Original Article

Thoracotomy Patients Under General Anesthesia: A Comparison on Intra-Operative Anesthetic and Analgesic Requirements, When Combined with Either Epidural Analgesia or Continuous Unilateral Paravertebral Analgesia

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ABSTRACT

Background and Objective: Regional analgesia is effective for post-thoracotomy pain. The primary objective of the study is to compare the intraoperative requirement of isoflurane and fentanyl between general anaesthesia (GA) with epidural analgesia and GA with paravertebral analgesia.

Methods and Material: A prospective observational comparative study was conducted on 56 patients undergoing open thoracotomy procedures. The patients were divided into two groups of 28 by assigning the study participants alternatively to each group: Group GAE - received thoracic epidural catheterization with GA, and Group GAP - received ultrasound guided thoracic paravertebral catheterization on the operative side with GA. Intraoperative requirement of isoflurane, fentanyl, postoperative analgesia, stress response, need of rescue analgesics and adverse effects were observed and analysed.

Results: 25 patients in each group were included in the data analysis. The intraoperative requirement of isoflurane (32.28 ± 1.88 vs 48.31 ± 4.34 ml; $p < 0.0001$) and fentanyl (128.87 ± 25.12 vs 157 ± 30.92 µg; $p = 0.0009$) were significantly less in the GAE group than in the GAP group. VAS scores and need of rescue analgesics and blood glucose levels were not statistically significant during the postoperative period ($p > 0.05$). The incidence of adverse effects was comparable except for hypotension and urinary retention which were significantly higher in the GAE group.

Conclusion: GA with epidural analgesia resulted in significant reduction in the intraoperative consumption of isoflurane and fentanyl in comparison to GA with paravertebral analgesia. However, both the techniques were equally effective in the postoperative period.

Keywords: Epidural and intraoperative fentanyl requirement, epidural and intraoperative isoflurane requirement, GA with epidural, GA with unilateral paravertebral catheter, paravertebral catheter and intraoperative fentanyl requirement, paravertebral catheter and intraoperative isoflurane requirement, thoracotomy pain unilateral paravertebral catheter

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INTRODUCTION

Although general anesthesia (GA) with lung isolation is the choice for thoracotomy procedures, the supplementation of regional anesthesia with GA has shown to lower the anesthetic and analgesic requirements and the blood loss,

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attenuates the stress response, and leads to a decrease in the intensity of pain scores.[1,2] Although an addition of epidural analgesia to GA has shown to reduce the intra-operative inhalational anesthetic requirements, the available literature studies are scanty describing the intra-operative combined effects of paravertebral block and GA techniques in thoracic surgeries. There are no head-to-head comparative studies done on the intra-operative inhalational and anesthetic requirements under GA with either epidural analgesia or paravertebral analgesia. Through this study, we aimed to evaluate whether GA when combined with paravertebral analgesia could reduce the intra-operative anesthetic and analgesic requirements and be as effective as GA with epidural analgesia for patients undergoing thoracotomy. For reducing the post-operative pain, epidural and paravertebral analgesia techniques are already proven to be effective under various studies, attenuating the stress response and improvement of ventilation function in patients undergoing lung surgeries.[3,4] The primary objective of this study was to compare the intra-operative requirement of isoflurane and fentanyl when GA is combined with either the epidural analgesia technique or paravertebral analgesia technique. The secondary objectives here were to compare for post-operative analgesia, post-operative oxygenation and ventilation, stress response, requirement of rescue analgesics, and adverse effects.

METHODS

This was a prospective, observational, single-blinded comparative study, conducted on patients scheduled for open thoracotomy procedures between December 2014 and July 2016, and it was approved by the institutional ethics board (SCT/IEC/705/October 2014). After obtaining written informed consent, patients who were aged between 18 years and 75 years and planned for elective thoracic surgeries were recruited for the study. The patients were divided into two groups (group GAE is GA with epidural and GAP is GA with paravertebral), each consisting of 28 patients. The group distribution was performed by the principal investigator by consigning consecutive study participants alternatively to each group. Exclusion criteria for the study included patients not consenting to participate, those with existing pre-operative coagulopathy, those with diabetes mellitus, those with a forced expiratory volume in 1 second on spirometry <50% of predicted, those with severe spine or chest wall deformity, those with history of cardiac diseases, those with pre-existing motor or sensory deficits, those with allergy to local anesthetics, and those with redo-surgeries.

All patients were pre-medicated with oral diazepam 10 mg on the night before and on the morning of surgery. In the operation room, after the placement of recommended monitors as per the American Society of Anesthesiologists and insertion of radial arterial cannula, GA was induced in all patients with injection propofol 2 mg/kg, injection midazolam 0.02 mg/kg, and injection fentanyl 3 μg/kg. After achieving adequate muscle relaxation with injection vecuronium 0.1 mg/kg, the trachea was intubated with an appropriate size of a double lumen tube and the lungs were mechanically ventilated. After performing central venous cannulation, patients were positioned in the lateral decubitus position for thoracic epidural or paravertebral catheterization. The regional blocks were performed by a single experienced operator for the study.

Thoracic epidural catheterization: The position of the vertebral spinous process between T4 and T6 levels was identified by bony landmarks. A 16G Tuohy needle was inserted into the epidural space and confirmed with "loss of resistance" technique. Once the epidural space was identified, an 18G multi-pore epidural catheter was threaded 5 cm into the epidural space.

Thoracic paravertebral catheterization: The position of the vertebral transverse process between T4 and T6 levels on the operative side was identified by bony landmarks. Under real-time ultrasound guidance with a linear transducer (6–13 MHz) and MyLab™One/Touch ultrasound system (Esaote, Genova, Italy), a 16G Tuohy needle was inserted into the paravertebral space in a longitudinal orientation 3 cm lateral to T6 spinous process corresponding to T5 transverse process, as described by Riain *et al*.[5] An 18 G multi-pore catheter was advanced 3 cm into the paravertebral space in the caudad-cephaloid direction.

After epidural or paravertebral catheterization, appropriate positioning of the catheter was confirmed by negative aspiration for blood or cerebrospinal fluid. A bolus (10 ml) of 0.25% bupivacaine with 4 μg/ml of fentanyl was injected through the catheter, and an infusion of the 0.125% bupivacaine with 4 μg/ml of fentanyl was started at a rate of 0.1 ml/kg/hour in both the groups. Anesthesia was maintained using inhalational administration of isoflurane and an oxygen/air mixture at a fresh gas flow of 2 Liters/min. The depth of anesthesia was monitored using bispectral index (BIS), and the dial settings of the isoflurane vaporizer were adjusted to maintain the BIS values between 40 and 60. Injection fentanyl boluses were administered whenever the heart rate and mean arterial pressure exceeded more than 20% of the baseline value despite target BIS values. The heart rate, mean arterial pressure, oxygen saturation, and central venous pressure were monitored throughout the intra-operative period. Isoflurane requirement in volume percent, the minimum alveolar concentration (MAC) value of isoflurane, and the total required fentanyl dose were recorded by an independent observer during the intra-operative period. The total volume of isoflurane consumed during the surgery was calculated using Dion's formula[6]: volume of isoflurane consumed (ml) = {isoflurane vaporizer concentration (%) x fresh gas flow (Lit/min) x duration of anesthesia (min) × 184.5 (molecular weight of isoflurane)}/ [2,412 × 1.496 (density of isoflurane)]. The trachea was extubated in all patients after the fulfilment of extubation criteria. The epidural or paravertebral infusions were continued for 48 hours in the post-operative period. If the VAS score at rest was ≥4 or whenever the patient demands, additional analgesia was provided with 0.1 mg/kg of intravenous morphine bolus for the first 24 hours and 1 g of intravenous paracetamol for the next 24 hours. Starting with 15 minutes after tracheal extubation, the following observations were recorded by an independent observer in the post-operative period: 1. pain scores (at rest and at cough) using the visual analog scale (VAS) – 2 hourly for the first 24 hours and 8 hourly for the next 24 hours. 2. Partial pressure of arterial oxygen (PaO_2), partial pressure of arterial carbon dioxide ($PaCO_2$), and blood glucose – 3 hourly for the first 24 hours. 3. Need of rescue analgesics 4. Adverse effects such as bradycardia, hypotension, nausea, vomiting, and urinary retention. Bradycardia (defined as heart rate <60/min) was treated with injection atropine 0.02 mg/kg, and hypotension (defined as a decrease in mean arterial blood pressure <20% of baseline or <60 mm Hg) was treated with fluid boluses and injection. phenylephrine 1 to 2 μg/kg. Post-operative nausea and vomiting were treated with injection. Ondansetron 0.1 mg/kg and poor coughing ability with retention of secretions were managed by chest physiotherapy. The intra-operative and post-operative study observers were blinded to the study groups, and their observations were blinded to each other.

Statistical analysis

Based on a previous study,[1] we expected an intra-operative mean isoflurane volume percent requirement of 0.67 ± 0.15 in the GAE group. Assuming an intra-operative mean isoflurane volume percent requirement of 0.80 ± 0.15 in the GAP group, a total sample size of 42 with 21 in each group is required to get a power of 80% and an alpha error of 5%. We included 56 patients (28 in each group) to adjust for the dropouts during the study. All statistical analyses were performed using SPSS, version 22.0 for Windows (IBM Corp, Armonk, NY). Quantitative data were expressed as mean ± standard deviation or as percentages. Kolmogorov–Smirnov test was used to test the normality of the data. Normally distributed continuous variables were compared using the Student *t*-test. Categorical variables were analyzed using the Pearson Chi-square test. For comparison of percentages between the two groups, a 2-sample *t*-test was performed. A *P* value <0.05 was considered to be statistically significant.

RESULTS

A total of 70 patients were eligible for this study, among

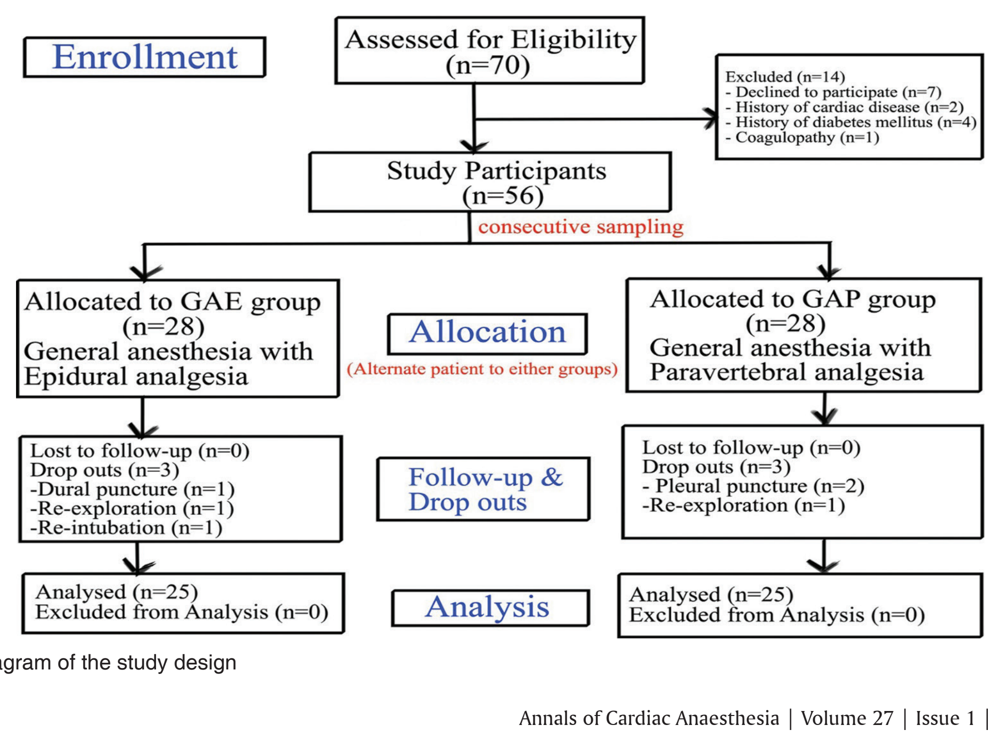

Figure 1: Flow diagram of the study design

Table 1: Comparison of demographic data, type and duration of surgery, and baseline hemodynamic and respiratory parameters between the two groups

Demographic variable	GAE group (*n*=25)	GAP group (*n*=25)	*P*
Age (years)	42.16±13.48	45.4±14.04	0.4093
Sex (male/female)	13/12	15/10	0.7761
Weight (Kg)	61.37±7.20	60.77±10.74	0.8175
Height (cm)	164.6±5.8	162.32±7.78	0.2459
Duration of Surgery (min)	302.4±29.98	295.2±24.0	0.3532
Type of surgeries			
Lobectomy	15 (60%)	18 (72%)	0.3753
Pneumonectomy	3 (12%)	2 (8%)	0.6407
Cyst excision	3 (12%)	2 (8%)	0.6407
Mass excision	2 (8%)	2 (8%)	1.0000
Bullectomy	2 (8%)	1 (4%)	0.5555
Baseline hemodynamic and respiratory variables			
Heart rate (per min)	84.2±11.43	81.46±9.37	0.3586
Mean arterial pressure (mm Hg)	92.84±10.79	94±9.66	0.6906
Respiratory rate (per min)	14.4±2.34	13.5±3.23	0.2648
PaO_2 (mm Hg)	88.18±7.82	90.38±7.97	0.3295
$PaCO_2$ (mm Hg)	38.9±2.46	40.24±3.15	0.1002

Values are expressed as mean±standard deviation or number (proportion). $P<0.05$ considered statistically significant. PaO_2 – partial pressure of arterial oxygen; $PaCO_2$ – partial pressure of arterial carbon dioxide

Table 2: Comparison of intra-operative isoflurane, fentanyl and phenylephrine requirement, total fluids administered, and total blood loss between the two groups

Intra-operative data	GAE group (*n*=25)	GAP group (*n*=25)	*P*
Isoflurane MAC	0.51±0.05	0.78±0.07	<0.0001
Isoflurane Volume %	1.02±0.12	1.56±0.11	<0.0001
Volume of isoflurane consumed (ml)	32.28±1.88	48.31±4.34	<0.0001
Total fentanyl dose (μg)	128.87±25.12	157.02±30.92	0.0009
Total phenylephrine dose (μg)	340±132.29	126±103.2	<0.0001
Total fluids administered (ml)	1845±242	1765±224	0.2311
Total blood loss (ml)	548±214	506±231	0.5080

Values are expressed as mean±standard deviation. $P<0.05$ considered statistically significant. MAC – minimum alveolar concentration

whom 14 patients were excluded based on the exclusion criteria [Figure 1]. The demographic data of the patients, type and duration of surgery, and baseline hemodynamic and respiratory characteristics were comparable between the two groups [Table 1]. The isoflurane requirement in volume percent (0.51 ± 0.05% vs 0.78 ± 0.07%; $P < 0.0001$), the MAC value of isoflurane (1.02 ± 0.12 vs 1.56 ± 0.11; $P < 0.0001$), the total volume of isoflurane consumption (32.28 ± 1.88 vs 48.31 ± 4.34 ml; $P < 0.0001$), and the total fentanyl requirement (128.87 ± 25.12 vs 157 ± 30.92 μg; $P = 0.0009$) were significantly less in the GAE group than in the GAP group, whereas the total amount of phenylephrine usage was significantly less in the GAP group than in the GAE group (126 ± 103.2 vs 340 ± 132.29 μg; $P < 0.0001$) [Table 2]. Total fluids administered and total blood loss during surgery were not significant between the two groups ($P > 0.05$) [Table 2]. The post-operative VAS scores at rest and during cough at different time intervals were less in GAE group in comparison to GAP group; however, they were not statistically significant at any time point during the study period ($P > 0.05$) [Figure 2a and b]. Post-operative requirements for rescue analgesic doses of morphine in the first 24 hours and paracetamol in succeeding 24 hours and also the number of patients requiring rescue analgesics were statistically not different between the two groups [Table 3]. Although the PaO_2 levels were less and $PaCO_2$ levels were higher at different time intervals in GAE group in comparison to GAP group, the difference was not significant and none of the patients in either groups had hypoxia or hypercarbia [Figure 3a and b]. The blood glucose levels were similar in both groups at different time intervals [Figure 3c]. The adverse effects were comparable between the two groups except for the hypotension and urinary retention, which were significantly higher in GAE group in comparison to GAP group [Table 3].

DISCUSSION

Thoracotomy pain is very severe, necessitating excellent analgesia and an adequate anesthetic depth to reduce the stress levels in the intra-operative and post-operative periods. Regional analgesia techniques in the form of thoracic epidural or paravertebral block are known to decrease the complications arising due to thoracotomy.[7] There is a paucity in the literature depicting efficacy of thoracic paravertebral analgesia in reducing the intra-operative anesthetic and analgesic requirements in patients undergoing thoracotomy. Hence, we compared the intra-operative efficacy of thoracic paravertebral analgesia with that of the gold standard thoracic epidural analgesia.

Studies have demonstrated benefits of combining GA with epidural anesthesia toward reduction in the intra-operative requirement of isoflurane during spine and major abdominal

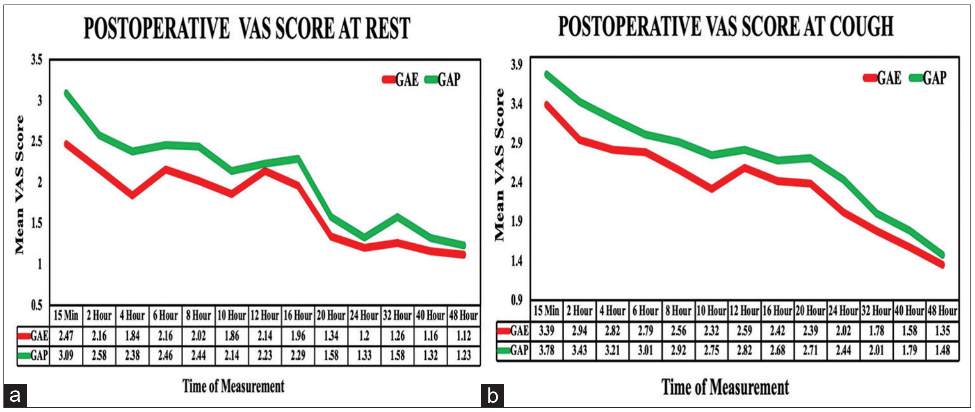

Figure 2: Comparison of (a) visual analog score at rest and (b) during cough between GAE and GAP groups at different time intervals of the post-operative period

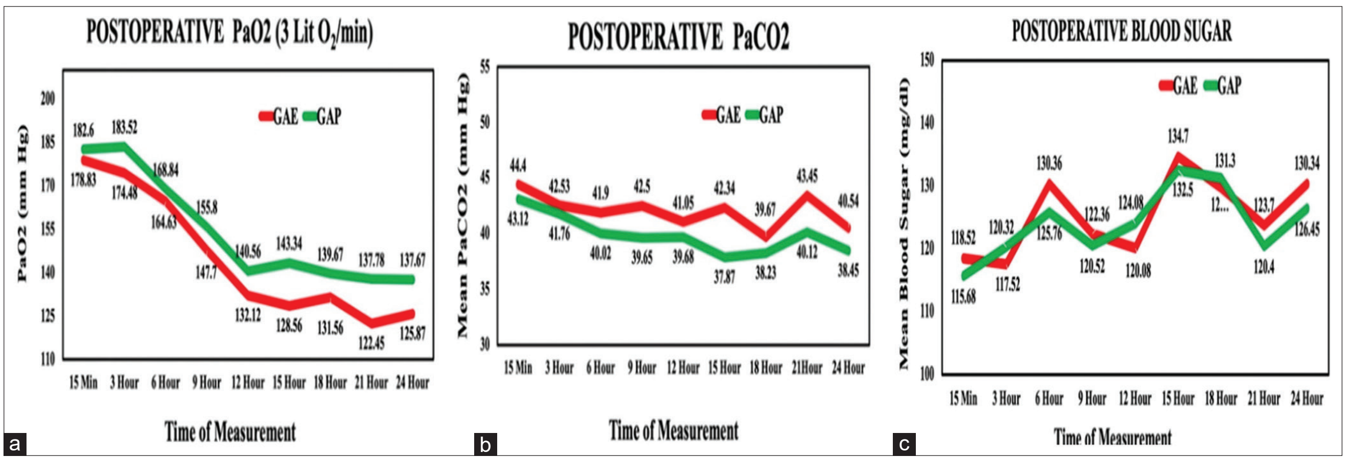

Figure 3: Comparison of (a) partial pressure of arterial oxygen (PaO_2), (b) partial pressure of arterial carbon dioxide ($PaCO_2$), and (c) blood sugar levels between GAE and GAP groups at different time intervals of the post-operative period

Table 3: Comparison of postoperative rescue analgesics requirement and incidence of adverse effects between the two groups

Rescue Analgesics	GAE group (*n*=25)	GAP group (*n*=25)	*P*
Injection morphine (0 to 24 h)			
Number of patients needed morphine	5 (20%)	11 (44%)	0.0717
Total morphine dose (mg)	6.29±1.31	7.02±1.58	0.0817
Injection paracetamol (24 to 48 h)			
Number of patients needed paracetamol	9 (36%)	14 (56%)	0.1602
Total paracetamol dose (g)	1.11±0.33	1.40±0.75	0.0831
Adverse effects			
Bradycardia	0	0	-
Hypotension	8 (32%)	2 (8%)	0.0357
Nausea	5 (20%)	4 (16%)	0.7156
Vomiting	0	1 (4%)	0.3173
Urinary retention	4 (16%)	0	0.0390

Values are expressed as mean±standard deviation or number (proportion). $P<0.05$ considered statistically significant

surgeries.[1,2] Addition of dexmedetomidine as an adjuvant to local anesthetics for thoracic paravertebral blockade significantly reduces the intra-operative requirement of propofol, isoflurane, and fentanyl in thoracic surgeries.[8]

In our study, we noticed that in order to maintain the BIS values within a target range, the intra-operative requirement of isoflurane and fentanyl was significantly less in the GAE group than in the GAP group. The possible mechanism for the reduced requirement of anesthetic and analgesic agents in GAE group may be explained by the bilateral effects of epidural anesthesia in blocking the sensory, motor, and sympathetic nerve bundles of the thoracic segments. The lateral thoracotomy decubitus and constant surgical retraction during the thoracic surgical procedure may be associated with severe post-operative pain in the thorax and shoulders.[9,10] By virtue of providing extensive analgesia, bilateral epidural blockade must have curtailed intra-operative requirements for the isoflurane and fentanyl. On the other hand, paravertebral blockade remains confined to limited spinal nerves on the side of thoracotomy, which may not completely abolish the pain of thoracotomy and radiating pain to the shoulder during the surgery. The amount of phenylephrine needed to maintain the target mean arterial pressure was significantly less in the

GAP group in comparison to GAE group. This could be attributed to the unilateral sympatholysis produced by the paravertebral anesthesia, which has less consequences on the cardiovascular system in comparison with the bilateral sympatholytic effects of epidural anesthesia.[11,12]

In our study, we observed that post-operative pain control (similar VAS scores at rest and during cough) was equally effective in both GAE and GAP groups. Also, the requirement of rescue analgesics during the post-operative recovery was similar between the groups. In the absence of surgical retraction after completion of the surgery, which was a constant source of intra-operative trauma, the post-operative pain was expected to become less severe and to remain confined only to the thoracotomy site. In our patients, although the thoracic paravertebral blockade was limited to the T4–T7 thoracic segments, it provided excellent analgesia to intercept the spinal nerve roots carrying sensory inputs from the thoracotomy incision.[13,14] This could be the reason for similar pain scores at different time intervals in both the groups. Our observations of equal analgesic potency of paravertebral blockade as that of epidural blockade for post-thoracotomy pain relief are supported by the previous studies.[15,16]

Regional analgesia technique is a safe and effective method for decreasing the post-operative respiratory complications and improving the pulmonary function after thoracotomies, thereby providing a better quality of life to the patient.[4,17] In our study, the PaO_2 and $PaCO_2$ levels of all the patients at different time intervals were within the normal limits and were found to be not significantly different between the GAE and GAP groups. The increase in stress response will result in an increase in blood cortisol levels, which in turn cause hyperglycemia. Thoracic epidural analgesia and paravertebral analgesia both were shown to suppress the post-operative stress response better than the systemic administration of opioids.[18,19] In our study, we measured the blood glucose levels to compare the effect of epidural and paravertebral blockade on the neuroendocrine stress response. The results revealed no statistically significant difference in both the techniques on the post-thoracotomy stress response.

In our study, the incidence of hypotension and urinary retention was significantly higher in GAE group than in the GAP group. These findings comply with the reports of previous studies.[3,20] The main reason for higher incidence of these complications in GAE group is attributed to the bilateral sympathetic blockade. Negative chronotropic and inotropic effects from thoracic epidural sympathetic blockade, along with the reduction in preload, cause a decrease of cardiac output, resulting in hypotension. The epidural anesthesia also influences micturition by blocking the sympathetic afferent and efferent supply to the bladder and interrupting micturition reflex arcs at the spinal cord level.[21] The other adverse effects like bradycardia, nausea, and vomiting were infrequent and comparable between the two groups.

We acknowledge existing limitations with our study. First, although the BIS values were maintained within the target range for depth of anesthesia, we did not evaluate the intra-operative awareness and recall after the surgery. Second, this study was conducted as a single observer-blinded observational study with a limited sample size. Third, the hemodynamic and blood gas parameters were monitored only for 24 hours in the post-operative period. Fourth, according to our institutional protocol, we placed the epidural catheterization under GA as there was no evidence to consider it as unsafe.[22,23] Finally, the pulmonary function testing was not performed using spirometry in the post-operative period.

CONCLUSION

This study highlights that combined GA with epidural analgesia resulted in significant reduction in the intra-operative consumption of isoflurane and fentanyl in comparison to combined GA with paravertebral analgesia. However, combined GA with paravertebral analgesia was equally effective as combined GA with epidural analgesia in terms of post-operative analgesia, hemodynamics, oxygenation and ventilation, stress response, and requirement of rescue analgesics.

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Conflicts of interest
There are no conflicts of interest.

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