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General Anaesthesia versus Combined Spinal Epidural (CSE) Anaesthesia for Patients Undergoing Laparoscopic Cholecystectomy.

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Abstract
Aims*: The purpose of this study was to assess whether thoracic combined spinal epidural anaesthesia (CSE) is a better alternative to the standard general anaesthesia in patients undergoing elective laparoscopic cholecystectomy.*
Material and Method*: Sixty patients of age group 18-65 years, scheduled for elective laparoscopic cholecystectomy were divided into two equal groups. Group A received thoracic combined spinal epidural anaesthesia (CSE) and Group B received general anaesthesia (GA). The number of attempts and the occurrence of any paraesthesia during CSE procedure were recorded. Surgeon and patient satisfaction score, and intraoperative parameters (heart rate, SBP, DBP, MAP) were recorded. Any anaesthesia or surgery related postoperative complication was also recorded. Postoperative pain was assessed by using the verbal rating scale (VRS).*
Results*: Demographic characteristics were insignificant among the two groups. In group A CSE block was performed in the first attempt in 25 patients and in the remaining a second attempt was made. Paraesthesias occurred in two patients (6.6%) transiently on needle insertion and were too short to locate dermatome affected in Group A. Haemodynamically, Group A was significantly more stable as compared to Group B. Two minutes onwards the MAP was higher in GA group at all time intervals and was statistically significant until end of surgery. Surgeon satisfaction score was higher in group A, but statistically not significant. Verbal rating scale (VRS) was higher in group B at all time intervals and statistically significant at 2 and 8 hours. The patient satisfaction score was higher in group A and statistically significant.*
Conclusion: *Thoracic CSE anaesthesia is safe, effective procedure for patients undergoing laparoscopic cholecystectomy and also leads to establishment of the superiority of the technique over general anaesthesia.*
Keywords*: Thoracic CSE, General anaesthesia, laproscopic cholecystectomy.*

I. Introduction

General anaesthesia and controlled ventilation comprise the accepted standard anaesthetic technique for laparoscopic procedures. But there are also some disadvantages with it like presser response to laryngoscopy and endotracheal intubation, increased oro-pharyngo-laryngeal morbidity, risk of failed intubation, gastric distension, decrease in functional residual capacity (FRC) and lung compliance. General anaesthesia increases endocrine stress response leading to increased release of cortisol, catecholamine and vasopressin which may be detrimental in patients with borderline cardiac status. There are increased chances of post-operative nausea vomiting (PONV), postoperative pain, postoperative pulmonary complications and sore throat. Lumbar spinal anaesthesia has been used successfully in healthy patients undergoing laparoscopic cholecystectomy and offers better postoperative pain control than general anaesthesia without limiting recovery. [1] Regional anaesthesia, blunts the "stress response" to surgery, decreases intraoperative blood loss and decreases the incidence of postoperative thromboembolic events. This technique allows awake patient who can communicate, facilitates early ambulation and results in decreased morbidity and mortality in high-risk surgical patients with the added advantage of being cost effective. In addition, both spinal and epidural techniques can be used to extend analgesia into the postoperative period, where their use has been shown to provide better analgesia than can be achieved with parenteral opioids.[2] However regional anaesthesia has its limitations in laparoscopic surgeries like anxiety, shoulder pain caused by diaphragmatic irritation due to CO_2 and hemodynamic changes associated with sympathetic blockade, but these changes can be overcome easily and no change is usually required in anaesthetic technique.

Very few studies have been conducted to compare thoracic spinal anaesthesia and general anaesthesia whereas no study has been conducted to compare thoracic combined spinal epidural anaesthesia with general anaesthesia. The purpose of this study was to assess whether thoracic combined spinal epidural anaesthesia (CSE) is a better alternative to the standard general anaesthesia (GA) for ASA I and II patients undergoing elective laparoscopic cholecystectomy.

II. Material And Methods:

After obtaining approval from the institutional ethical committee, the present study was conducted in the department of anaesthesiology and intensive care, Acharya Shri Chander College of Medical Sciences and Hospital, Jammu. This prospective randomized study included 60 ASA I and II patients, aged 18-65 years, undergoing elective laparoscopic cholecystectomy. The study was conducted only on the patients who gave written and informed consent for the procedure and study. They were divided randomly by computer generated numbers in two equal groups. Group A (n=30) patients were given thoracic combined spinal epidural anaesthesia (CSE). Group B (n=30) patients were given general anaesthesia (GA). Patients with any contraindication for spinal or epidural anaesthesia, MI >30 kg/m^2, acute cholecystitis, acute cholangitis, acute pancreatitis, suspected CBD stones and obstructive jaundice, patients of severe cardiac, pulmonary or renal disease and patients with known allergy to the study drugs were excluded from the study. All patients were made clear about pain scoring on the verbal rating scale (VRS; 0: no pain and 10: worst possible pain) and scoring of symptoms (discomfort, nausea and vomiting, urinary retention, headache, and other neurologic sequelae) (0, nil; 1, mild; 2, moderate; 3, severe). Every patient was kept fasting eight hours prior to surgery. All patients received, via the oral route tablet Midazolam 7.5 mg, Pantoprazole 40 mg and Domperidone 10 mg at bed time on the night prior to surgery. In the pre-operative room, an 18-gauge intravenous catheter was secured in all patients and every patient received pre-loading with Ringer Lactate 10 ml/kg over 30 minutes, ondansetron 0.1 mg/kg intravenously and 50 mg of ranitidine hydrochloride intravenously. The patients were then shifted to operation theatre and all routine monitoring namely, non invasive blood pressure (NIBP), peripheral oxygen saturation by pulse oximetry (SpO2), ETCO2 and electrocardiogram (ECG) started. Baseline values of heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, respiratory rate, ETCO2 and oxygen saturation (SpO2) were recorded. Inj. Midazolam 1mg intravenously was given to every patient just prior to the start of the procedure in order to allay the anxiety and apprehension.

CSE was performed with the patient in the sitting position. Under all aseptic precautions, 2% lignocaine was used for infiltrating skin at the T9-T10 or T10-T11 interspinous space. Combined spinal epidural (CSE) block was performed either at the T9-T10 or T10-11 thoracic interspace using an 18-gauge Tuohy needle and a mid-line approach. The epidural space was identified using the 'loss of resistance' to air method, the distance from skin to epidural space being calculated from the length of the needle protruding from the skin. After entering the epidural space, a 27-gauge pencil point Whitacre spinal needle was advanced through the Tuohy needle until the resistance of the duramater was felt, allowing the measurement of its distance from the tip of Tuohy needle. The dura was then pierced and the two needles secured together by a locking device which ensures that the spinal needle does not move any further beyond the tip of the Tuohy needle. After confirming the free and clear flow of CSF 2 ml of preservative free isobaric Bupivacaine 0.5% (5 mg/ml) + 25µg (0.5 ml) of Fentanyl was injected and then the spinal needle was removed. The epidural catheter was then threaded into place keeping the hub cephalad and fixed at 4 cm within the epidural space. The epidural catheter was introduced for providing intra-operative and post-operative analgesia as and when needed. Once the sensory block (target block T4–T12 as assessed by pinprick) was achieved, surgery was commenced. If the sensory block was inadequate even after 30 minutes, conversion to general anaesthesia was done. Intraoperative anxiety was treated with Midazolam 1 mg intravenous boluses upto total 5mg. Referred shoulder pain following pneumoperitoneum was managed with reassurance, shoulder massage and Fentanyl 25 µg intravenous boluses upto total 100 µg. Hypotension (fall in systolic BP less than 90 mmHg or decrease in mean arterial pressure more than 20 % from baseline value) was managed with Mephentermine 6 mg boluses and fluid bolus 10 ml/kg Ringer Lactate and bradycardia (heart rate below 20% of baseline) with Atropine 10 µg/kg intravenously. General anaesthesia patients received same premedication as of CSE group. Induction was done with Propofol 2 mg/kg intravenously, Fentanyl Citrate 1 µg/kg intravenously and Isoflurane 0.5% to 2 %. Tracheal intubation was facilitated with Rocuronium in the dose 0.6 mg/kg intravenously. For analgesia patients were given infusion of Diclofenac Sodium 75mg intravenously in 100 ml normal saline intra-operatively. Maintenance of anaesthesia was done with Isoflurane and bolus doses of Rocuronium dose 0.15 mg/kg. At the end of surgery neuromuscular blockade was reversed with Neostigmine 50 µg/kg and Glycopyrolate 10 µg/kg. After extubation patients were shifted to PACU.

The surgical technique was modified in both groups; to use lower levels of intra-abdominal pressure (less than 10 mmHg) and minimal or no change in the operation table position. The flow rate of Carbon dioxide administration was maintained at the rate less than or equal to two litres/minute. Nasogastric tube was inserted only on surgeon demand. The surgeons were preinformed to ask for general anaesthesia if they felt that the anaesthetic technique is adding to the technical difficulty of the procedure.

Analgesia in general anaesthesia patients was given with Diclofenac Sodium 75mg intramuscularly when VRS for pain was more than 3, upto total three doses in 24 hours. Patients having inadequate pain relief with diclofenac sodium were given Tramadol 1mg/kg intravenously up to total three doses in 24 hours. In patients of CSE, epidural analgesia top-up was given when VRS for pain was more than 3 with 0.125 %

Bupivacaine 8-10 ml. Epidural catheter was removed on the next morning after surgery. The patients were discharged 24 hours after the procedure after excluding any complications.

The number of attempts at each phase of the CSE procedure and the occurrence of any paraesthesia were recorded. Intraoperative parameters (heart rate, SBP, DBP, MAP, SpO_2, respiratory rate and $ETCO_2$) were recorded in all patients every two minutes for first ten minutes, every five minutes for next fifteen minutes and every ten minutes thereafter till the completion of surgical procedure. Patients were encouraged to report any discomfort like abdominal or shoulder pain, nausea, vomiting and headache. Operative difficulty (surgeon satisfaction score): post-operatively all surgeons were asked to score the operative conditions on a scale of 1 to 10 (1-3: unsatisfactory, 4-6: satisfactory, 7-8: very good, 9-10: excellent.) Every event was recorded. Any conversion in anaesthesia or surgical technique was noted with its reason. Any anaesthesia or surgery related postoperative complication was also recorded. Post-operatively parameters (heart rate, SBP, DBP, MAP, SpO_2, respiratory rate and $ETCO_2$) were recorded every fifteen minutes in PACU. Patients given general anaesthesia were monitored until they attained modified Aldrete recovery score of 10. Patients given thoracic CSE were monitored until the sensory block regressed to T12 dermatome. Postoperative analgesia: Postoperative pain was assessed by using the verbal rating scale (VRS; 0: no pain and 10: worst possible pain) at 2, 8, 16 and 24 hours after the completion of the procedure. Analgesic requirement in each group was recorded. Patient satisfaction score was recorded before discharge from the hospital on a scale of 1 to 10 (1-3: unsatisfactory, 4-6: satisfactory, 7-8: very good, 9-10: excellent).

Observations at different time periods were compared for each parameter in the group and intergroup comparison was done. All the data was analysed and subjected to statistical analysis for significance. Non-parametric data was compared using the Chi-square test and Mann-Whitney U test and parametric data was compared using Student t-test using SPSS 16.0 software. The level of significance was set at $p < 0.05$ for all analysis.

III. Results

Demographic characteristics were insignificant among the two groups (table 1). Thoracic combined spinal epidural block was performed in the first attempt in 25 patients at T9-T10 interspace and in the remaining five patients after the failure of the first attempt a second attempt was made at T10-T11 interspace. Paraesthesia occurred in two patients (6.6%) transiently on Whitacre needle insertion which disappeared spontaneously without any change in needle position. The paraesthesias were too short to locate dermatome affected.

No patient in group A had tachycardia whereas 11 patients (36.7 %) in group B had tachycardia (p-value 0.000) (table2).

Table 1: demographic characteristics of two groups

Parameters	group A (n=30)	Group B (n=30)	p value
Age (yrs)	45.30 ± 10.409	46.33 ± 12.093	0.724
Weight (kg)	69.83± 10.353	69.57 ± 8.985	0.916
Sex (M/F)	15/17	13/17	0.605
ASA (I/II)	17/13	18/12	0.793
BMA	24.81 (20-28)	25.60 (19-30)	0.714
Duration of surgery (min)	35.53±7.176	39.60 ±9.30	0.63
Data expressed in numbers (n), mean±SD			

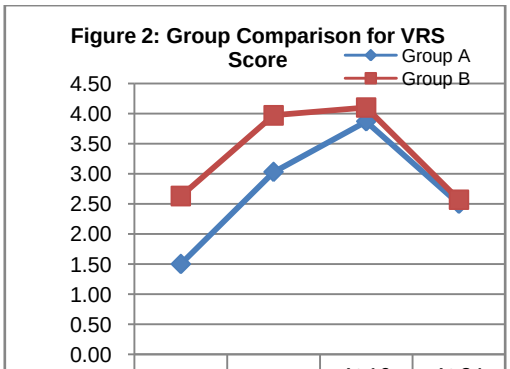
12(40.0%) patients in group A had hypotension as compared to 4(13.3%) in group B, the difference was statistically significant (p-value <0.05). No patient in group A had hypertension whereas 10 patients (33.3 %) in group B had hypertension, the difference was statistically significant (p-value 0.001) (table2). Heart rate at 2, 6, 8, 10 and 15 minutes were statistically significant in group B as compared to group A ($p<0.05$).

table 2: Perioperative events and patient satisfaction score in two groups

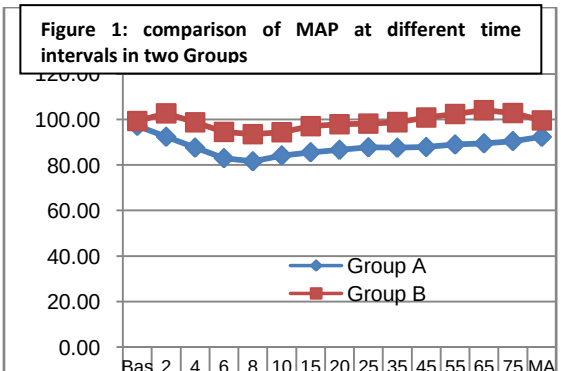
Parameters	Group A (n=30)	Group B (N=30)	p value
Hypotension	12 (40.0%)	4 (13.3 %)	0.020
Hypertension	0 (0.00%)	10 (33.3)	0.001
Bradycardia	18(86.7%)	27(90%	0.688
Tachycardia	0 (0.00%)	11(36.7%)	0.000
Surgeon satisfaction score - Excellent - Very good	 29 (96.7%) 1 (3.3%)	 26 (86.7 %) 4(13.3)	0.161
Data expressed in numbers (n) and percentage (%)			

Table 3: Comparison of patient satisfaction score in group A and B				
	Excellent	very good	satisfactory	unsatisfactory
Group A	19 (63.3%)	10 (33.3%)	0 (0.0%)	1 (3.3%)
Group B	10 (33.3%)	9 (30.0%)	9 (30.0%)	2 (6.7%)
p value	0.007			
Data expressed in numbers (n) and percentage (%)				

Two minutes onwards the MAP was higher in GA group at all time intervals and was statistically significant until end of surgery (figure 1). Comparison of surgeon satisfaction score in group A and B showed the satisfaction score was higher in group A, but statistically not significant (table 2).



	At 2 hr	At 8 hr	At 16 hr	At 24 hr
Group A	1.50	3.03	3.87	2.50
Group B	2.63	3.97	4.10	2.57



	Baseline	2 Mins	4 Mins	6 Mins	8 Mins	10 mins	15 mins	20 mins	25 mins	35 mins	45 mins	55 mins	65 mins	75 mins	MAP end
Group A	9	9	8	8	8	8	8	8	8	8	8	8	8	9	9
Group B	9	1	9	9	9	9	9	9	9	9	1	1	1	1	9

Comparison of verbal rating scale (VRS) in group A and B showed that the mean rank calculated according to Mann-Whitney U Test was higher in group B at all time intervals and statistically significant at 2 and 8 hours (figure 2). The patient satisfaction score was higher in group A and statistically significant (table 3).

Table 4: Postoperative events		
Parameters	Group A	Group B
Surgical complications (n)	0	0
Analgesia requirement (in 24hours)	3.5 (3-6)	3.8 (3-6)
Opioid requirement (n)	0 (0%)	12 (40.0%)
Post-op pulmonary complications	0	0
Post-op nausea and vomiting (PONV)	0	12 (40.0%)
Ambulation; Day 0:1	30:0	12:18
Discharge from hospital; day 1:2:3	30:0:0	28:2:0

IV. Discussion

Conventionally laparoscopic cholecystectomy is performed under general anaesthesia based on the assumption that laparoscopic procedure necessitates endotracheal intubation in order to prevent aspiration and respiratory embarrassment secondary to induction of CO_2 pneumoperitoneum, which may not be well tolerated by a patient under regional anaesthesia who is awake during the procedure. Surprisingly in the era of minimally invasive surgery the use of regional anaesthesia in laparoscopic cholecystectomy has not been popular and has been done only sparingly and that too in high risk patients with either respiratory or cardiac compromise. The irony is that this technique is advocated for high risk patients and has not been used for ASA I and II patients in whom the risk will be even lower.

With this background our study was conceptualized to compare these two techniques of administering anaesthesia for laparoscopic cholecystectomy.

Paraesthesia occurred in two patients (6.6%) transiently on Whitacre needle insertion which disappeared spontaneously without any change in needle position. The paraesthesias were too short to locate dermatome affected. Imbelloni LE (2010) performed thoracic spinal at T10 in 300 patients; incidence of paraesthesia in his study was 6.6 %, but no signs of any permanent neurological damage reported.[3] Ellakany M (2013) in his study reported 10% patients had paraesthesia. [4] Yousef GT (2012) reported 3.3% patients had paraesthesia in both thoracic and lumbar spinal groups.[5]

Paraesthesia during spinal needle insertion indicates that the tip of the needle is adjacent to spinal nerve roots, or, potentially, the spinal cord. Most of the studies have not reported any permanent neurological deficit in these patients. However in one retrospective study by Horlocker T (1997), he reported 0.13% patients had

permanent neurological deficit after spinal anaesthesia and paraesthesia was one of the important risk factors associated with subsequent development of permanent neurological deficit.[6]

A possible anatomical explanation for the absence of any damage or injury to spinal cord during the accidental perforation of the thoracic duramater is that, at the thoracic level the distance between the dura and spinal cord is more than that at the lumbar level. This was proved by Imbelloni LE et al he studied the anatomy of the thoracic spinal canal with magnetic resonance imaging (MRI) in 50 patients. [3] The space between the duramater and spinal cord in the thoracic region measured with MRI was 5.19 mm at T2, 7.75 mm at T5, and 5.88 mm at T10. Introduction of the epidural needle at angle of almost 50 degrees further elongates the distance from the tip of the needle to the posterior surface of the cord. Furthermore use of a CSE system which limits the length of needle which can project beyond the tip of the epidural needle also minimizes the risk of contact with neural tissue. The sitting position for neuraxial block further increases margin of safety as shown by Lee et al, he investigated the human anatomic positions of the spinal canal (spinal cord, thecal tissue) in various postures with magnetic resonance imaging and found that in a head-down sitting posture, the posterior separation of the duramater and spinal cord is increased. In our study we performed CSE in the sitting position.[7]

The heart rate at different time intervals intra-operatively was higher in the GA group and was statistically significant from 2 to 15 minutes. Tachycardia was recorded in 11(36.7%) patients of GA group and none in CSE group. Tachycardia was seen mostly during the times of intubation and extubation. Our study correlates with the studies done by Ellakany M and Yousef GT et al. Who reported bradycardia in 40% patients of thoracic spinal group, while and 0% in general anaesthesia group.

Patients in Group A were haemodynamically more stable regarding the SBP, DBP and MAP as compared the group B in our study. The results of our study were somewhat similar to other studies, in which they observed more hypotension in patient who received spinal anaesthesia as compared the patients received the general anaesthesia. [1, 3, 4, 5, 8]

Comparison of verbal rating scale (VRS) in group A and B showed the mean rank calculated according to Mann-Whitney U Test, was higher in group B at all time intervals and statistically significant at 2 and 8 hours. Higher mean rank in group B means that the group B had more cases with high VRS score. The results of our study are somewhat similar to other studies. Bessa SS (2012) reported that the VAS at 2 and 4 hours were significantly lower in spinal anaesthesia group compared to general anaesthesia group.[9] Ellakany M (2013) reported that the VAS at 4, 8, 12, and 24 hours was significantly less in thoracic spinal group patients when compared with general anaesthesia group patients.[4] Yeager et al (1987) demonstrated a significant decrease in morbidity and mortality in high-risk patients undergoing epidural anaesthesia and postoperative analgesia versus patients receiving high-dose narcotic anaesthesia and parenteral narcotic analgesia.[10] Epidural analgesia has been found to significantly reduce pain scores as compared to parenteral opioid analgesia. [11]

Postoperative pain management remains a key issue for the success of any surgical procedure. Keulemans Y et al (1998) found that postoperative pain was the primary reason for both delayed discharge and prolonged convalescence following ambulatory laparoscopic cholecystectomy.[12] Various methods have been attempted to decrease postoperative pain following laparoscopic cholecystectomy such as peritoneal instillation of normal saline or local anaesthetic and wound infiltration with local anaesthetic (Tsimoyiannis EC 1998).[13] Less pain scores in CSE group in our study can be due to avoidance of endotracheal intubation and extubation related discomfort, the presence of adequate levels of analgesia for the first few hours after the completion of the surgical procedure owing to the existing activity of the anaesthetic injected in the subarachnoid space, superiority of epidural analgesia over narcotics and the potentially minimal stress response associated with a minimal invasive anaesthetic procedure.

Comparison of patient satisfaction score in group A and B showed the satisfaction score was higher in group A and statistically significant. Similar results were recorded by Yousef GT (2012) and Ellakany M (2013).[4,5] Better patient satisfaction in thoracic CSE may be due to; first, the patient is awake and oriented at the end of the procedure. Second, the immediate postoperative period is viewed positively by patients because of the absence of general anaesthetic side effects (e.g., nausea and vomiting) and less pain experienced due to the effect of persistent neuraxial blockage. Third, patients who have received spinal anaesthesia tend to ambulate earlier than patients receiving general anaesthesia (Lennox PH et al 2002).[14]

The goal of anaesthetic management in the laparoscopic procedures includes management of pneumoperitoneum, achieving adequate level of sensory blockade without any respiratory compromise, management of shoulder tip pain, provision of adequate post-operative pain relief and ambulation as early as possible. Regional anaesthesia fulfils all the above criteria and aids in quick and uneventful recovery and thus has been suggested to be a suitable alternative to general anaesthesia for laparoscopic surgeries. The analysis of our study not only confirms the safe and effective use of combined thoracic spinal epidural anaesthesia in ASA 1 and II patients undergoing laparoscopic cholecystectomy but also leads to establishment of the superiority of the technique over general anaesthesia in terms of significant post-operative benefits. However there is still fear of cord damage among the conventionally trained anaesthesiologists about inserting the spinal needle above the termination of spinal cord. Therefore a greater amount of evidence needs to be gathered before our fellow

colleagues both surgeons and anaesthesiologists come to terms with the merits and efficacy of using thoracic CSE in patients posted for laparoscopic cholecystectomy.

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