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Original Research Article

Comparison of hemodynamic changes in thoracic segmental spinal anaesthesia and general anaesthesia for laparoscopic cholecystectomy

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ABSTRACT

Background and Aims: General anesthesia (GA), which has been a gold standard for laparoscopic cholecystectomy (LC), has limitations in certain patients. This randomised controlled trial compared the hemodynamic changes between GA and an alternative anesthetic technique, thoracic segmental spinal anesthesia (TSSA) for LC.

Materials and Methods: Hundred adult patient scheduled for elective LC were randomised into group T(TSSA) and Group G (GA) of 50 patients each. Group G patients received conventional GA with intubation and mechanical ventilation while group T patients received TSSA (1.5 ml of 0.75% ropivacaine with dexmedetomidine 6mcg as an adjuvant was injected intrathecally in one of the interspinous space between T7- T12). Primary objective of our study was to compare the intra operative hemodynamic changes. Secondary objective was to compare the intraoperative and post operative adverse effects. Statistical Package for Social Sciences (SPSS) software version 22 was used for statistical analysis after entering the data into Microsoft Excel spreadsheet.

Results: All 100 patients were analysed for study. Group T showed greater hemodynamic stability after an initial dip (at 5 min) in heart rate, systolic and diastolic blood pressure. Group G showed greater rise in intra-operative hemodynamic parameters at all time points after insufflation. There was no neurological complication in group T. Incidence of post operative pain abdomen in the first six hours and sore throat was more in group G.

Conclusion: TSSA provides greater hemodynamic stability with minimal side-effects as compared to GA and offers an effective and acceptable alternative for LC.

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1. Introduction

General anaesthesia (GA), which has been a gold standard for laparoscopic cholecystectomy (LC) involves the side effects of airway instrumentation and mechanical ventilation besides causing wide hemodynamic fluctuations due to pneumoperitoneum and position changes. Pneumoperitoneum induces its effects due to absorption of CO_2, increased intra- abdominal pressure and by increasing the neuroendocrine stress response to surgery.[1–6]

Thoracic segmental spinal anaesthesia(TSSA) is an effective and acceptable alternative technique for LC. In certain situations, it offers greater benefits by overriding the drawbacks of GA.[7–10] MRI studies have confirmed the anterior placement of the spinal cord with respect to duramater in the thoracic region as compared to cervical and lumbar levels. The presence of thinner nerve roots and the lesser volume of CSF attribute to an almost immediate onset of action of local anaesthetic (LA) at thoracic level, even with half the dose used at lumbar level. This lesser dose of LA provides better hemodynamic stability, limited thoracic motor block and a very fleeting lumbar

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motor block. The transient lumbar motor block enables early voiding and ambulation postoperatively.[11–14] Since the requirement of relaxation in laparoscopic surgeries is not much, lower doses of isobaric drugs can be used to achieve a preferential sensory block. Their spread being unaffected by table tilts gives an additional edge.[15,16] Penetration of ropivacaine into thicker myelinated motor fibres is restricted by its low lipophilicity which facilitates a preferential sensory blockade.[17,18] Addition of an adjuvant like dexmedetomidine, a selective alpha 2 adrenergic receptor agonist, extends the duration and quality of postoperative analgesia.[19–23]

This study was planned to compare conventional GA with the alternative technique, TSSA in patients undergoing LC. To compare the intra operative hemodynamic variation between two techniques was the primary objective. Secondary objective of this study was to compare them on the basis of intraoperative and postoperative adverse effects.

2. Materials and Methods

After obtaining approval of Institutional Ethics Committee, this randomised controlled study was registered prospectively with Clinical Trial Registry of India (www.ctri.nic.in) with registration number CTRI/2023/06/053758 and was conducted keeping in mind the principles of the Declaration of Helsinki. This study was undertaken on 100 patients undergoing LC from June 2023 to August 2023 in the general surgery operation theatre of a tertiary care medical centre.

Patients of ASA grade1, 2 and 3, age 18-75years and those who gave written informed consent were included. Exclusion criteria were patients with BMI>35 Kg/mt^2 and the presence of any condition contra-indicating spinal anaesthesia or elective surgery. Patients were randomised into two groups- T (thoracic segmental spinal anaesthesia) and G (general anaesthesia), with the help of computer generated randomisation and concealment was done using sealed envelope method. The sealed envelope was opened by the anaesthesiologist conducting the cases and the anaesthesia technique was accordingly chosen. A written informed consent was obtained after counselling and reassurance to group T about the administration of systemic medication or GA if needed. Pre- anaesthesia check-up was done as per hospital protocols and patients were scheduled for surgery. Patients were kept fasting as per standard guidelines.

After receiving patient into the operating room, intravenous (IV) access with 18G cannula was done and infusion of lactated ringer started (10 ml /kg in approximately 15minutes). ASA standards of basic anaesthetic monitoring including of pulse-oximetry, electrocardiogram, non-invasive blood pressure, capnography were followed and baseline vitals were recorded. After a safety check of all emergency medicines and anaesthesia work station, ondansetron 4mg, glycopyrrolate 0.2 mg and midazolam 1mg were administered intravenously as premedication.

Group T patients received sub arachnoid block under strict asepsis by midline or para-median approach in a sitting position in one of the interspinous space between T7 to T11. Maximum 3 attempts at dural puncture were taken in a patient due to ethical concerns, after which GA was administered. Quincke spinal needle 25 G were used. Injection ropivacaine 0.75% (isobaric), 1.5 ml, along with injection dexmedetomidine 6 μg, (as adjuvant), was administered intrathecally once clear CSF flow was established. After giving a supine position, all patients received oxygen via Hudson's mask at 5 l/min. Anaesthesia time was noted. Vital parameters were noted every minute for initial 15 minutes and subsequently every 5 minutes. Sensory block were assessed by pinprick every 1-2 min after performing TSSA. Time of onset of block was noted when minimum block levels between T6 to L1 were achieved. Motor block was evaluated according to the modified Bromage scale at this point(0-able to lift extended leg, 1- just able to flex knee, 2-no knee movement and some ankle movement, 3- complete lower limb paralysis). Failure to attain sensory block in the required dermatomes even after 10 minutes was considered as block failure. Surgery was commenced after establishing the block. At this point Injection fentanyl 50μg I V was given. Injection ketamine 30 mg intravenously(iv) was administered at the start of carbon dioxide insufflation to ease the sensory discomfort of stretching of central part of the diaphragm (sensory nerve supply via phrenic nerve C3, C4, C5). The intra-abdominal pressure (IAP) was limited to 12 mm Hg. Adverse events during surgery (bradycardia, hypotension, desaturation etc) were recorded and managed. Bradycardia (HR<55) was managed with injection atropine 0.6mg (I V). Hypotension (Systolic BP<80 mm Hg) was managed with 6mg boluses of Injection mephentermine and fast (I V) fluids. Ketamine was administered in aliquots of 20 mg I V in case of any hand movements. Drugs and fluids administered were noted. The intraoperative fluid used was ringer lactate at the rate of approximately 25ml/min.

Group G patients received GA. After the administration of premedication that was common to both groups, fentanyl 2mcg/kg IV was given. After pre-oxygenation for 3 minutes with 6-8 l/min flow and 1.0 FiO2 of oxygen, induction was done with IV propofol (1.5-2.5 mg/kg) followed by intubation with IV atracurium besylate (0.5 mg/kg). Mechanical ventilation was commenced on volume controlled mode with a tidal volume of 6 to 8 ml/kg, and the respiratory rate adjusted to maintain a PaCO2 of 35 to 40 mmHg. Anaesthesia was maintained with isoflurane 1.0-1.2% with 40% oxygen in air. On completion of surgery, residual neuromuscular block was reversed with 2.5 mg of neostigmine and 0.5mg of glycopyrrolate.

Post-operatively, patients of both groups were given 75 mg of diclofenac sodium IV infusion and this was repeated every 8 hours. Patients were transferred to the PACU and were shifted to the ward when they met the discharge criteria of transfer from PACU. These included mental alertness, stable vital signs, absence of nausea or vomiting, control of pain.

Side-effects recorded were the incidence of intraoperative or postoperative hypertension (SBP>140 mm Hg), hypotension (SBP<80 mm Hg), nausea, vomiting, pruritis, shoulder pain, sore throat, headache, backache, urine retention, pain severe enough to require IV rescue analgesics(VAS 3) in first six hours. Acetaminophen infusion (500mg) and supplementary tramadol 50 mg IV was used as a rescue analgesic. Postoperative side effects were recorded and managed on day 0, day 1 and day 2. Patients were discharged on day 2 as per the hospital protocol if they fulfilled the discharge criteria.

Sample size was calculated according to cochran's formula for a infinite population ($n\infty = z^2pq \div e^2$); then using modified Cochran's formula for a finite population $n_\circ = \frac{n\infty}{1+(n\infty-1\,/N)}$, where n_∞ = 385, N=100 (considering that we conducted approximately 30-50 laparoscopic cholecystectomies per month and we had to complete our study in 3 month period), $n_\circ$ was 80. So we conducted our study in 100 cases.

The data analysis was facilitated using SciPy (version 1.3.1) of Python programming language (version 3.7.4). Continuous variables are described as median with range (min, max) since means are more sensitive to outliers. Absolute numbers and percentages are used to express qualitative data. The hypothesis testing was performed on qualitative data. Chi-squared tests and Fischer's exact tests were used for this purpose as per requirements. In this study, a P-value <0.05 was considered statistically significant and a P-value<0.001 was considered highly significant.

3. Results

A total of 100 patients enrolled in the study were allocated randomly into two groups group G and group T of 50 each. All study patients had successful intervention and were analysed in this study.(Figure 1)

The baseline demographic parameters in both groups were comparable (Table 1). The data analysis indicates that there were no statistically significant differences observed between Group T and Group G in terms of age, gender, height, weight, BMI, ASA class distribution, duration of surgery, and the distribution of comorbidities.

3.1. Primary objectives

The heart rate data analysis (Table 2) indicates that Group T consistently had lower mean heart rates compared to Group G at all time points after 5 minutes of insufflation. The differences in heart rate between the two groups at 5 minutes (during insufflation) and at 10 minutes (after insufflation) were insignificant. The data analysis of systolic blood pressure (SBP) (Table 3) indicates that Group T consistently had lower mean SBP compared to Group G at all time points without significant difference in SBP at the beginning of procedure (0 minutes) between the two groups. Data analysis of diastolic blood pressure (Table 4) indicates that Group T consistently had lower mean DBP compared to Group G at all time points without significant difference in DBP at 0 minutes between the two groups. An initial dip (at 5 min) was observed in SBP, DBP and HR in all 50 patients of group T.

3.2. Secondary objectives

In group T, 16 patients had intra-operative hypotension and 3 patients had bradycardia and were easily managed. Intraoperative hypertension was observed in 24 patients of group G and was easily managed with fentanyl. In the post-operative period, incidence of pain in the first six hours and sore throat after surgery was significantly more in group G (Table 5) There was no neurological side effects in group T patients and two patients suffered from headache which was managed with analgesics, oral fluids and bed rest. All patients were discharged on day 2 of surgery with no significant residual complaints.

4. Discussion

In this study, hemodynamic parameters that were compared were heart rate, systolic and diastolic blood pressure as primary objective. It was seen that hemodynamic stability in thoracic segmental spinal anaesthesia was better as compared to general anaesthesia. In group T, a slight initial dip (at 5 min) was seen in all three hemodynamic parameters due to segmental block. This dip was further enhanced by anti-trendelenburg tilt and raised intra-abdominal pressure due to pneumoperitoneum. Mild intraoperative hypotension (as per definition) occurred in 32% patients of group T and was easily managed with small boluses (6mg) of mephentermine and crystalloid infusion. Bradycardia occurred in 6% patients of group T and was easily managed with 0.6mg atropine. As compared to this group G patients demonstrated an increase in all three hemodynamic parameters after CO2 insufflation with 48% patients exhibiting intraoperative hypertension (as per definition), which was managed with additional dose of fentanyl.

Our secondary objective was to compare the intraoperative and postoperative adverse effects. The adverse effects related to endotracheal intubation like postoperative soreness of throat was present in 8 out of 50 group G patients. The incidence of postoperative pain (> VAS 3) in the first six hours was significantly greater

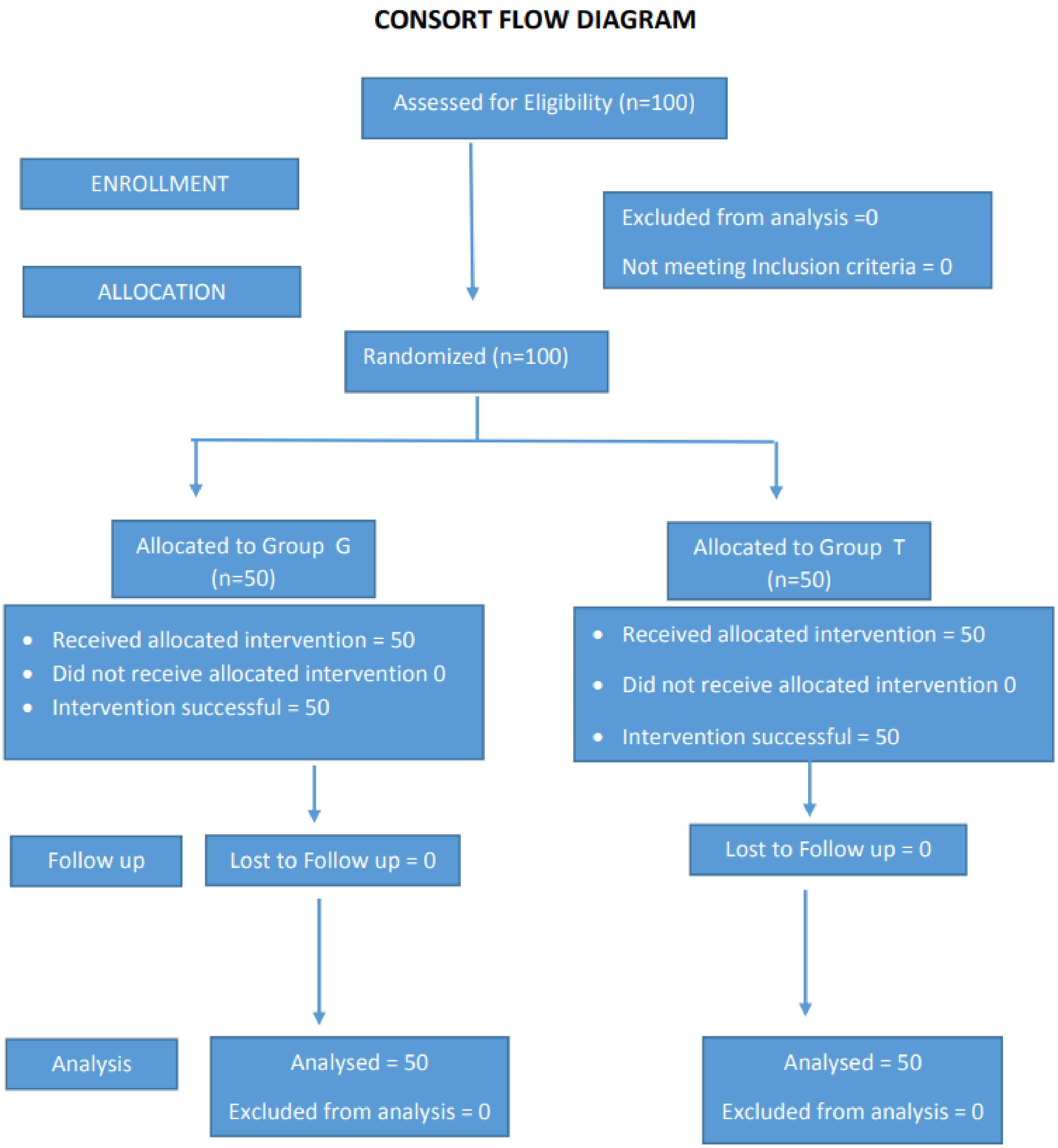

Figure 1:

Table 1: Demographic data

Variable	Group T (n=50)	Group G (n=50)	P value
Age (years)	44.26±14.26	43.26±11.41	0.700
Gender (m/f)	41/9	38/12	0.623
Height (cm)	156.58±9.34	155.44±7.94	0.512
Weight (kg)	61.82±8.96	62.06±7.36	0.235
BMI (kg/mt)	23.55±3.84	22.54±3.83	0.312
ASA 1/2/3	28/20/2	37/13/0	0.094
Duration of Surgery(min)	38.48±5.25	39.15±4.28	0.126
Comorbidity summary: HT/DM/COPD/ Hypothyroid	10/5/3/2	8/6/4/4	1.00

Table 2: Comparison of heart rate between the two groups (beat/min)

Variable	Group T		Group G		P value
	Mean	SD	Mean	SD	
0 min(baseline)	105.69	22.24	89.16	15.92	p<0.005
5 min (during insufflation)	92.08	25.47	88.96	13.86	0.455
10 min after insufflation	85.92	15.88	90.84	13.90	0.106
15 min after insufflation	85.21	14.50	92.54	12.40	0.008
20 min after insufflation	83.50	14.35	93.24	12.46	0.0005
30 min after insufflation	80.58	12.74	92.34	11.05	p<0.001
40 min after insufflation	78.65	10.98	92.58	10.91	p<0.001
At exsufflation	75.85	11.43	92.68	12.50	p<0.001
10 min after exsufflation	75.98	11.40	93.42	10.54	p<0.001

Table 3: Comparison of systolic blood pressure (mm Hg) between the two groups

Variable	Group T		Group G		P value
	Mean	Std. Dev.	Mean	Std. Dev.	
0 min (baseline)	135.42	17.28	128.72	16.32	0.051
5 min (during insufflation)	106.23	18.04	122.38	13.51	p<0.001
10 min (after insufflation)	99.25	17.60	124.32	18.04	p<0.001
15 min (after insufflation)	98.25	22.49	130.20	16.74	p<0.001
20 min (after insufflation)	99.50	13.52	130.88	16.63	p<0.001
30 min (after insufflation)	99.79	10.31	132.40	13.73	p<0.001
40 min (after insufflation)	101.48	10.42	130.50	11.99	p<0.001
At exsufflation	101.52	9.70	131.10	11.28	p<0.001
10 min (after exsufflation)	102.67	12.29	130.74	11.69	p<0.001

Table 4: Comparison of diastolic blood pressure (mm Hg) between the two groups

Variable	Group T		Group G		P value
	Mean	Std. Dev.	Mean	Std. Dev.	
0 min (baseline)	78.40	20.75	81.10	10.60	0.422
5 min (during insufflation)	63.88	14.61	78.40	7.92	p<0.001
10 min (after insufflation)	62.81	13.22	78.92	14.69	p<0.001
15 min (after insufflation)	60.69	14.93	83.80	12.31	p<0.001
20 min (after insufflation)	63.15	10.21	77.62	21.38	p<0.001
30 min (after insufflation)	62.50	9.52	84.04	15.91	p<0.001
40 min (after insufflation)	63.17	8.53	83.76	11.46	p<0.001
At exsufflation	64.40	9.21	83.18	9.31	p<0.001
10 min (after exsufflation)	66.58	9.67	84.20	9.93	p<0.001

Table 5: Intraoperative and postoperative adverse effects

		Group T (n=50)	Group G (n=50)	P value
Intraopera-Tive	Hypotension	16	0	p<0.001
	Bradycardia	3	0	0.241
	Hypertension	0	24	p<0.001
Postoperative	Headache	2	0	0.475
	Backache	1	0	1.000
	Neurological symptoms	0	0	-
	Sore throat	0	8	0.010
	Post op. pain abdomen	0	13	p<0.001
	Shoulder pain	2	3	1.000
	Urinary retention	4	2	0.674
	Nausea vomiting	4	5	1.00

in group G patients with requirement of rescue analgesic in 13 patients out of 50. There were no post-operative neurological side-effects in any of the patients of group T. The incidence of shoulder tip pain, PONV, POUR was comparable in both groups in the present study.

Review of literature revealed that Van Zundert et al. (2007) provided preliminary evidence regarding the efficacy of TSSA in LC in a group of 20 healthy patients with minimal side-effects. He also stated that cardiovascular changes might be more in older patients and in patients with comorbidities.[7] Though several studies have compared GA and spinal anaesthesia in LC, but studies comparing TSSA and GA for LC are very few.[5,6] Ellakany (2013) studied and compared TSSA and GA in LC cases.[9] Paliwal et al. (2020) also conducted a similar comparative study.[10] Our results were comparable with both above studies.

In GA, both mechanical and neurohumoral effects lead to an increase in blood pressure. The abdominal distension leads to a reflex increase in systemic vascular resistance and also the absorbed CO2 from peritoneal cavity causes sympathetic stimulation.[3,4] The fall in systolic blood pressure after exsufflation is because of the reversal of these effects of carbo-pneumoperitoneum. The heart rate rises to compensate for decreased venous return and cardiac output and also because of sympathetic stimulation due to hypercarbia caused by CO2 insufflation and subsequent release of catecholamines.[1,2]

On the contrary, neuraxial anaesthesia attenuates the neuroendocrine stress response to surgery and hence patients under TSSA showed greater hemodynamic stability. Additionally, sympathetic blockade of the blocked segments (T4-L1) causes venous pooling in hepatosplanchnic circulation preventing rise in BP. The lower sympathetic segments are spared preventing an exaggerated hypotension. Moreover, absence of hypercarbia in TSSA group prevents sympathetic stimulation favours greater hemodynamic stability.[9,10,12] In TSSA, the central respiratory control is intact and the absorbed CO2 due to carboperitoneum is washed out by a physiological rise in respiratory rate. The main inspiratory muscle is diaphragm, which is innervated by C3,C4,C5 is unaffected in TSSA and expiratory is a passive phenomenon. Forceful expiration and coughing is affected because of motor blockade of intercostal muscles of the blocked segments. This motor block in TSSA is short lasting because of the use of low dose isobaric drug.[15,16] Previous studies have concluded that a relatively larger dose of local anaesthetic, particularly in a COPD patient could be deleterious as in these patients lung ventilation depends on active expiration.[8,9,24]

An important factor in LC is to limit the IAP during surgery to facilitate adequate diaphragmatic excursions. Raised intra-abdominal pressure can also stimulate vagal stimulation causing bradycardia. CO2 Insufflation rate should not exceed 5-6 L/min and IAP<14mmHg with a slightly restrained degree of anti-trendelenburg tilt during surgery.[1–3]

Several studies on the incidence of paraesthesia and temporary or permanent neurological impairment in TSSA have been conducted. Imbelloni et al (2010) observed paraesthesia in 6.6% patients during low thoracic spinal needle placement without incidence of any permanent neurological deficit.[25] Paraesthesia indicates needle contact with neuronal structures. At mid-thoracic levels, the depth of the posterior subarachnoid space (T5 = 5.8 mm) was greater than upper (T2 = 3.9 mm) and lower (T10 = 4.1 mm) thoracic levels. The angulated needle entry at 45° because of spine angulation at mid-thoracic levels (T5) further increased this distance. MRI studies by Imbelloni confirmed a greater depth of the posterior subarachnoid space at mid-thoracic levels than at lumbar and upper thoracic levels.[25–27]

5. Limitations in the study

This study included a small sample size. More RCTs with larger sample size are needed to substantiate our findings. Also, though the study was randomised, it could not be blinded because of the procedural differences.

6. Conclusion

This study confirmed that thoracic segmental spinal anaesthesia provided greater hemodynamic stability with minimal side-effects as compared to general anaesthesia and can be used successfully for laparoscopic cholecystectomy in healthy patients by experienced anaesthesiologists.

7. Source of Funding

None.

8. Conflict of Interest

None.

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