ORIGINAL RESEARCH   **REGIONAL ANESTHESIA**

Feasibility of segmental thoracic epidural anesthesia in cancer patients undergoing feeding jejunostomy: A randomized controlled trial

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Abstract

Background: Malnourishment is very common in cancer patients secondary to the disease progression as well as the adverse effects of the treatment. Patients with gastroesophageal cancers and head and neck tumors are more prone to malnourishment. The enteral nutrition is the route of choice for nutritional support. Feeding jejunostomy is one of the routes used for long-term enteral nutrition. We compared the analgesia produced and the need of analgesics with the use of segmental thoracic epidural anesthesia (STEA) and general anesthesia (GA) for feeding jejunostomy.

Methodology: A total of 43 cancer patients scheduled for surgical feeding jejunostomy were enrolled and randomized into two groups; segmental thoracic epidural anesthesia group (Group STEA) (n = 21) and general anesthesia group (Group GA) (n = 22). The primary outcome was percentage of patients requiring rescue analgesia intraoperatively. Secondary outcome measures included hemodynamics, Visual Analogue Scale (VAS) scores, time to receive the first postoperative analgesic, total morphine consumption and any possible side effects or complications. Data were handled by SPSS v.25 (IBM©, Chicago, IL, USA). Data were expressed as mean ± standard deviation and analysed by unpaired student t-test, or median (range) and analysed using Mann Whitney-test. $P < 0.05$ was considered statistically significant.

Results: Significantly higher percentage of patients in the Group GA required intraoperative rescue fentanyl (59%) and postoperative morphine consumption (100%) compared to the Group STEA. Patients in GA group had higher heart rate (HR) and mean arterial blood pressure (MAP) values. Group SETA showed lower VAS scores in post anesthesia care unit (PACU) and throughout the first 24 hours postoperatively. The Group STEA had significantly higher patient satisfaction scores (PSS) and showed earlier ambulation.

Conclusions: Segmental thoracic epidural anesthesia has a better analgesic profile and can be used as a safe and effective alternative to general anesthesia in cancer patients undergoing surgical feeding jejunostomy.

Abbreviations: GA – General anesthesia; HR – Heart rate; IQR – Interquartile range; MAP – Mean arterial pressure; PACU – Post anesthesia care unit; PSS – Patient satisfaction score; STEA – Segmental thoracic epidural anesthesia; VAS – Visual Analogue Scale

Key words: Anesthesia, Epidural; Anesthesia, General; Enteral Nutrition; Jejunostomy; Malnutrition.

1. Introduction

Patients with advanced gastroesophageal, head and neck tumors usually suffer from malnourishment.[1,2] Several factors contribute to the malnourishment status of these patients including cancer related cachexia and anorexia, as well as the local tumor effect. Almost 50% of cancer patients suffer from weight loss during the course of their disease, with cachexia being more eminent in the end-stage cancer patients.[3] Moreover, patients receiving chemotherapy and radiotherapy may suffer from the therapy related side effects exacerbating their malnutritional status.[1]

Nutritional disturbances carry an important prognostic implication in patients with malignancy. Significant weight loss and impaired nutrition are associated with poor survival, unfavorable treatment outcomes and impaired quality of life.[4]

Nutritional support can be offered either through enteral or parenteral routes; the enteral nutrition being preferable in cases with a functional gastrointestinal tract, which helps in maintaining gut integrity and function with less risks and cost.[5]

Feeding jejunostomy is carried out as a palliative procedure for patients in which oral route is not available due to any cause.[6] In operable cases it supplies enteral nutrition from the preoperative to early postoperative period.[7, 8] Feeding jejunostomy is usually performed under radiological guidance as an outdoor procedure, except for special cases in which open surgical intervention is required. Surgical feeding jejunostomy is an upper abdominal surgery with intraperitoneal approach; hence, it is usually done under general anesthesia and controlled mechanical ventilation.[2]

Patients with advanced hypopharyngeal carcinoma carry the risk of difficult intubation.[2] Consequently, alternatives to general anesthesia should be considered. Feeding jejunostomy was reported to be done under local anesthesia in some cases.[9,10] However, patient's discomfort is common due to peritoneal traction during the procedure.

Epidural anesthesia can be placed at any level allowing for segmental or selective block, and it is considered a good alternative to general anesthesia in upper and lower abdominal surgeries.[11]

The aim of the current study was to investigate the safety and efficacy of performing surgical feeding jejunostomy under segmental thoracic epidural anesthesia (STEA); to allow for its future application as an alternative to general anesthesia in patients with contraindication to general anesthesia.

2. Methodology

This parallel- group (1:1), randomized, controlled trial was conducted at the National Cancer Institute, Cairo, Egypt, between June 2019 and April 2021.

2.1. Ethical considerations

An approval of the Institutional Review Board of our Institute (IRB number; AP1904-50103) was obtained, and the study was registered at ClinicalTrials.gov (NCT04376086). https://clinicaltrials.gov/ct2/show/NCT04376086. The study was conducted in agreement with the principles of the Declaration of Helsinki. Patients were enrolled in the study after obtaining a written informed consent.

2.2. Sample size

Sample size was calculated using MedCalc Statistical Software version 15.8 (MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org; 2015). The effect size was calculated based on the difference in the percentage of patients complaining of pain during the recovery period between the two groups as reported by Apan et al.[12] Assuming an alpha error level of 0.05, a power of 0.80, and an allocation ratio of 1:1, 40 patients (20 per group) were required to detect an effect size of 40% difference in percentage of patients complaining of pain. The final sample size was 44 patients (22 per group) after adding 10% to account for loss to follow-up.
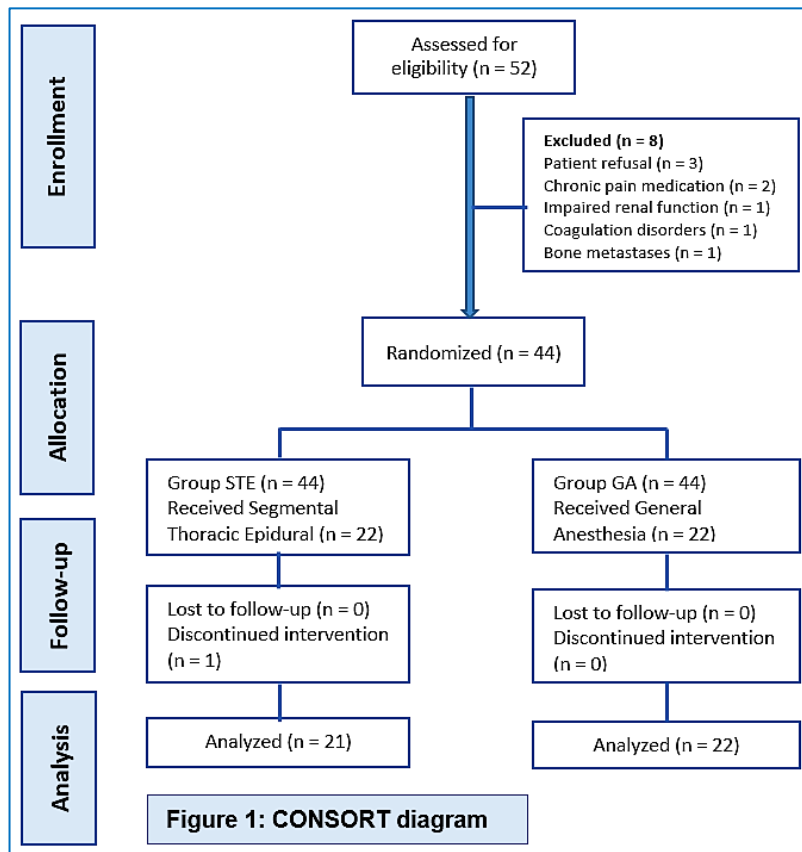
Randomization and masking

We used the sealed, sequentially numbered envelope method for randomization and allocation concealment. We prepared 22 identical, opaque, letter-sized envelopes, each containing a white allocation paper marked as "Treatment–A", and 22 envelops with a paper marked "Treatment–B". The two sets (44 envelops) were shuffled thoroughly and numbered sequentially from 1 to 44 on the front of each envelope. An investigator (not involved in sequence generation and allocation concealment) assessed patients for eligibility and assigned eligible patients to either the segmental thoracic epidural anesthesia (STEA) group or the general anesthesia (GA) group. The data analyst was blinded to treatment allocation.

Eligibility criteria

We enrolled adult patients (18 to 65 y old) with malignancy, American Society of Anesthesiology (ASA) II or III, scheduled to undergo feeding jejunostomy. We excluded patients who were on chronic pain medications; those with suspected difficult intubation; or had bone metastasis, thrombocytopenia, coagulation defects, local infection at the site of injection, or impaired liver or kidney functions.

Interventions:

Assessed for
eligibility (n = 52)

Excluded (n = 8)
Patient refusal (n = 3)
Chronic pain medication (n = 2)
Impaired renal function (n = 1)
Coagulation disorders (n = 1)
Bone metastases (n = 1)

Randomized (n = 44)

Group STE (n = 44)
Received Segmental
Thoracic Epidural (n = 22)

Group GA (n = 44)
Received General
Anesthesia (n = 22)

Lost to follow-up (n = 0)
Discontinued intervention
(n = 1)

Lost to follow-up (n = 0)
Discontinued intervention
(n = 0)

Analyzed (n = 21)

Analyzed (n = 22)

Figure 1: CONSORT diagram

Enrollment
Allocation
Follow-up
Analysis

Our primary outcome was percentage of patients who required analgesia. Secondary outcome measures were hemodynamics (including intraoperative and postoperative MAP and HR), intraoperative rescue fentanyl, VAS scores, time to the first postoperative morphine dose, total morphine consumption, PSS, and any possible side effects or complications.

In the holding area patients were monitored using the standard monitoring (pulse oximetry, electrocardiogram (ECG) and non-invasive arterial blood pressure). An 18G cannula was inserted and fixed, and patients were premedicated using intravenous midazolam 0.02 mg/kg.

Upon arrival to the operating room, all patients received preloading with crystalloids (10-15 ml/kg) to restore and maintain their intravascular volume. Patients of the GA group received general anesthesia using fentanyl (2 µg/kg), propofol (2 mg/kg), and rocuronium (0.6 mg/kg) followed by single lumen endotracheal intubation and controlled mechanical ventilation with 50% FiO_2 and sevoflurane 2%. Patients of the STEA group received thoracic epidural anesthesia. Patients were placed in the sitting position, and the procedure started after skin preparation and draping of the injection site. Lidocaine 1% was then infiltrated at the site of entry, an 18G epidural Tuohy needle was advanced into the epidural space at T6-T7 level using the loss of resistance

technique; the epidural catheter was threaded up in a cephalic direction for 3 cm, then a test dose of 2-3 ml of lidocaine 2% with adrenaline (1:200000) was injected to exclude inadvertent intrathecal or intravascular insertion. Levobupivacaine 0.5% combined with fentanyl 2 µg/ml were injected at a volume of 1-1.5 ml per segment according to the patient's age, height, and weight to achieve block from T4 to T10. Block height was assessed after 20 min of epidural injection using wrapped ice pack.

If satisfactory sensory level was not achieved, the block was to be converted to GA. After sensory level confirmation, levobupivacaine + fentanyl solution was continuously infused through the epidural catheter a rate of 6-10 ml/h till the end of the surgery. Patients received dexmedetomidine 1 µg/kg given over 20 min, followed by a continuous infusion of 0.5 µg/kg/h. Supplement oxygen (4 L/min) was given via face mask.

The heart rate (HR), arterial oxygen saturation and the mean arterial blood pressure (MAP) were measured periodically. Hypotension (a fall in MAP ≥ 20% of the baseline) not responding to intravenous fluids was managed using ephedrine. To maintain adequate intraoperative analgesia, all patients were closely monitored for any sign of insufficient analgesia (increased HR or MAP ≥ 20% above the baseline), in addition to any patient complaint in STEA group. In case of insufficient analgesia 0.5 µg/kg fentanyl was supplemented and recorded. All surgical procedures were done by the same surgeon through short (about 7 cm) midline incision between the xiphoid process and the umbilicus.

After the end of surgery, the patients were transferred to the post anesthesia care unit (PACU), and the HR, MAP, and Visual Analogue Scale (VAS) scores were recorded on arrival, then at 2, 4, 8, 12, 24 h postoperatively. Time to receive the first postoperative morphine dose, total morphine consumption, patient satisfaction score (PSS), ambulatory time, and any adverse event were recorded. Patients in STEA group received postoperative epidural infusion of levobupivacaine (0.125%) combined with 2 µg of fentanyl/ml at a rate of 4-6 ml/h according to their hemodynamic response.

The VAS was explained to all patients (0 represents no pain and 10 represents the most severe experienced
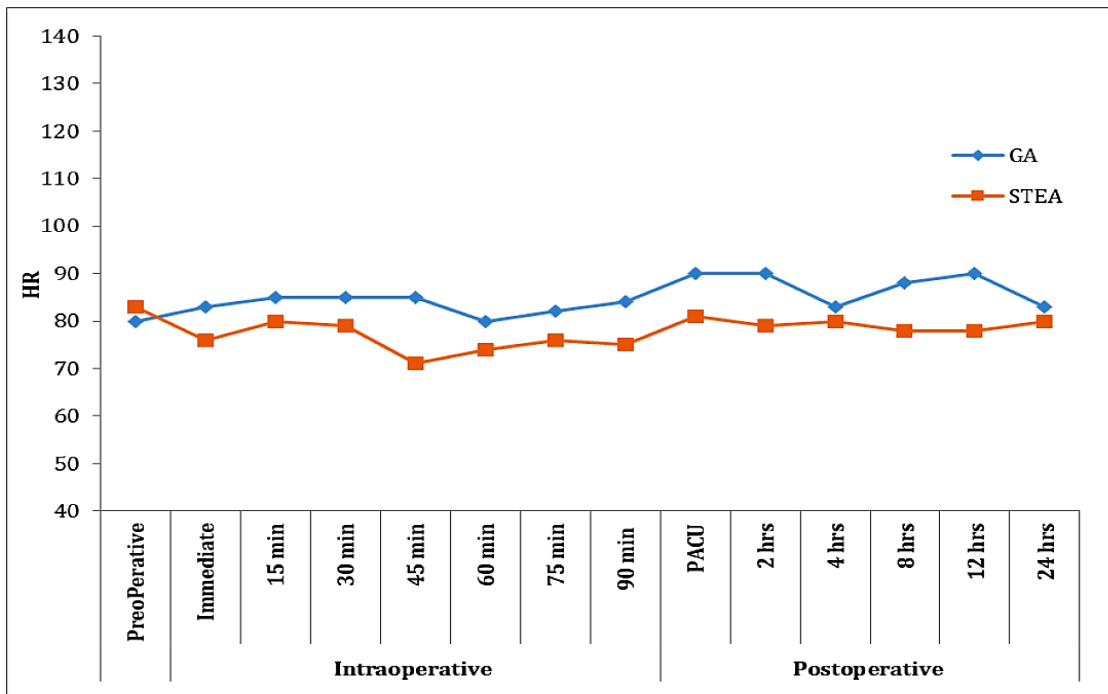
Figure 2: Comparative heart rates (beats/min) in two groups at different times
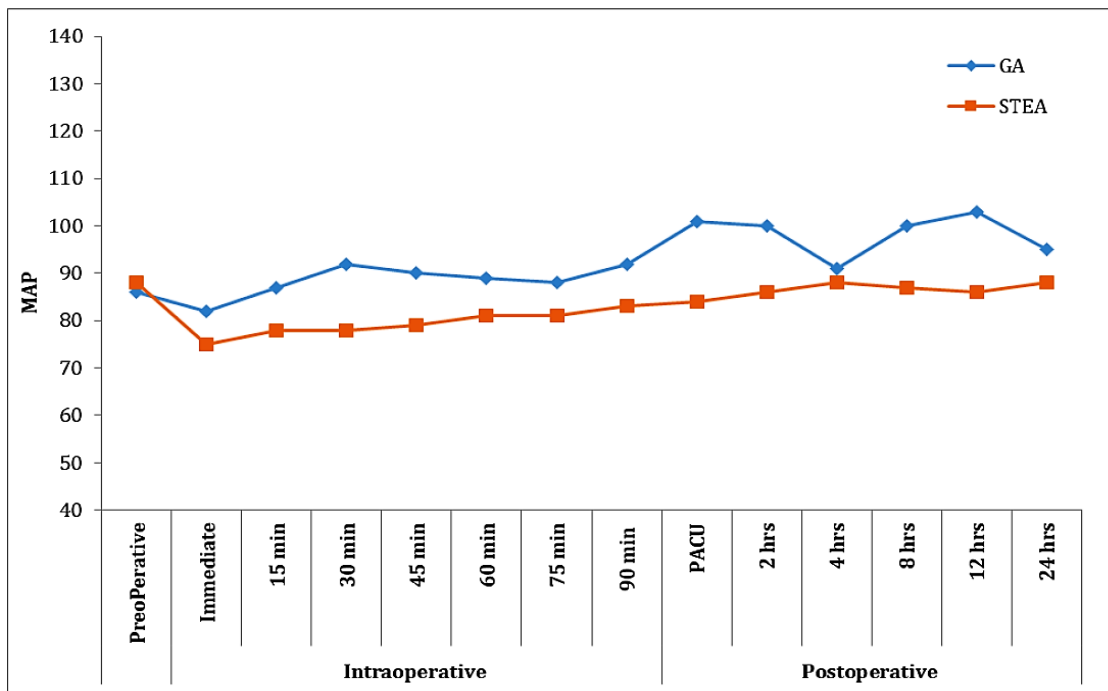

Figure 3: Comparative mean arterial pressure (mmHg) in two groups at different times

pain).

Any patient in both groups who experienced pain with a VAS score ≥ 4 was given a bolus dose of 0.1 mg/kg. morphine (3 mg). If the pain was not improved, the dose was repeated. Scores of 0-2, 3-5, 6-8, and 9-10 were considered very poor, poor, fair, and good, respectively.

Statistical analysis:

Table 1: Demographic data, clinical characteristics, and type and duration of surgery

Parameter		Group GA (n=22)	Group STEA (n=21)	p value
Age (y)	Mean ± SD	53.8 ± 7.7	56.6 ± 5.8	0.188
	Range	41–65	47–65	
Gender	Females	10 (45.5)	11 (52.4)	0.650
	Males	12 (54.5)	10 (47.6)	
Weight (kg)	Mean ± SD	59 ± 8.8	55.7 ± 7.5	0.196
	Range	49–73	45–69	
Height (cm)	Mean ± SD	165.1 ± 6.9	163.2 ± 5.7	0.321
	Range	155–177	153–176	
BMI (kg/m^2)	Mean ± SD	21.5 ± 1.9	20.9 ± 2.3	0.311
	Range	19.2–24.3	17.1–25.5	
Comorbidity	Present	8 (36.4)	8 (38.1)	0.907
Type of comorbidity	HTN	5 (22.7)	4 (19.0)	1.000
	DM	5 (22.7)	5 (23.8)	0.933
Type of cancer	GEJC	3 (13.6)	6 (28.6)	0.634
	NPC	6 (27.3)	4 (19.0)	
	Esophagus	7 (31.8)	5 (23.8)	
	PCC	6 (27.3)	6 (28.6)	

SD – standard deviation; GA – General anesthesia; STEA – Segmental epidural anesthesia; GEJC – gastroesophageal junction carcinoma; NPC – nasopharyngeal carcinoma; PCC – post cricoid carcinoma; p ≤ 0.05 is statistically significant

Age, weight, height and BMI, are expressed as mean ± standard deviation and are analysed by unpaired student t-test. VAS scores are presented by median (range) and analysed using Mann Whitney-test. Gender, comorbidities, type of cancer, patients who received rescue fentanyl and postoperative morphine data are presented as number and percentage and Chi-square (X2) or Fisher's Exact tests are used as appropriate to compare these data. A p < 0.05 is considered statistically significant. Data handled by SPSS v.25 (IBM©, Chicago, IL, USA).

3. Results

Fifty-two patients scheduled for surgical feeding jejunostomy were screened for eligibility, 44 met the eligibility criteria and were randomly allocated to receive either GA (n = 22) or STEA (n = 22), 1 patient in SETA group complaint of pain and burning sensation not responding to fentanyl and was converted to GA (Figure 1).

The two groups were comparable regarding their demographic data, clinical characteristics, type and duration of surgery (Table 1).

There was no statistically significant difference in the HR and MAP in the two studied groups during the preoperative period (P= 0.184 and 0.186 respectively). On the other hand, the GA group showed statistically significant higher HR and MAP values compared to the STEA group throughout the intraoperative and postoperative period (p < 0.05), (Figure 2, 3). Thirteen (59%) patients in the GA group required intraoperative rescue fentanyl during surgery time after appearance of signs of inadequate analgesia with average consumption (18.6 ± 16.7 µg). Only one patient in the STEA group needed analgesia, after complaining of discomfort sensation (P< 0.001), (Table 2). During the first 24 h postoperatively all GA patients received morphine with average consumption (12.1 ± 1.9 mg) vs 4.8 % of STEA patients (p < 0.001) (Table 2). STEA group had significantly lower VAS scores compared to the GA group in PACU and throughout the first 24 h postoperatively (Table 3).

Five patients in STEA group, and three in the GA group developed hypotension. Four of the patients in STEA group, and two in the GA group responded to fluid infusion, while one patient in STEA group required 15 mg IV ephedrine and one patient in GA required 10 mg

Table 2: Percentage of patients received intraoperative rescue fentanyl and postoperative morphine

Analgesics used	Group GA (n=22)	Group STEA (n=21)	p value
Rescue fentanyl	13 (59.0)	1 (4.8)	0.001
Morphine	22 (100.0)	1 (4.8)	< 0.001

Table 3: VAS scores at PACU and first 24 hours postoperatively

VAS score	Group GA	Group STEA	p value
PACU	3 (0–7)	0 (0–1)	< 0.001
2 h	5 (0–7)	0 (0–2)	0.003
4 h	1 (0–3)	1 (0–4)	0.383
8 h	4 (0–7)	0 (0–2)	< 0.001
12 h	5 (0–7)	0 (0–3)	< 0.001
24 h	2 (0–6)	0 (0–2)	0.004

$P \leq 0.05$ is statistically significant; Data given as Median (Range)

Table 4: Ambulation and patient satisfaction score

	Group GA	Group STEA	P value
Ambulation (h)	4 (2–7)	2 (2–5)	< 0.001
Patient satisfaction score	8 (5–9)	10 (6–10)	< 0.001

$P \leq 0.05$ is statistically significant; Data given as Median (Range)

IV ephedrine ($p > 0.05$). Arterial oxygen saturation was maintained and comparable in both groups throughout the study time.

Patients in the STEA group experienced significantly earlier ambulation and had significantly higher PSS values compared to those in the GA group (Table 4). There was no significant difference between the two groups regarding the incidence of postoperative nausea and vomiting. No respiratory complications or complications related to epidural insertion (including hematoma or neurological deficit) were reported.

4. Discussion

This study aim was to assess the safety and efficacy of STEA as an anesthetic approach for cancer patients undergoing surgical feeding jejunostomy and its future implication as a suitable alternative in patients with contraindications to GA.

Opioids are considered by many anesthesiologists as the cornerstone analgesic for perioperative pain control. However, opioids carry a wide spectrum of side effects, such as postoperative nausea and vomiting, ileus, pruritus, respiratory depression, and immunosuppression.[13,14]

Epidural anesthesia emerged as a reliable anesthetic technique that potentially reduces the degree of perioperative physiologic stress and inflammatory response to surgery and thereby decreases surgical complications and improves outcome. As well, it improves respiratory outcome by establishing pain-free ventilation.[15–18]

The thoracic epidural technique can be considered the gold standard analgesic procedure for abdominal surgeries. It produces both somatic and visceral analgesia and shows a superior anesthetic/analgesic profile with lower perioperative opioid consumption.[19,20] Using epidural anesthesia is associated with earlier ambulation, better hemodynamic stability, longer time to postoperative analgesic requirement, and lower rate of postoperative nausea and vomiting and ileus. Furthermore, it plays an important role in improving blood flow to the mesentery through sympathetic blockade thus promoting anastomosis healing in gastrointestinal surgeries.[18] Segmental epidural anesthesia is a form of regional anesthesia characterized by selective nerve blockade of a desired area.[11]

The current study results showed that STEA provided a safe, effective anesthesia and reduced the perioperative opioid consumption in patients undergoing surgical feeding jejunostomy. Adding epidural fentanyl offered a denser block through acting on spinal cord opioid receptors.[21] We demonstrated that STEA was comparable to GA in maintaining intraoperative and postoperative hemodynamics but produced more effective perioperative pain control than GA with reduced opioid consumption. This agrees with the results reported by Bhosle and colleagues who retrospectively analyzed the validity of using segmental epidural anesthesia for patients undergoing upper and lower abdominal surgeries and revealed that it can be

considered a good anesthetic alternative in various surgical procedures including feeding jejunostomy and gastrojejunostomy. Segmental epidural anesthesia has the merits of better perioperative analgesia, reduced blood loss with more stable cardiovascular response, and decreased incidence of postoperative pulmonary complications.[11]

During the last few years, the use of thoracic epidural anesthesia has been increased as it was associated with less airway manipulation and reduced respiratory complications.[22] Consani and colleagues performed thoracic epidural anesthesia in two high-risk patients undergoing subtotal gastrectomy and considered that technique a promising, valid alternative to GA in cases of upper abdominal surgeries.[18] Efficacy and safety of segmental epidural anesthesia was investigated by Apan and colleagues. They compared this technique to general anesthesia in patients undergoing percutaneous kyphoplasty and found that segmental epidural anesthesia was a safe, reliable technique that offered better postoperative analgesia, shorter PACU stay time, and earlier recovery.[12]

Another study by Ganvir and colleagues reported that segmental epidural anesthesia can be used for percutaneous nephrolithotomy as an alternative to general anesthesia. The authors compared ropivacaine to bupivacaine and declared that both can be used efficiently with superiority of former regarding its shorter onset of action.[23] Likewise, Parikh and colleagues emphasized the use of segmental epidural technique as a good alternative to general anesthesia in selected patients undergoing percutaneous nephrolithotomy. They identified possible benefits of using segmental epidural as being accompanied with faster recovery, better patient satisfaction and favorable pain control.[24] On the other hand, they reported possible risks associated with its use as intraoperative patient discomfort or movement, and risk of unprotected airway related to supplementation of anesthetic drugs. However, same risks were not encountered in our study, may be because we used dexmedetomidine infusion to avoid patient discomfort while maintaining airway.

The safety of segmental thoracic epidural anesthesia for breast surgery was studied by Groeben et al., who concluded that it can be used as a safe, well-tolerated alternative to general anesthesia for chest wall surgeries.[25] In 2016, Dhansura et al. reported the feasibility of using segmental epidural anesthesia as an anesthetic technique in obese patients undergoing surgeries in prone position, with maintaining hemodynamic stability and adequate pulmonary functions.[26]

Based upon the findings of the present study, STEA can be used as a reliable anesthetic technique for patients undergoing surgical feeding jejunostomy providing effective intraoperative and postoperative analgesia with minor adverse effects. This allows favorable patient satisfaction with early postoperative ambulation.

5. Limitations

We should view this study with the limitation of small number of recruited patients, as feeding jejunostomy procedures are commonly done under day–case interventional procedures. However, in some cases, the procedure may have to be done using the surgical approach. Another limitation was that the STEA needs to be performed by an experienced anesthetist. Additionally, STEA should be avoided in patients with bony metastases. We did not compare the time spent in the procedures and the cost of both procedures.

6. Conclusion

We conclude that segmental thoracic epidural anesthesia is a safe, effective anesthetic modality for cancer patients undergoing surgical feeding jejunostomy. Compared to GA, it was better in terms of perioperative pain control and hemodynamic stability. Both GA and STEA were well-tolerated and exhibited a good safety profile during intraoperative and postoperative period. We recommend that whenever possible, STEA should be used for cancer patients undergoing surgical feeding jejunostomy especially in patients in which general anesthesia can be of a risk.

7. Competing interests

The authors declare that they have no competing interests. The researchers did not receive any external funding.

8. Authors' contribution

WE: Initiated the study idea, shared in patient recruitment and data collection, major contributor in writing the manuscript.

KS: Shared in patient recruitment, data collection, revising the manuscript.

AE: Shared in patient recruitment, data collection.

MI: Contributed to study idea, interpreted and analyzed the data, shared in writing the manuscript.

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