Original Article

Comparison of block characteristics and outcomes in opioid-free and opioid-based thoracic continuous spinal anaesthesia in patients undergoing major abdominal surgery: A double-blinded randomised controlled trial

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ABSTRACT

Background and Aims: Thoracic continuous spinal anaesthesia (TCSA) is emerging as the sole anaesthetic for major abdominal surgery due to its better perioperative outcomes. This study was designed to evaluate block characteristics and outcomes in 'opioid-free' and 'opioid-based' TCSA. **Methods:** After ethical approval, trial registration and written informed consent, 50 adult patients undergoing major abdominal surgery were randomised into 'opioid-free' (bupivacaine alone) and 'opioid-based' (bupivacaine with fentanyl) groups. After confirmation of T4-L1 dermatome level of spinal anaesthesia, sedation by intravenous (IV) midazolam (0.02–0.05 mg/kg), ketamine (0.25 mg/kg) and dexmedetomidine (bolus dose of 1 μg/kg IV over 10 min followed by 0.2–0.7 μg/kg/h infusion) were started. The primary outcome measured was postoperative pain scores for 72 h in both groups. The secondary objectives were rescue opioid requirement, and the dose of bupivacaine required to achieve T4 level. Data were compared using the two-sided Student *t*-test, Mann-Whitney and Fisher's exact tests. **Results:** The 'opioid-based' group performed significantly better compared with the 'opioid-free' group concerning pain scores at rest at 0 h ($P = 0.023$), 18 h ($P = 0.023$) and 24 h ($P = 0.016$) postoperatively, decreased intrathecal bupivacaine requirement [(induction ($P = 0.012$) and maintenance ($P = 0.031$)], postoperative rescue fentanyl requirement ($P = 0.018$) and patient satisfaction ($P = 0.032$) at the cost of increased postoperative nausea and vomiting ($P = 0.049$). **Conclusion:** The 'opioid-based' TCSA provided better postoperative analgesia with significantly lesser postoperative pain scores when compared to the 'opioid-free' group in patients undergoing major abdominal surgery.

Keywords: Continuous spinal anaesthesia, dexmedetomidine, fentanyl, ketamine, major abdominal surgery, postoperative pain, rescue opioid requirement, thoracic spinal anaesthesia

INTRODUCTION

Thoracic continuous spinal anaesthesia (TCSA) for major abdominal surgery has found renewed interest due to its utility as a sole anaesthetic.[1-3] It has decreased cardiorespiratory complications[4] while providing better pain control.[5] It provides better block height control and cardiorespiratory stability with minimal local anaesthetic (LA) doses.[1-3]

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The opioids are often added to TCSA to prolong the duration of analgesia but are known to cause respiratory depression, nausea, vomiting and pruritus.[3] Due to the paucity of literature on 'opioid-free' TCSA, this study was designed to evaluate block characteristics and outcomes in 'opioid-free' and 'opioid-based' TCSA in major abdominal surgery in a double-blind randomised controlled trial (RCT).

The primary objective was to estimate and compare the postoperative pain for 72 h postoperatively in two groups. The secondary objectives were to estimate and compare the rescue fentanyl requirement, the intrathecal dose required to achieve T4-L1 sensory levels, conversion to general anaesthesia (GA), haemodynamic stability, morbidity and in-hospital mortality, opioid-related side effects and complications of TCSA in both groups. We hypothesised that 'opioid-free' TCSA would reduce the opioid-related side effects without compromising the postoperative pain scores when compared to 'opioid-based' TCSA.

METHODS

A double-blind RCT was conducted in a tertiary care hospital after institutional ethics committee approval (vide approval number AIIMS/IEC/21/54 dated 12/02/2021) and after registration in the Clinical Trials Registry-India (vide registration number CTRI/2021/03/032309, www.ctri.nic.in), from April 2021 to September 2022. The study was conducted in accordance with the principles of the Declaration of Helsinki (2013) and adhered to good clinical practice.

Patients undergoing major abdominal surgery were recruited, and written informed consent was obtained for participation in the study and use of the data for research and educational purposes. Patients included were aged >18 years, of both genders, belonging to the American Society of Anesthesiologists (ASA) physical status I–III. Patients with body mass index (BMI) >35 kg/m^2, severe systemic illness, any contraindication to spinal anaesthesia and haemodynamically unstable were excluded from the study. All patients underwent pre-anaesthetic evaluation for airway, spine and comorbidities (Charlson's Comorbidity Index) and optimisation. The standard protocol was followed regarding preoperative fasting and premedication.

We recruited 50 cases (25 in each group) undergoing major abdominal surgery. The 'opioid-based' group received intrathecal bupivacaine with fentanyl, and the 'opioid-free' group received bupivacaine alone. The randomisation was performed by a computer-generated random number table. Subsequently, patients were allocated into one of the two groups by serially numbered, sealed, opaque envelopes concealing the group. Patients, anaesthesiologists and surgeons who assessed outcomes were blinded. An anaesthesiologist, who was not part of the study, opened the sealed envelope, prepared the study drugs according to randomisation and labelled them as study drugs under all aseptic precautions. They did not participate in assessment of the study outcomes.

All standard ASA monitors were attached in the operating room, two-wide bore intravenous (IV) access was obtained, and IV pre/co-loading was performed with 20 mL/kg of the ringer lactate solution. Invasive monitoring and arterial blood gas analysis were considered when required. The patients were made to sit, thoracic and lumbar fields were cleaned and draped, and T10–T11 thoracic intervertebral space was identified. The 21G Sprotte tip spinal needle (PAJUNK, Geisingen, Germany) was inserted till the free flow of cerebrospinal fluid (CSF) was achieved, and a 25 G catheter was inserted 3–5 cm beyond the tip of the spinal needle. The number of attempts and paraesthesia, if any, was noted. The patients were then made supine, and oxygen was delivered at 5 L/min through a facemask.

In the 'opioid-based' group, the patient received intrathecal fentanyl 0.3 μg/kg (50 μg/ml) once, and 2.5 mg of 0.5% hyperbaric bupivacaine was administered every 3 min till the desired sensory dermatomes were blocked (T4-L1). The dose required was noted as an induction dose of LA. In the 'opioid-free' group, an equivalent volume of 0.9% normal saline (NS) was administered as an adjuvant, and LA drug was administered for the 'opioid-based' group. The induction dose thus noted (LA plus adjuvant) was administered in a continuous intrathecal infusion through a syringe pump (Mindray, Shenzhen, China) on an hourly basis; this avoided the consequences of bolus dose (like hypotension) and risk of infection associated with repeated handling during intermittent boluses. The infusion was stopped at the time of skin closure, approximately 30 min before the end of surgery.

After confirmation of T4-L1 dermatome level of anaesthesia, patients were sedated with IV midazolam (0.02–0.05 mg/kg) and ketamine (0.25 mg/kg) in half-divided doses, 3–5 min apart before skin incision

and the same dose of ketamine was given if the patient complained of shoulder pain anytime during surgery. The dexmedetomidine sedation was started with a bolus dose of 1 μg/kg IV over 10 min followed by 0.2–0.7 μg/kg/h IV infusion throughout the procedure and titrated to achieve a modified Ramsay sedation scale score of 2–3.

Rescue doses of spinal anaesthetic were considered if the patient complained of pain [visual analogue scale (VAS) >4/10)] or sensory block regressed by two segments, with 0.5 ml of study drug administered every 3 min till the pain subsided or desired dermatomes were achieved. If the pain did not subside, they were given rescue analgesia with IV fentanyl 0.5 μg/kg. The amount of sedation required and any rescue analgesia were noted in both groups.

The decision to convert to GA was taken when there was failed spinal anaesthesia or severe haemodynamic instability due to haemorrhage. IV fluids were administered according to the Holliday-Segar formula, and blood loss was replaced by crystalloids and blood products.

For postoperative analgesia, the 'opioid-based' group received 0.2% preservative-free lignocaine with fentanyl 2 μg/ml in 0.9% NS as an intrathecal infusion of 4 mL/h for the first 24 h and 2 mL/h in the next 48 h through an elastomeric pump (Smiths Medicals, Bhiwandi, India) and the 'opioid-free' group received 0.2% preservative-free lignocaine in 0.9% NS administered at the same rate.

After surgery, patients were monitored for vitals (heart rate (HR), blood pressure, respiratory rate (RR) and oxygen saturation (SpO_2)) and pain scores (VAS) measured at time points 0 (end of the surgery), 3, 6, 12, 24, 48 and 72 h postoperatively. IV paracetamol 1 g was given if VAS >4. Rescue IV fentanyl 0.5 μg/kg was given if the pain did not subside after paracetamol. The total rescue fentanyl required was noted. All patients received ondansetron 4 mg IV three times a day. Patient satisfaction score at 72 h on a Likert scale (1/5—very dissatisfied, 2/5—dissatisfied, 3/5–neutral, 4/5—satisfied and 5/5—very satisfied) was noted. Any morbidity, including requirement of intensive care unit (ICU) admission, mechanical ventilation and in-hospital mortality, was noted. Any intraoperative respiratory depression (defined as RR <10/min or SpO_2 <90% by pulse oximetry for at least 3 min) was treated with bag and mask ventilation for 3–5 min; if not improved, endotracheal intubation was considered. Hypotension (defined as mean arterial pressure (MAP) <60 mmHg or systolic blood pressure <90 mmHg) was initially managed with IV fluid bolus of 250 ml of crystalloids, if not corrected mephentermine 3–6 mg IV boluses to a maximum of 30 mg, further hypotension was managed with norepinephrine infusion 0.5–1.5μg/kg/min titrated to the blood pressure goal (MAP >60 mmHg) and bradycardia (defined as HR <50/min) was treated with atropine 0.6 mg IV. All the above events and their management in both groups were noted and analysed.

The sample size was based on a study by Vincenzi *et al*.[3], who reported a mean (standard deviation (SD)) VAS score in the two groups of 6.24 (1.21) and 6.3 (1.09), respectively. Thus, taking the expected SD to 1.15 and minimal clinically important difference (MCID) of 1 for VAS, 95% confidence interval (CI) and 80% power and allowing for 10% attrition, the sample size calculated was 25 per group. Normally distributed continuous data (age and height) were reported as the mean and SD and compared using the two-sided Student *t*-test. Non-normally distributed continuous data (weight, BMI and Charlson's Comorbidity Index) were reported as the median and range and compared using the Mann-Whitney test. Categorical variables (gender) were analysed with the Chi-square and Fisher exact tests. A P value of <0.05 was considered significant.

RESULTS

Fifty patients were included in the analysis, 25 in each group [Figure 1]. The two groups' demographic parameters and surgical characteristics were comparable [Tables 1 and 2]. Intraoperatively, intrathecal bupivacaine requirement to achieve T4-L1 dermatomes (P = 0.012) and maintenance doses (P = 0.031) were significantly lesser in the 'opioid-based' group. The intraoperative rescue fentanyl requirement and total dexmedetomidine were comparable between the two groups [Table 3]. Intraoperative events, desaturation, bradycardia and hypotension requiring interventions were comparable between the two groups [Table 4]. Intraoperative vitals at different time points were comparable between both groups.

The VAS at rest and movement was significantly higher in the 'opioid-free' group when compared to the 'opioid-based' group at 0, 18, 24 h post-surgery and 0 h, respectively [Table 5]. Postoperative nausea and vomiting (PONV) were significantly higher

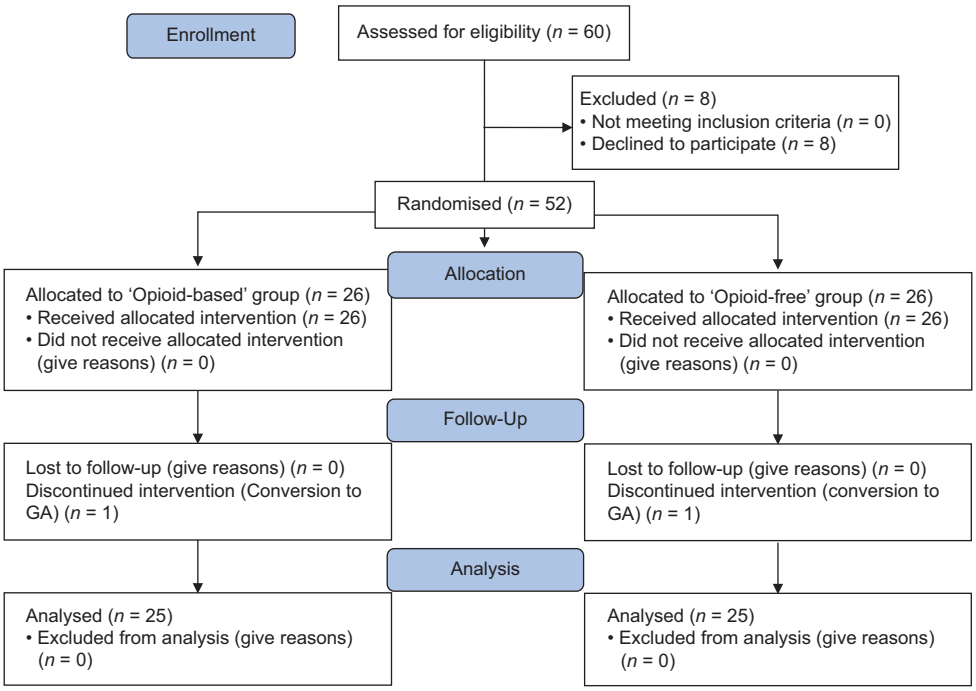

Figure 1: Consolidated standard of reporting trials (CONSORT) flow chart

Table 1: Comparison of demographic variables (*n*=50)

Parameters	'Opioid-based' group (*n*=25)	'Opioid-free' group (*n*=25)
Age (years)	54 (43–57)	51 (42–60)
Gender (male/female) (*n*)	7/18	11/14
Height (cm)	158 (156–168)	163 (158–167)
Weight (kg)	50 (50–60)	53 (45–58)
BMI (kg/m^2)	20.4 (19.3–22.8)	20.2 (17.6–23.4)
ASA-PS (*n*)		
I/II/III	2/9/14	4/15/6
Charlson Comorbidity Index	4 (3–4)	3 (1–4)

Data are expressed as median (interquartile range) or number. *n*=number of patients, ASA-PS: American Society of Anesthesiologists—Physical Status; BMI=body mass index

in the 'opioid-based' group when compared to the 'opioid-free' group (96% versus 72%, $P = 0.049$). Patient satisfaction ($P = 0.032$) was significantly better in the 'opioid-based' group; haemodynamic stability was equivalent in both groups. No major morbidities (respiratory, cardiac, renal, ICU stay, re-exploration and re-admission) and in-hospital mortality were observed in any of the groups, except for a minor leak in the pancreaticojejunostomy anastomosis in one patient of Whipple's procedure ('opioid-based' group), which was managed conservatively, and the patient got discharged in a healthy state.

DISCUSSION

The postoperative pain scores were significantly lesser in the 'opioid-based' group as compared to the 'opioid-free' group. Similarly, in the 'opioid-based' group, there was a decreased need for rescue opioid requirement postoperatively, decreased induction and maintenance dose of intrathecal bupivacaine and improved patient satisfaction as compared to the 'opioid-free' group (secondary objectives).

The opioids, through G-protein-coupled receptors, enhance the anti-nociception of LA. Fentanyl, when given intrathecally, extends the duration and scope of sensory block; studies comparing intrathecal 'LA with opioids' to 'LA alone' (either as a single shot or continuous spinal anaesthesia) showed improved pain scores and reduced need for rescue analgesia in the 'opioid-based' groups.[6] This synergistic effect of LA and opioids has been effectively used in numerous abdominal surgeries.[1-3,6] Our results align with the above studies.

In our study, haemodynamic stability in both groups was comparable. The stability may be due to preloading, graded intrathecal induction, and maintenance drugs being administered as a continuous infusion by a syringe pump throughout the surgery.[7]

Our study did not observe any major morbidity or in-hospital mortality. The incidence of cardiopulmonary complications in patients undergoing major abdominal surgery under TCSA

Table 2: Surgical characteristics

Parameters	'Opioid-based' group (*n*=25)	'Opioid-free' group (*n*=25)	*P*
Diagnosis (*n*)			0.119
CA colon	2	5	
Adnexal mass and ovarian CA, CA endometrium	7	1	
Choledocholithiasis and choledochal cyst	4	4	
Periampullary CA and CA of head of pancreas and cholangiocarcinoma	4	1	
CA gall bladder	1	3	
CA bladder and renal cell CA	3	2	
Ileocecal mass and CA appendix and mesenteric cyst	1	3	
Recurrent large incisional hernia and loop ileostomy	1	5	
Chronic calcified pancreatitis	1	1	
Neuroendocrine CA of jejunum	1	0	
Surgery performed (*n*)			0.110
Exploratory laparotomy and staging laparotomy	9	3	
Hemicolectomy	3	6	
Whipple's surgery and Frey's procedure, and modified Puestow surgery	4	2	
CBD exploration and choledochal cyst excision and hepaticojejunostomy	4	3	
Radical cholecystectomy	1	3	
Radical cystectomy and radical nephrectomy	3	1	
Cytoreduction surgery	1	1	
Stoma reversal	0	3	
Transverse abdominal release, component separation and mesenteric cyst excision	0	3	

Data expressed as numbers. *n*=number of patients, CA=carcinoma

Table 3: Intraoperative block characteristics, duration of surgery and anaesthesia

Parameters	'Opioid-based' group (*n*=25)	'Opioid-free' group (*n*=25)	Mean difference (95% CI)	*P*
Subarachnoid bupivacaine requirement (0.5%, hyperbaric)				
Bupivacaine induction dose (T4-L1) (mL)	2 (2–2)	2.5 (2–2.5)	0.33 (0.08 to 0.58)	0.012
Bupivacaine maintenance dose (mL)	8 (7.5–10)	10 (8–12.5)	2.58 (0.38 to 5.54)	0.031
Fentanyl IV rescue (µg) requirement	0 (0–20)	20 (0–20)	0.6 (-17.3 to 18.5)	0.268
Total IV dexmedetomidine given (µg)	96 (50–160)	90 (72–128)	-18.3 (-63.4 to 26.7)	0.748
Duration of anaesthesia (min)	290 (270–360)	300 (270–330)	0.2 (-72.1 to 72.5)	0.667
Duration of surgery (min)	270 (230–330)	270 (240–300)	-4.8 (-74.6 to 65.0)	0.830

Values are expressed as median (interquartile range) or number. 95% CI: 95% confidence interval, n=number of patients, IV=intravenous

Table 4: Intraoperative events

Parameters	'Opioid-based' group (*n*=25)	'Opioid-free' group (*n*=25)	Mean difference (95% CI)	*P*
Episodes of desaturation requiring bag and mask ventilation (N)	2	0	(-2.6% to 19%)	0.490
Episodes of bradycardia requiring atropine	0 (0–0)	0 (0–0)	-0.08 (-0.19 to 0.03)	0.161
Episodes of hypotension requiring mephentermine	3 (1–4)	3 (2–5)	0.32 (-0.91 to 1.55)	0.473
Total mephentermine given (mg)	18 (6–24)	18 (12–30)	1.92 (-5.46 to 9.3)	0.473
Episodes of hypotension requiring noradrenaline (N)	6	2	(-3.8% to 36%)	0.247
Total norepinephrine dose (µg)	0 (0–0)	0 (0–0)	-1.92 (-142.58 to 138.74)	0.140
Total blood loss (mL)	400 (300–760)	400 (300–700)	69.6 (-200.82 to 340.02)	0.961
Total urine output (mL)	550 (400–900)	550 (450–600)	-94.4 (-289.33 to 100.53)	0.992
Intraoperative fluid transfusion				
Total fluid given (mL)	3100 (2200–3500)	2450 (2100–3100)	-496.8 (-1130.97 to 137.37)	0.150
Crystalloid transfused (mL)	3100 (2200–3500)	2450 (2100–3000)	-596 (-1190.46 to 1.54)	0.050
Colloid transfused (mL)	0 (0–0)	0 (0–0)	50 (-40.86 to 140.66)	0.540
Blood product transfused				
PRBC transfused (mL)	0 (0–350)	0 (0–0)	28 (-111.9 to 167.09)	0.919
FFP transfused (mL)	0 (0–0)	0 (0–0)	29.2 (-13.58 to 71.98)	0.162
Platelet transfused (mL)	0 (0–0)	0 (0–0)	10 (-10.11 to 30.11)	0.337

Data expressed as median (interquartile range) or number (*n*), PRBCs=Packed red blood cells, FFP=Fresh frozen plasma, CI=Confidence interval, *n*=Number of patients

Table 5: Change in postoperative pain scores (VAS) at rest and movement over time in the two groups

Parameters	'Opioid-based' group (*n*=25)	'Opioid-free' group (*n*=25)	*P*
Postoperative pain scores (VAS) at rest			
VAS at 0 h	0 (0–0)	0 (0–1)	0.023
VAS at 3 h	0 (0–1)	0 (0–1)	0.817
VAS at 6 h	1 (0–3)	2 (1–2)	0.297
VAS at 12 h	2 (0–2)	2 (1–3)	0.061
VAS at 18 h	1 (0–2)	2 (1–3)	0.023
VAS at 24 h	1 (0–1)	1 (1–3)	0.016
VAS at 48 h	0 (0–1)	0 (0–1)	0.472
VAS at 72 h	0 (0–1)	0 (0–0)	0.840
Postoperative pain scores (VAS) at movement			
VAS at 0 h	0 (0–0)	0 (0–0)	0.041
VAS at 3 h	0 (0–0)	0 (0–2)	0.465
VAS at 6 h	1 (0–2)	1 (0–3)	0.200
VAS at 12 h	2 (1–3)	2 (0–3)	0.953
VAS at 18 h	2 (1–3)	2 (1–3)	0.921
VAS at 24 h	2 (1–2)	2 (2–2)	0.506
VAS at 48 h	1 (1–2)	1 (0–2)	0.552
VAS at 72 h	1 (0–2)	0 (0–2)	0.332

Data expressed as median (interquartile range) or number.VAS=Visual analogue scale, *n*=Number of patients

was 13.2–23.3%; cardiac failure was 10.5–21.7%; neurological complications were 15%; acute kidney injury was 5.3–13.3%; and mortality was 5.6%.[2,3] The higher rates of postoperative complications in these studies might be due to the high number of elderlies with associated comorbid participants belonging to ASA-III and ASA-IV physical status.

Neuraxial opioids are associated with adverse effects such as nausea, vomiting, pruritus, delirium and respiratory depression. In our study, there was no episode of respiratory depression causing desaturation due to intrathecal opioids, which may be due to the slower intrathecal infusion of study drugs adopted in our protocol, the smaller doses carrying the advantage of preventing high peak concentration of opioids in the CSF as compared to the bolus doses. Two of our initial patients (4%), who are around 30- to 30-40 year old females weighing 50–60 kg, ASA-II, developed apnoea and desaturation during the initiation of sedation (before incision) immediately after confirmation of sensory level from T4-L1, ruling out a higher level of spinal anaesthesia. The concomitant administration of IV sedative drugs may increase the risk of respiratory depression and apnoea in patients who are receiving intrathecal opioids. Both events were transient and were managed with bag and mask ventilation for 2–5 min. After regaining normal respiration, surgical incision was taken, and the rest of the surgery was uneventful. The lipophilic opioid adjuvant is known to produce lesser respiratory depression than hydrophilic opioids. However, Vincenzi *et al*.[3] observed significant respiratory depression of 23.3% in the intrathecal 'LA plus fentanyl (opioid)' group when compared to 5.2% in the 'LA plus ketamine and midazolam (non-opioid)' group in TCSA; this might be due to elderly comorbid study participants.

In our study, there were no episodes of nausea and vomiting intraoperatively in both groups. However, postoperatively, nausea and vomiting were significantly higher in the 'opioid-based' group when compared with the 'opioid-free' group. The reported literature shows an incidence of 10% nausea and vomiting in continuous thoracic spinal anaesthesia.[2] None of the patients experienced pruritus intraoperatively or postoperatively in the groups. However, this low incidence does not provide any definitive conclusions. CSA can be technically challenging; with an incidence of 0-4.3% of facing difficulty while inserting a 20G catheter, however, we did not find such difficulty.[8]

Anaesthesiologists are often concerned with conducting spinal anaesthesia above the level of L1, given the possibility of spinal cord injury. However, no major neurological complications were reported.[1-3] In our study, 24% of patients developed transient paraesthesia without neurological deficits. The literature shows an incidence of 0–33% paraesthesia in the CSA technique.[1-3] In our study, 20% of patients developed PDPH, consistent with the incidence in reported literature (0–40%), depending on age,

gender and needle size in studies using single-shot or continuous techniques.[8] The PDPH in CSA techniques for major abdominal surgery reported a 1–3.4% incidence.[2] The lower incidence may be due to elderly study participants. The neuraxial catheters carry the risk of infections, so it is preferable to remove them as soon as possible; we did not observe any infections.

The limitations of this study were the small sample size and being a single-centre study. Therefore, more studies with larger sample sizes and involving people with different comorbidities or demographic profiles could lead to the validation of the usage of TCSA in major abdominal surgeries.

CONCLUSION

The 'opioid-based' TCSA provided better postoperative analgesia with significantly lesser postoperative pain scores as measured by VAS score when compared to the 'opioid-free' group in patients undergoing major abdominal surgery. However, more studies with larger sample sizes and different optimal combinations of drugs are required to establish the role of continuous thoracic spinal anaesthesia in major abdominal surgery.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared upon request.

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Conflicts of interest

There are no conflicts of interest.

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