ($p=0.63$). The surgeon satisfaction score ($p=0.48$) and the patient satisfaction score ($p=0.51$) were also comparable in both the groups. Rescue analgesic was not required in any of the patients.

Conclusion: Thoracic SSA is a reliable and effective alternative for laparoscopic cholecystectomy. Both drug combinations evaluated in this study provided good anaesthesia and can be effectively used for segmental spinal technique. While the duration of segmental spinal lasted significantly more in the ropivacaine and dexmedetomidine group, the haemodynamic parameters and the satisfaction scores were higher in the ropivacaine group.

Keywords: Patient satisfaction score, Surgeon satisfaction score, Thoracic spinal anaesthesia

INTRODUCTION

Era of the medical field has changed after the introduction of laparoscopic approach to various surgeries because of its advantages like smaller scar size, less bleeding and reduced perioperative complications minimising the hospital stay. One of the most common general surgical procedures amongst these is laparoscopic cholecystectomy. The gold standard technique considered for conducting laparoscopic cholecystectomy is GA [1]. In cases, where General Anaesthesia (GA) is contraindicated, Lumbar Spinal Anaesthesia (LSA) has also been administered for laparoscopic cholecystectomy. Some patients with associated cardiovascular and respiratory complaints might be at a higher risk for GA. Avoiding the need for airway instrumentation and the

associated risks like Postoperative Nausea and Vomiting (PONV) etc., is a major benefit of spinal anaesthesia [2].

First Thoracic Spinal Anaesthesia (TSA) was performed in early 1908 following which many anaesthesiologists have gained interest in this unconventional technique. TSA has been shown to be a safe and successful technique for multiple surgical procedures, including laparoscopic cholecystectomies, breast cancer lumpectomies, and abdominal cancer surgeries [3]. Although not commonly employed, TSA offers several advantages, such as reduced respiratory and cardiac complications, enhanced suppression of the neuroendocrine stress response, decreased incidence of deep vein thrombosis, effective postoperative analgesia, and a lower occurrence of nausea and vomiting [4].

The SSA refers to blocking of the required dermatomes essential for the proposed surgical procedure with very low effective local anaesthetic drug dose [5]. It however requires puncture of the dura at high lumbar or thoracic levels rather than the conventional spinal below L1. Segmental TSA (STSA) has not only been considered but also popularised as an alternative to GA for upper abdominal and thoracic surgery (mostly breast surgery) [6,7]. Studies have compared haemodynamic changes in thoracic SSA and GA for laparoscopic cholecystectomy and have proved SSA to be a safer technique especially for high-risk patients under GA [8-10]. Various studies have also been conducted and published describing the use of both hyperbaric and isobaric local anaesthetic drugs for STSA [11-13].

Adding an adjuvant to local anaesthetic for spinal anaesthesia prolongs the duration of the block. Dexmedetomidine in a dose of 5-10 micrograms has been used as an effective adjunct in spinal anaesthesia [11,14]. When SSA is attempted at lower thoracic levels as in the case of laparoscopic cholecystectomy, a dose of 3-6 micrograms has been shown to effectively prolong the duration of anaesthesia and analgesia while decreasing the incidence of hypotension and bradycardia [1,15]. A single dose of 0.75% of isobaric ropivacaine has also been shown to be effective for SSA [11].

Despite the fact that TSA is being used for abdominal surgeries in the recent times, there is still insufficient data in literature comparing two different concentrations of isobaric drug for the same. Either drugs have been compared with different baricity or different doses but here, different concentrations of the same isobaric drug were compared between the two groups with an intention to find out whether adding an additive to a lower concentration of the drug is more beneficial than a single dose of higher concentration alone [1,11,15].

In this study, two combinations of drugs were used for administering STSA to patients who were scheduled for laparoscopic cholecystectomy surgery and were at high risk for GA. This study aimed to evaluate the efficacy of SSA for laparoscopic cholecystectomy and to determine which drug combination is better for this technique. The Primary objective was to assess the efficacy and safety of thoracic SSA in laparoscopic cholecystectomy surgery, as observed by intraoperative haemodynamics, complications and satisfaction scores. The secondary objective was to assess which drug combination was better for thoracic SSA, as observed by duration of anaesthesia, analgesia and incidence of intraoperative/postoperative haemodynamics and complications.

MATERIALS AND METHODS

The present randomised control study was done in the Department of Anaesthesia at Gautam Buddha Chikitsa Mahavidyalaya, a tertiary care centre from November 2024 to July 2025. Approval from Institutional Ethics Committee (GBCM/IEC/2024/11-03) was obtained for the conduction of the study. Since there is no similar study in literature which compares both these combination of drugs, it is considered as a pilot study.

Sample size calculation: Based on a reference study by Paliwal NW et al., the sample size estimation was performed using comparison of two independent means assuming equal group allocation [5].

The sample size was calculated for comparison of MAP between two independent groups using the standard formula for comparison of two means.

$$n = \frac{2 (Z_{1-\alpha/2} + Z_{1-\beta})^2 S^2}{\Delta^2}$$

Where:

- n=required sample size per group
- S=pooled standard deviation
- Δ=expected mean difference between groups
- $Z_{1-\alpha/2}$ =standard normal deviate corresponding to 5% significance level (1.96)

- $Z_{1-\beta}$ = standard normal deviate corresponding to 80% power (0.84)

Assumed values:

Pooled standard deviation (S) = 6.0 mmHg

Minimum clinically significant difference (Δ) = 5.9 mmHg

α = 0.05, Power = 80%

Stepwise numerical calculation:

$$n = 2 (1.96 + 0.84)^2 \times 6^2 / 5.9^2$$

$$n = 2 (2.8)^2 \times 36 / 34.81$$

$$n = 2 \times 7.84 \times 36 / 34.81$$

$$n = 564.48 / 34.81$$

$$n = 16.2$$

Thus, the calculated sample size was approximately 16 participants per group. Therefore, a total sample size of 32 patients (16 in each group) was included in the study.

The subjects were briefed about the procedure preoperatively. Any queries were addressed and a written informed consent obtained from all the patients before the study. The inclusion and exclusion criteria were as follows.

Inclusion criteria: Patients in the age group of 50-75 years, patients belonging to ASA grade 2,3. 32 patients were included in the study and eight were excluded.

Exclusion criteria: Patient refusal for surgery, refusal for SSA, conversion to GA during surgery, Electrocardiogram (ECG) changes (sinus bradycardia and heart block), spinal abnormality/deformity, any pre-existing coagulation abnormality, severe co-morbidities and systemic illness, other contraindications for spinal anaesthesia, any pre-existing neurological deficits.

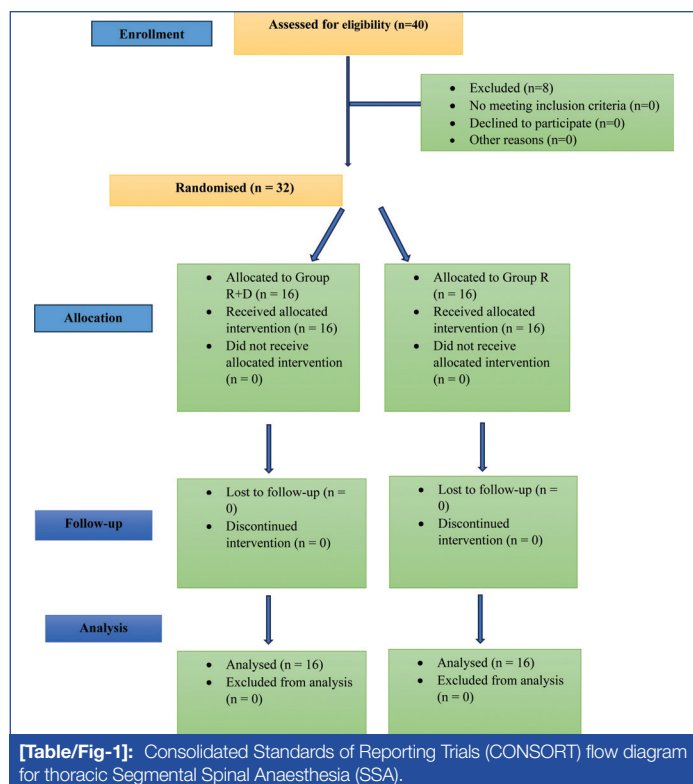
Study Procedure

Pre-Anaesthetic Checkup (PAC) of the patients was done along with counseling about the procedure one day prior to surgery. Patients were counseled that any apprehension or pain if occurs would be taken care of by providing systemic drug or GA if required. Additionally, reassurance was given to surgeons that they can ask for administration of GA if they feel that there was any technical difficulty due to segmental spinal during surgery.

Thirty two patients were randomised into two groups Group R+D and Group R using the fish bowl method of randomisation. The groups were numbered and placed in a bowl, which was opened by the attending anaesthesiologist just before transferring the patient to the operating theatre. The same anaesthetist who was participating in the study prepared the chit mentioned drugs for that patient and administered the block. Subjects in Group R+D were administered 1.8 mL of injection ropivacaine 0.5% + 5 micrograms dexmedetomidine whereas subjects in Group R were administered 2 mL of 0.75% injection ropivacaine [Table/Fig-1]. The volume of drugs used in each study were based on using similar dosages in other studies [11,14]. A second investigator who was not present intraoperatively followed up the patients postoperatively.

After ensuring adequate overnight fasting of the patients, Inj. ondansetron 4 mg and Inj. ranitidine 50 mg were given to all patients as part of the pre-operative protocol. Patient was shifted to operation theatre and multiparameter monitor was attached. Baseline parameters (HR, SBP and DBP and MAP) were recorded. Following all aseptic practices, TSA was given to all the patients in sitting position by midline approach at T8-T9 or T9-T10 levels using a 25G Quincke spinal needle. Backflow of CSF was confirmed and the drug was given. Segmental spinal was attempted for not more than 2-3 attempts. Subjects were excluded from the study if more attempts were needed or if required conversion to GA.

Assessment of sensory block: Sensory block was assessed using pinprick test. Pin prick test was done to check for the dermatomal



spread of the drug. After confirming adequate effect of the block (Dermatome level - T3-L2), surgery was started.

All the patients were operated by the same surgery team using a standard four-port technique with CO₂ pneumoperitoneum (10-12 mmHg). Intra-abdominal pressure was kept same in all the patients and all of them were positioned in a reverse Trendelenburg posture with a left tilt [9]. Patient was administered oxygen via nasal prongs at 2-4 litres/min. Baseline parameters like HR, SBP and DBP were recorded and compared in both the groups.

Intraoperative parameters (HR, SBP, DBP, MAP) were recorded for every five minutes till 30 minutes and after that for every 10 minutes till 60 minutes. Injection paracetamol 1 gm intravenously was given to all patients before establishment of pneumoperitoneum. Bradycardia and hypotension at any time were defined as $\geq 20\%$ reduction in Non-Invasive Blood Pressure (NIBP)/HR [16]. Intraoperative hypotension was managed by boluses of 6 mg of injection mephentermine if required. Bradycardia was managed by 0.6 mg of injection atropine. Shoulder tip pain if complained of, was managed by injection ketofol intravenously (1:1 ratio ketamine: Propofol in a 10 mL syringe, that is 50 mg propofol and 50 mg ketamine combined together in a 10 mL syringe) with dosage as required (Boluses of 1mL=5mg/mL of each constituent).

If the patient was still complaining of abdominal pain or the surgeon was not satisfied with relaxation, the patient was administered GA and eventually excluded from the study. 8 patients were excluded from the study. Time taken for total surgery was noted.

Patient satisfaction score and Surgeon satisfaction score were obtained from the patient and surgeon respectively at the end of the surgery. The reference for scores was taken from a study by Geetanjali S et al., [1]. However, these scores were modified according to this study.

Patient Satisfaction Score (1 point for each)

1. Intraoperative comfort
2. Absence of postoperative pain
3. Absence of below postoperative complications
 - a) Urinary retention
 - b) Nausea/Vomiting
 - c) Any other complication

Surgeon Satisfaction Score (1 point for each)

- 1) Adequate relaxation
- 2) Absence of postoperative side-effects
- 3) Early mobilisation

Postoperatively, patient was followed up for 12 hours after surgery. Duration of block and side effects if any, were recorded. Rescue analgesic (injection tramadol 50 mg i.v.) was given if Visual Analog Scale (VAS) >4 postoperatively. PONV was managed by 4 mg of injection ondansetron intravenously.

The primary outcome was to assess the efficacy and safety of thoracic SSA in laparoscopic cholecystectomy surgery, as observed by intraoperative haemodynamics, complications and satisfaction scores. The secondary outcome was to assess which drug combination was better for thoracic SSA, as observed by duration of analgesia and incidence of intraoperative/postoperative haemodynamics and complications.

STATISTICAL ANALYSIS

The data was entered in MS Excel and was analysed using IBM Statistical Package for Social Sciences (SPSS) software version 22. Sociodemographic variables were expressed in terms of frequency and percentages while the variable age was represented using descriptive statistics. Repeated measures ANOVA was applied for comparing the means of one group in different time intervals. For comparing the means between two independent groups, independent t-test was used. The p-value less than 0.05 was considered statistically significant.

RESULTS

The present study was done mainly on female subjects. Eight patients were excluded from the study who required conversion to GA. Age was comparable in both the groups ($p=0.07$). Duration of surgery was also comparable in both the groups ($p=0.57$). The patients selected mainly were of ASA grade 2 and 3 and were comparable in both the groups [Table/Fig-2].

Variables	Group		p-value
	R+D (n%)	R (n%)	
Age (in years)	56.75±13.86	60.06±5.11	0.07
Duration of surgery (in minutes)	70.63±16.92	67.50±13.91	0.57
Duration of sensory spinal block (in minutes)	200±13.12	170±15.21	<0.01
ASA Grading n (%)	2	12 (37.5%)	0.69
	3	4 (12.5%)	

[Table/Fig-2]: Comparison of baseline demographic parameters.

Baseline parameters (HR, SBP, DBP and MAP) were recorded and compared in both the groups. For the first half an hour, which is supposed to be the time when the greatest alteration happens in haemodynamic parameters, the changes were recorded every five minutes followed by every 10 minutes till 60 minutes during surgery [Table/Fig-3].

Variables		Group R+D	Group R	p-value
		Mean±SD	Mean±SD	
MAP (mmHg)	Baseline	82.50±16.37	87.81±14.04	0.33
	Start	81.88±15.77	81.63±10.18	0.96
	5 min	81.19±17.09	79.38±9.08	0.71
	10 min	78.06±14.93	76.88±9.64	0.79
	15 min	75.88±12.63	76.44±10.26	0.89
	20 min	76.19±13.85	77.13±12.47	0.84
	25 min	77.56±12.07	73.81±10.07	0.35
	30 min	77.31±12.68	74.75±9.60	0.52
	40 min	74.88±11.70	75.31±8.69	0.91
50 min	76.38±11.15	73.50±10.55	0.46	

	60 min	75.06±12.21	74.44±9.58	0.87
	p-value	0.07	0.40	
DBP (mmHg)	Baseline	87.56±13.08	86.00±14.21	0.75
	Start	86.19±10.32	80.56±13.40	0.19
	5 min	82.50±10.37	76.88±12.54	0.18
	10 min	79.75±10.38	75.94±10.47	0.31
	15min	79.56±8.32	76.81±10.27	0.41
	20 min	78.50±8.21	77.00±11.02	0.67
	25 min	78.81±7.91	72.81±14.72	0.16
	30 min	78.63±9.46	71.44±13.03	0.08
	40 min	76.88±6.65	73.63±11.06	0.32
	50 min	76.69±6.94	71.75±9.40	0.10
	60 min	76.88±5.69	74.44±8.35	0.34
	p-value	0.09	0.04	
SBP (mmHg)	Baseline	138.81±15.91	141.50±21.74	0.69
	Start	133.06±16.78	126.25±14.36	0.23
	5 min	127.63±18.36	117.50±7.88	0.04
	10 min	126.00±15.20	117.31±12.78	0.09
	15 min	121.88±18.87	114.06±13.21	0.18
	20 min	118.19±15.01	115.06±18.04	0.60
	25 min	119.44±12.19	114.63±14.92	0.33
	30 min	118.25±11.73	114.25±11.49	0.34
	40 min	118.88±10.78	115.00±10.73	0.32
	50 min	120.56±12.72	118.19±11.10	0.58
	60 min	122.19±10.95	117.25±8.42	0.16
	p-value	0.03	0.19	
HR (bpm)	Baseline	88.56±16.11	80.75±19.09	0.22
	Start	86.75±17.85	77.00±17.39	0.13
	5 min	85.19±14.74	74.44±17.49	0.07
	10 min	84.19±15.79	74.19±17.64	0.10
	15 min	82.13±15.34	73.19±13.90	0.09
	20 min	81.19±12.92	74.81±16.27	0.23
	25 min	81.94±11.95	69.25±19.80	0.04
	30 min	82.00±13.53	72.38±11.38	0.04
	40 min	81.38±11.45	72.94±11.22	0.04
	50 min	80.88±11.29	70.56±11.18	0.01
	60 min	81.25±10.61	71.06±10.33	0.01
	p-value	0.33	0.13	

[Table/Fig-3]: Comparison of haemodynamic parameters in both the groups.

In Group R+D, the mean HR recorded at 25 minutes was found to be 81.94±11.95 beats per minute (bpm) and in Group R, the mean HR recorded at 25 minutes was 69.25±19.8 bpm and this difference was found to be statistically significant ($p=0.04$). The difference was also noted to be significant at 30,40 and 50 minutes ($p=0.04$), ($p=0.04$), ($p=0.01$). At 60 minutes, the mean HR recorded was 81.25±10.61 bpm in Group R+D and in Group R, it was noted to be 71.06±10.33 bpm. The p-value was found to be statistically significant ($p=0.01$).

The recording in SBP was noted to be significant at a time interval of five minutes intraoperatively. The mean reading in R+D group was 127.63±18.36 mmHg and in Group R was 117.50±7.88 mmHg ($p=0.04$). At all other time intervals, the readings recorded were slightly lower in the R group but none of the difference was found to be statistically significant. When there was comparison of the group within, the p-value was significant for the SBP in Group R+D ($p=0.03$) and the value was significant for DBP in Group R ($p=0.04$). So, there was significant hypotension produced in the groups but the difference was not significant while comparing with each other.

The patient satisfaction score was noted to be 3.88±0.72 in Group R+D and was noted to be 4.06±0.85 in Group R. Though the

patient satisfaction scores were higher in Group R, however this difference was not found to be statistically significant ($p=0.51$). The mean surgeon satisfaction scores were 2.56±0.51 in Group R+D and in Group R, it was noted as 2.69±0.48. This difference was not found to be clinically significant ($p=0.48$) [Table/Fig-4].

Variables	Group R+D	Group R	p-value
	Mean±SD	Mean±SD	
Patient satisfaction score	3.88±0.72	4.06±0.85	0.51
Surgeon satisfaction score	2.56±0.51	2.69±0.48	0.48

[Table/Fig-4]: Comparison of patient and surgeon satisfaction score in both the groups.

The intraoperative incidence of side effects was comparable in both the groups (0.63) [Table/Fig-5].

Side-effects	Group R n (%)	Group R+D n (%)
Hypotension	7 (43.75%)	8 (50%)
Shoulder pain	2 (12.5%)	3 (18.75%)
Nausea	0	2 (12.5%)

[Table/Fig-5]: Incidence of different side-effects in both the groups.

Standard institutional protocol for postoperative pain management was followed. (1 gram paracetamol eighth hourly postsurgery). Rescue analgesic was not required in any of the patients.

DISCUSSION

Laparoscopic cholecystectomy has emerged as the preferred mode of management for patients with symptoms of cholelithiasis. Thoracic SSA has been established as a safe modality for patients undergoing laparoscopic surgeries [17]. This has been proved even better for high risk patients undergoing surgery under GA [18,19]. In the present study, thoracic SSA is given for female patients belonging to ASA grade 2 and 3 in the age group of 50-75 years scheduled for elective laparoscopic surgeries.

In the current study, two different concentrations of isobaric ropivacaine have been compared for thoracic SSA. There has been no study in literature yet which compares two different concentrations of ropivacaine. Both the drug combinations in this study were found to be safe and effective. In their study, Vailati D et al., have defined the various drugs and their combinations that can be used for SSA. They advocate the use of low concentration of drugs (0.25%-0.33%) along with dexmedetomidine as the preferred adjuvant in a dose of 3-15 mcg [20]. Verma AK et al., in their study have compared the effectiveness and safety of thoracic SSA for laparoscopic cholecystectomy surgeries using isobaric levobupivacaine 0.5% and hyperbaric levobupivacaine 0.5% [21]. They found that hyperbaric levobupivacaine is a safe and effective anaesthetic choice for laparoscopic cholecystectomy surgeries offering predictable block spread and fewer adverse effects. Different baricity and combination of drugs have also been used by Nagar S et al., in their study where they have compared different techniques using different thoracic vertebral spaces and baricity of drugs as combination. They found that hypobaric and isobaric ropivacaine provide relief in shoulder tip pain and better haemodynamic stability [22] isobaric ropivacaine (0.75%) has been used for thoracic SSA in high-risk patients who were not fit for GA [23]. Geetanjali S et al., have used isobaric ropivacaine 0.75% with 6 mcg of dexmedetomidine as an additive in laparoscopic cholecystectomy surgeries [1].

A dose of 3-5 micrograms of dexmedetomidine has been effectively used as an adjuvant to STSA. It prolongs the duration of anaesthesia postoperatively. In this study, addition of 5 micrograms of dexmedetomidine prolonged the duration of anaesthesia and the difference was significant between the groups. In their study by Chandra R et al., which was a large feasible observational study, 5 micrograms dexmedetomidine was added to hyperbaric bupivacaine and the mean time for regression of sensory blockade was 136 minutes [17]. In a case series and review of

literature by Aljuba YM et al., 5 micrograms of dexmedetomidine has been added to various concentrations of hyperbaric and isobaric local anaesthetics with a good duration of sensory blockade [10].

Mean haemodynamic parameters were compared in both the groups. In this study, an initial dip was noted in HR, SBP and DBP in both sets of study subjects. The dip was more marked in the group of patients who received 0.75% of isobaric ropivacaine, although the difference was not clinically significant. These results were similar to a study by Geetanjali S et al., where haemodynamic parameters were compared in both the groups. In the group of patients that received TSSA for laparoscopic surgeries, the haemodynamics were mostly stable after an initial dip in SBP and DBP [1].

In the present study, the common side-effects recorded were hypotension, nausea, and shoulder tip pain. They were managed accordingly and successfully. In their study, Geetanjali S et al., have reported the incidence of shoulder tip pain, urinary retention and headache [1]. Hamdi T et al., found that thoracic SSA has been associated with a higher risk of hypotension and a lower incidence of postoperative vomiting [24]. Bradycardia and hypotension have been the most common side-effects studied for TSSA in a study by Verma AK et al., [21].

In the present study, the satisfaction scores were noted for both the surgeons and the patients. The satisfaction scores were more for the patients who received 0.75% of ropivacaine though the difference was not clinically significant. In the study by Hamdi T et al., higher patient and surgeon satisfaction scores were noted in patients who received thoracic SSA for breast surgery [24].

Limitation(s)

More studies are needed in this respect to draw a significant conclusion. There is potential for future studies to explore individualised dosing strategies based on type of surgery for spinal segmental dermatomes and patient-specific factors.

CONCLUSION(S)

Thoracic SSA is a safe and effective technique for laparoscopic cholecystectomy surgery. Both combination of drugs used in this study were good for SSA. While the use of 0.75% isobaric ropivacaine provided better intraoperative haemodynamics and better satisfaction scores with reduced postoperative complications, 0.5% isobaric ropivacaine with dexmedetomidine produced significant duration of spinal block postoperatively. The usage of drugs and their combinations is a personal discretion of the anaesthetist. More studies are needed in this respect with a bigger sample size.

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