ORIGINAL RESEARCH

Prospective Analysis of epidural analgesia in oncosurgeries in a tertiary cancer centre - An analysis of 600 cases.

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Submitted: 05 Oct 2025
Revised: 14 Oct 2025
Accepted: 20 Oct 2025
Published: 05 Nov 2025

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How to cite this article: Hally.T, Divya Gladstone. Prospective Analysis of epidural analgesia in oncosurgeries in a tertiary cancer centre - An analysis of 600 cases. TAISAK 2025; 1(2):10-18

ABSTRACT

Aims and objective: The aim of the study is to improve individual epidural practice outcome and to ensure the best safe practice outcome in our institution. The primary objective is to assess the efficacy and outcome of epidural analgesia (EA) and the secondary objective is to assess complications of EA. **Study design:** Prospective observational study. **Setting:** Regional Cancer Centre, Thiruvananthapuram. **Patients:** Sample sizes were taken over a period of 6 months. Inclusion criteria are age between 18 to 65yrs, all laparotomy cases which needs epidural insertion for post operative periods. **Interventions:** We have followed up the patients requiring EA for 72 hrs (till we remove the epidural catheters) following that, patients were asked to score their level of satisfaction with regards to postoperative pain relief. All observations were recorded in the epidural care chart incorporated with the anaesthesia record and any complications related to EA technique were also noted and addressed. **Measurements:** We measured the outcome variables as pain scores of >3 at any point during the postoperative period and patient satisfaction assessed by using a questionnaire. We gave a score 1 – excellent, score 2- good, score 3- average, score 4- below average, score 5- poor. Incidence of postoperative pulmonary complication and their relationship with postoperative pain score was assessed. We also observed suppression of autonomic reflexes during light plane of general anaesthesia (GA), which is defined as sevoflurane minimum alveolar concentration (MAC) of 0.7. **Main results:** Pain score, patient satisfaction and the incidence of complications associated with EA were assessed. Out of 303 patients with excellent satisfaction, 270 patients did not have postoperative pulmonary complications (POPC). Out of 258 patients with good satisfaction, 201 patients did not have any pulmonary complications which was statistically significant (P <0.001). We also found significant association (P = 0.0004) between patient satisfaction and suppression of autonomic response at light planes of GA. Significant association (P = 0.001) observed between patient satisfaction and post op pain score < 3 at any point of time. Incidence of dural puncture in our study was 1.2%, whereas incidence of bloody tap is 4.2%. We had one case of failure to site and 21 cases of failure to provide an effective block with incidences of 0.16%and 3.5% respectively. POPC were reported in

hypercoagulable response and stress response it can be taken as an integral part of postoperative analgesia in oncosurgical patients. In our study we got a strong association between postoperative analgesia and decreased incidence of POPC. It also has got an opioid sparing effect which is necessary for an improved oncologic outcome. Hence we recommend EA in all laparotomies and thoracotomies.

Introduction:

The use of EA is an integral part of Enhanced Recovery After Surgery (ERAS) protocol. Effective EA plays a great role in postoperative pain control. Pain control without an effective epidural block is a difficult task for anaesthesiologist and intensivist and results in polypharmacy and its complications. EA and nerve block are superior to any other methods in managing acute postoperative pain and related POPC.(1) Oncosurgeries are usually prolonged and involve extensive resection for tumour clearance and have high analgesic requirements. Perioperative pain is a potent trigger for the stress response which activates autonomic system and has potential adverse effects including micro metastases to other organs.(2) Placement of an effective epidural catheter and introduction of local anaesthetics (LA), opioids or both for covering adequate dermatome is important for good postoperative outcome.(3) Analgesia can be optimized while balancing adverse effects, allowing for decreased sedation compared to intravenous opioids.(4) Epidural analgesia facilitates early mobilization resulting in reduced risk of POPC and venous thrombo embolisms (VTE). Since our hospital is a tertiary oncology centre, we offer EA for all laparotomy, and thoracotomy procedures. This study was intended to assess the efficacy of EA and also to look at POPC in relation to postoperative pain score.

Methodology:

This prospective observational study was approved by Institutional Review Board IRB NO: dated 07/2018/09. Six hundred patients belonging to American Society of Anaesthesiologists Physical Status (ASA PS) I,II,III undergoing laparotomy and thoracotomy surgeries in which epidural insertion required were studied over a period of 6 months. Patients who refused EA and those who were unable to communicate regarding pain score were excluded from the study.

Written informed consent had been taken from all patients. Standard ASA fasting guidelines were followed and patients were premedicated with tab. Alprazolam 0.01 mg/kg and tab. Pantoprazole 0.2 mg/kg on night before surgery and in the morning on day of surgery. On arrival standard ASA monitors were attached and baseline values recorded. An intravenous cannula was placed and sedation given with inj. Midazolam 0.02 mg/kg and inj. Fentanyl 0.1 mcg/kg . Patients were positioned in lateral or sitting position according to the preoperative physical spine assessment. Under all aseptic precautions, epidural space was identified using loss of resistance (LOR) technique with air using touhy needle. Epidural catheter was inserted and fixed according to the depth of space in each case and test dose of 3ml 2% lignocaine with 1 in 2 lakh adrenaline was given to rule out any intrathecal or intravascular placement and to ensure correct position of the catheter. Depending on the status of the patient and plan of surgery, patients were administered GA or spinal anesthesia along with EA or given sole EA.

Intraoperatively, epidural infusions were continued with LA with or without opioids unless contraindicated. The concentrations of LA varied according to the individual requirement. Vitals were monitored throughout the intraoperative and postoperative period. Suppression of autonomic reflex during light planes of GA was noticed by looking at the MAC values. Epidural infusions with or without opioid boluses were continued in the postoperative period according to hemodynamic status and Visual Analoge Score (VAS) score.

Patients were monitored routinely by qualified anaesthesiologists according to the acute pain management service protocol of our institution. Demographic data including patients name, age, sex, cancer registry number, Body Mass Index (BMI) were noted. Data entered regarding position of patient for epidural insertion, nature of anaesthesia, needle length and the length at which epidural catheter was placed. The various epidural drug regimens such as 0.2% ropivacaine, 0.5% ropivacaine, with or without fentanyl or morphine were used in intraoperative and postoperative period. 0. 2 % ropivacaine was given as epidural infusion in the post-operative period with or without Buprenorphine boluses according to BMI and VAS.

Rescue analgesia with epidural boluses was given if patient has VAS score > 3. Multimodal analgesia administered intravenously by treating anaesthesiologists/intensivists according to institutional protocol, if pain still persists. Regular epidural catheter care was given, and epidural catheters were removed within 72 hours on an average. Rarely catheter was kept for up to 5 days. All patients were followed up regularly for 72 hours. After removal of epidural catheter, patients were asked to score their level of satisfaction with regards to postoperative pain relief (1- Excellent, 2- Good, 3- Average, 4- Below average, 5- Poor). All observations were recorded in the epidural care chart incorporated with the anaesthesia record and epidural complications, if any were noted and addressed.

Statistical analysis done using SPSS version 11.0 (SPSS Ltd, Chicago, IL). A P value < 0.05 was considered to be statistically significant. The categorical variables were represented using frequencies and percentages. The continuous variables were represented using mean and standard deviation. Chi-square/ Fisher's exact was used to assess categorical variables and response variables. Student's t test was used for assessing continuous variables and the response variables. Association between the data was done using chi-square and ANOVA.

Results:

In our study we analysed a total population of 600 over a period of 6 months in which 239 (39.8%) were males and 361 (60.2%) were females. Most of the surgeries were elective surgeries 530 (88.3%). Preoperative physical assessment of spine was done in 592 patients (98.7%). Ultrasound spine assessment done in 22 patients, in whom we anticipated difficult epidural. Routinely, patients are positioned in lateral position for EA after premedication. In our study 565 patients were positioned laterally for epidural insertion (94.2%), whereas 35 (5.8%) patients with anticipated difficulty or history of difficult epidurals were positioned in sitting position. Intravenous premedication before epidural was given for 593 (98.8 %) patients and not administered in the remaining 7 patients (1.2%). Pre-induction epidural were done in 574 patients(95.7%), whereas only in 5 patients epidural catheter inserted after surgery for postoperative pain relief. 17 cases were done with combined spinal epidural anaesthesia and 4 cases were under sole epidural and EA was continued postoperatively.

598 cases were performed using 10 cm 18 g tuohy needle, and only 2 patients required 15 cm tuohy needle. Thoracic Epidural Anaesthesia (TEA) were performed in 547 cases (91.2%), 29 cases had (4. 8%) lumbar epidural and 24 had (4%) thoracolumbar epidurals (T12-L1). Most of the TEA was performed at the level of T9-T10 and T10-T11 163 and 159 respectively (27.2 % and 26.5%). About 80 percent of patients had hypotension following epidural bolus and was managed with fluid boluses and vasopressors.

Out of 600 cases, seven cases had dural puncture with an incidence of 1.2 %, and 25 cases of bloody tap (4.2%). There was one case of failure to site (0. 16%) and 21cases of failure to provide effective block (35%). We had 11 reported cases of paresthesia (1.8%) all of them were transient and relieved by stoppage of epidural drug. 15 cases had (2.5%) false track, of which in four patients (0.7%) epidural catheters were found in the pleural cavity during surgery, and others may be due to the false

LOR track in the subcutaneous plane and all patients were managed with multimodal analgesia. 532 patients (88.7%) with epidurals had no complications, out of total study population of 600. Epidural infusions were continued intraoperatively in 584 cases (97.3%) whereas 16 cases (2.7%) did not require intraop epidural infusions.

We have studied the ease of epidural insertion and have given a grading such as easy, slightly difficult, and very difficult according to the number of attempts. We came across one case of abandoning the procedure (0.2%) due to difficulty, 307 (51.2%) cases had easy epidurals, 249 cases (41.5%) had slight difficult epidurals and 43 cases had difficult epidurals (7.2%). The reason for difficulty was assessed and found narrow space as the most common reason. Out of 293 difficult epidurals, 169 had narrow epidural space (57.6%).Other factors were lack of cooperation 32 cases (10.9%), elderly 53 cases (18.08%), anatomical abnormalities 29 cases (9.8%). We observed suppression of autonomic reflexes in 579 cases (96.66%) out of 599 during light planes of GA which is an indirect indicator of an effective epidural, when MAC values were <0.7.

Out of 600 patients, we used injection fentanyl as intraoperative adjuvant in 523 patients (87.2%) and for others inj. Paracetamol (2.3%), inj. Tramadol (4. 3%), inj. Morphine (2.2%) and inj. Diclofenac (4%) were used. Postoperatively, inj. Paracetamol was used in 463 patients (77.2%) and inj. Fentanyl in 101 patients (16.8%) and rest were given inj. Tramadol, inj. Morphine and inj. Diclofenac as adjuvants. In our study 318 patients (53%) received buprenorphine as epidural boluses postoperatively. POPC were reported in only 104 (17.3%) patients, the rest 496 (82. 7%) did not develop any pulmonary complications. With EA 303 (50.5%) had excellent analgesia, 258 (43%) had good analgesia and 6 patients reported average. Only 2 patients had below average and 1 patient reported poor analgesia.

532 EA (88.7%) were performed by residents and the rest 33 were done by consultants. In 3 patients both consultant and resident were involved.

297 epidurals (49.5%) were secured with first attempt and 224 epidurals (37.3%) with two attempts .In 23 cases (3.8%), multiple attempts were required for securing epidural. 476 patients (79.3%), had VAS < 3 at any time during rest compared to 124 patients (20.7%) out of 600.
We have also analysed the association with the outcome variables such as pain score, patient satisfaction and POPC. Patients with VAS < 3 at any point of time, did not have POPC, indicating significant association between pain score and POPC (P = 0.001). There is a strong association between patient satisfaction and POPC as well. Out of 303 patients with excellent satisfaction, 270 patients did not have POPC and in 258 patients with good satisfaction, 201 patients did not have any pulmonary complications (P <0.001).

There was a significant association between patient satisfaction and suppression of autonomic response at light planes of GA (P = 0.0004). Out of 303 patients with excellent satisfaction, and 258 patients with good satisfaction, 295 patients and 249 patients had suppression of autonomic responses at light planes of GA respectively. There is significant association observed between patient satisfaction and VAS < 3 at any point of time (P = 0.001). Patients with VAS < 3 had patient satisfaction. Out of 303 patients with excellent satisfaction, 284 had VAS < 3 and 258 patients with good satisfaction, 182 VAS < 3 at any point of time.

Discussion:

The primary outcome of efficacy of epidural is pain relief and patient satisfaction. The secondary outcomes are incidence of complications including association with POPC with postop pain relief and patient satisfaction. Our study group included patients who underwent oncosurgeries which include gynaecological oncosurgeries as well which resulted in predominant female population.

Out of 600 populations, we could not perform preoperative physical examination of spine in eight patients due to the poor physical status and emergency nature of procedure In anticipated

difficult epidural procedure, we have done an ultrasonographic assessment of spine preoperatively to reduce the incidence of complications. We observed an easy conduct of procedure in those patients and hence we recommend preoperative ultrasonographic assessment of spine in anticipated difficult epidurals. Sitting position is associated with better intervertebral spaces, which aids in securing epidural in anticipated difficult spine.

As a routine, premedication is administered for all patients undergoing thoracic, abdominal and lower limb surgeries in our institution. In our study premedication was given for 593 (98.8%) patients. Premedication was avoided in seven patients, who had poor general health. Post induction epidurals were done, when diagnostic laparotomies were converted to definitive open extensive surgeries. In our study we had five such cases, for which epidural was inserted postoperatively for analgesia.

Tuohy needle of 10 cm length is routinely used and found to be sufficient to access the epidural space. Only 2 morbidly obese patients required extra long 15 cm tuohy needle.

Thoracic epidurals were preferred over lumbar epidural anaesthesia. For upper abdominal and thoracic surgeries, thoracic epidurals are associated with lower incidence of severity of perioperative hemodynamic stress response. TEA attenuates surgical stress response, improves myocardial oxygen balance and stabilizes intraoperative hemodynamics without hypertension and tachycardia (5), also it offers significant pre-emptive analgesic effect.(6)

Hypotension following EA bolus occurs due to suppression of autonomic nervous system and vasodilatation, which can be managed with fluids and vasoconstrictors. Selective sympathectomy with epidural can dilate constricted coronary vessels, decreasing heart rate and myocardial oxygen demand and protects myocardium thereby minimizing perioperative cardiovascular events; on the other hand hypotension can compromise coronary blood flow and organ perfusion. Therefore, extreme care must be taken to prevent unwanted hemodynamic flucatuations. Graded epidural, co-loading with vasopressors and fluids can offset this effect.

The primary measure of efficacy of any analgesic regimen especially in postoperative period is dynamic pain relief rather than pain relief at rest. EA is an effective technique for postoperative analgesia.(7) Our results are consistent with excellent postoperative dynamic pain relief.

It is noted that postoperative pain often remains under-treated in oncosurgical patients due to fear of side effects. Effective postoperative pain management leads to earlier mobilization and reduction in the immediate complications like infectious, neurological, cardiovascular, and VTE caused by immobility.(8) This shortens hospital stay, reduces hospital costs, increases patient satisfaction, and leads to early postoperative rehabilitation(9) resultiing in an early Return of Intended Oncologic Therapy (RIOT). EA with continuous infusion of the analgesic drugs through the epidural catheter is widely regarded as a superior technique in providing prolonged duration of postoperative pain relief after surgery.(7) In our study 50.5% patients had excellent analgesia and 43% had good analgesia. TEA based on clinical evidence from various studies showed effectiveness and lower incidence of complications.(10,11) We had only 1.2% of accidental dural puncture which is less than the reported incidence of 1.5 -2.6% and of which only one patient reported post dural puncture headache (PDPH). We routinely inject 10 ml of saline into the epidural space to prevent PDPH.(12) TEA is widespread for intraoperative and postoperative analgesia as it reduces sympathetic activity and thereby influences perioperative function of vital organ systems. Results of recent studies suggest that TEA decreases postoperative morbidity and mortality. In our hospital we prefer to do TEA in all laparotomies as there is better pain control with in a wide range of surgical procedures.(5)

The meta-analysis by Popping et al.(13) in abdominal and thoracic procedures showed a significant reduction in myocardial infarction (MI) with the use

of TEA. It protects against pneumonia following abdominal or thoracic surgery. In our study we had significant association with postoperative pain control and decreased incidence of pulmonary complications. 88.2% patients with VAS <3 did not developed POPC (P value of <0.001). TEA reduced the need for prolonged ventilation or reintubation, improving lung function and blood oxygenation, but has increased the risk of hypotension, urinary retention(14), and pruritus.(13,15)

The improvements of pulmonary function related to EA is due to blocking of reflexes inhibiting diaphragmatic function demonstrable after abdominal and thoracic surgery, with a beneficial effect on pulmonary mechanics(16) and effective pain relief allowing the patient to take deep breaths, cough and cooperate with physiotherapy.(17) Unrelieved pain after upper abdominal and thoracic surgery causes splinting of diaphragm, basal atelectasis, pooling of secretions, ineffective cough and resultant pneumonitis. Avoidance of high dose systemic opioids reduces respiratory depression; and reduce stress response to surgery reducing the level of postoperative immunosuppression, which may contribute to decreasing in POPC.(18) This decrease in level of immunosuppression has an added advantage in oncology patients who were already immunosuppressed due to the effect of chemotherapeutic agents . There is significant reduction in the incidence of pulmonary infection(19), respiratory failure(17), reintubation, prolonged ventilation(20) and prolonged intensive care unit stays with TEA in patients undergoing abdominal or thoracic surgery(21) Our study results are also consistent with these findings. In oncosurgeries there is a trend to administer opioid free anaesthesia for perceived oncologist benefits.

EA attenuates the hypercoagulable response to surgery and improves fibrinolytic function by attenuating the stress response as malignancy is a pro thrombotic state.(5) Attenuation of stress response in oncopatients reduces the probability of micro metastasis and improves patient outcome. Tuman et al.(22) reported a significant reduction in vascular graft occlusion with use of EA (P < 0.007).

In addition, they found that GA administered patients are hypercoagulable, whereas the epidural group maintains normal coagulation. TEA provides benefits on coagulation by improved venous blood flow, attenuation of the sympathetic response to surgery, the anticoagulant properties of LA, early mobility, and lowering of mean arterial pressure.(23) Cochrane meta-analysis from Parker et al.(24) reported significantly reduced incidence of perioperative VTE with the use of EA. We did not include postoperative incidence of VTE in our study because all our patients have received prophylaxis (both pharmacologic and non pharmacologic in the form Thrombo Embolus Deterrent stockings or Sequential Compression Devices) which may confront our findings.

Postoperative ileus is very common after abdominal surgery (>90% in many series) and may increase resource utilization by prolonging hospital stay.(25) TEA causes sympatholysis, depression of postoperative reflex, inhibition of gastrointestinal motility, reduced inflammatory response and opioid consumption and superior pain therapy, that contribute to reduced duration of postoperative ileus(21) and improved microcirculation with subsequent improved bowel function(20) TEA exerts beneficial effects on intestinal perfusion as long as its hemodynamic consequences are adequately controlled.(26)

TEA attenuates postoperative nitrogen excretion, amino acid oxidation, and decreased muscle protein synthesis while minimizing whole body protein catabolism. Muscle mass may be spared(27) and has a beneficial effect in poorly nourished oncology patients.

The intraoperative use of epidural LA for abdominal aortic surgery results in reduced need for intraoperative inhalational and intravenous opioid anesthetics, which allows early extubation of the trachea; excellent postoperative analgesia, and earlier recovery of pulmonary and gastrointestinal function(5).

Some analyses showed superior analgesic effects of TEA that may lead to increased patient

satisfaction, reduced intensive care unit stay, and better health related quality of life.(25) Greater improvements were noted when the regimen included LA and when level of epidural catheter matched site of surgery.

There is modest evidence for reduction of mortality with EA. Analysis of clinical registries indicate modest association between EA and reduced mortality.(28) The biggest prospective trial of the outcome effects, the Multicentre Australian Study of Epidural Anaesthesia (MASTER) trial(17) randomized 915 high risk patients to combined general/epidural anaesthesia followed by 72 hours of postoperative EA with local anaesthetic and opioids vs GA followed by systemic opioid treatment and showed that overall mortality rates were similar between groups (5.1 vs 4.3%).

Complications may be directly related to the performance of the technique or may result from poor management of the block. Neurovascular injury during catheter placement and LA reactions are uncommon. Sympatholysis leads to hypotension and bradycardia,(5) A prospective multicenter randomized trial shown that the incidence of hypotension is 41% after epidural combined with GA, and 23% after use of GA alone (P = 0.049).(29) In this study we had 80% incidence of hypotension following bolus dose of LA, probably because we performed high TEA in most of the cases 91.2%. Reports of dysesthesia, paresthesias, weakness, and local anesthetic toxicity are rare.(30) Catheter complications result from inadvertent penetration of the dural space, damage to neurovascular structures, or infection. In our study we have four cases of catheter false tracking to thoracic cavity noticed by the surgeons during thoracoscopy. The incidence of epidural hematoma formation was estimated to be < 1 in 150,000 in one study and found to be none in a second series of 100,000.(5) In our study there is no reports of epidural haematoma since we had done our study only in 600 patients. Timely diagnosis and treatment of spinal compression or infection are crucial to ensure patient safety with TEA. The benefits of TEA outweigh the risks with respect to the perioperative outcome and organ protection.

TEA provides optimal pain therapy in a wide range of surgical procedures and may contribute reduction of perioperative morbidity and mortality after major abdominal and thoracic surgeries. Improvement in outcome can probably be achieved when the skills of individual practitioners are improved and regional anaesthesia is used judiciously leading to reduced failure rates. Good operating procedures and a high level of awareness can largely improve the safety of TEA in patients receiving antiplatelet and anticoagulant drugs. There is a high level of safety when TEA is used as established in guidelines.(5) We have also found out the association between suppression of autonomic response in the light pain of GA. We have not analysed postoperative cardiovascular complications in this study because our study population has lot of other confounding factors for cardiovascular complications such as history of chemotherapy and electrolyte imbalance and so on.

CONCLUSION:

EA has been proven to decrease POPC .As it also reduces the hypercoagulable response and stress response it can be taken as an integral part of postoperative analgesia in oncosurgical patients. In our study we have got a strong association between postoperative analgesia and decrease incidence of POPC. It also has got an opioid sparing effect which is favorable for an improved oncologic outcome. Thoracic epidural is a valuable adjunct in all laparotomies and thoracotomies.

DISCLOSSURES:

No funding from external agencies, No conflict of interest.

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