



OPIOID-FREE ANAESTHESIA VERSUS OPIOID-BASED ANAESTHESIA: A PROSPECTIVE RANDOMIZED STUDY OF POSTOPERATIVE PAIN, OPIOID USE AND RECOVERY IN ONCOLOGIC SURGERY

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ABSTRACT

Background: Opioid-based anaesthesia (OBA) has traditionally been used for perioperative analgesia in oncologic surgery; however, opioid-related adverse effects such as postoperative nausea and vomiting (PONV), respiratory depression, and increased opioid consumption have raised concerns. Opioid-free anaesthesia (OFA), employing multimodal non-opioid analgesic strategies, has emerged as a potential alternative aimed at improving postoperative recovery.

Objectives: To compare opioid-free anaesthesia with conventional opioid-based anaesthesia in patients undergoing elective oncologic surgery with respect to postoperative pain scores, opioid consumption, incidence of PONV, rescue analgesic requirement, and recovery parameters over the first 72 postoperative hours.

Methods: This prospective randomized controlled study included 60 adult patients (ASA I–III) undergoing elective oncologic surgery under general anaesthesia with thoracic epidural analgesia. Patients were randomized into two groups: OBA (n = 30) and OFA (n = 30). Postoperative pain was assessed using the Visual Analogue Scale (VAS) at 2, 6, 12, 24, 36, 48, and 72 hours. Total postoperative morphine consumption, incidence of PONV, need for rescue analgesia, intraoperative analgesic requirements, and PACU stay were recorded. Statistical analysis was performed using appropriate parametric and non-parametric tests.

Results: VAS scores were significantly lower in the OFA group at most postoperative time points ($p < 0.01$). Postoperative morphine requirement was markedly reduced in the OFA group (1.30 ± 1.6 mg vs. 6.60 ± 1.3 mg; $p < 0.0001$), with fewer patients requiring opioids. PONV occurred in 60% of OBA patients and none in the OFA group ($p < 0.0001$). PACU stay was shorter in the OFA group without increased adverse events.

Conclusion: Opioid-free anaesthesia provides superior postoperative analgesia, significantly reduces opioid consumption and PONV, and enhances recovery in oncologic surgery, making it a safe and effective alternative to opioid-based techniques.

KEYWORDS: Opioid-free Anaesthesia, Opioid-based Anaesthesia, Oncologic Surgery, Postoperative Pain, Multimodal Analgesia, Postoperative Nausea and Vomiting.

Introduction

Effective perioperative pain management is essential in oncologic surgeries due to the high levels of postoperative pain linked with surgical trauma and comorbidities[1]. While opioid-based anaesthesia (OBA) has been commonly used, concerns about respiratory depression and dependency risks have led to increasing interest in opioid-free anaesthesia (OFA)[2]. OFA employs non-opioid agents for pain control, aiming to minimize opioid use, thereby potentially reducing complications and enhancing patient recovery[3]. The challenge of cancer treatment calls for efficient anaesthetic strategies that facilitate recovery and mitigate opioid-related issues. Existing research indicates that OFA may lessen postoperative opioid requirements and improve recovery quality, although further studies are warranted, particularly in the Indian context[4]. This study intends to directly compare OFA and OBA for elective oncologic surgeries, evaluating pain scores, opioid consumption, postoperative nausea and vomiting (PONV), and recovery, to provide substantial evidence for the broader adoption of opioid-sparing techniques.

Several studies have evaluated the efficacy of OFA in comparison with conventional opioid-based techniques across different surgical populations. Beloeil et al[5] demonstrated that OFA using dexmedetomidine and lidocaine significantly reduced postoperative opioid consumption and PONV in major abdominal surgery. Similarly, Forget et al[6] reported improved pain scores and reduced opioid requirements with lidocaine-based multimodal analgesia. In oncologic surgery, emerging evidence suggests that OFA may offer additional benefits. Studies have shown lower postoperative pain scores, reduced need for rescue opioids, and improved quality of recovery scores in patients receiving OFA. Some observational studies have also suggested a potential association between reduced perioperative opioid exposure and improved oncologic outcomes, although definitive conclusions require further investigation. Despite these encouraging findings, existing literature is heterogeneous with respect to drug combinations, dosing regimens, use of regional techniques, and outcome measures. Moreover, data from Indian tertiary care settings, particularly involving patients undergoing major oncologic surgeries with thoracic epidural analgesia, remain limited. Most available studies have focused on non-oncologic procedures or have not systematically evaluated pain trajectories beyond the immediate postoperative period.

Considering the rising burden of cancer surgeries, the limitations of opioid-based anaesthesia, and the evolving role of multimodal analgesia, there is a clear need for well-designed prospective studies evaluating opioid-free anaesthesia in oncologic patients. The present study was undertaken to compare opioid-free anaesthesia with conventional opioid-based anaesthesia in patients

undergoing elective oncologic surgeries, with specific emphasis on postoperative pain scores over the first 72 hours, opioid consumption, incidence of PONV, and recovery parameters. By incorporating standardized anaesthetic protocols, thoracic epidural analgesia, and systematic postoperative assessment, this study aims to generate robust evidence on the safety and efficacy of OFA in an Indian tertiary care setting. The findings are expected to contribute to evidence-based anaesthetic practice and may support the wider adoption of opioid-sparing strategies in oncologic surgery, aligning with ERAS principles and patient-centred care.

Aim

To compare opioid-free anaesthesia (OFA) with opioid-based anaesthesia (OBA) in patients undergoing oncologic surgery, focusing on postoperative pain (first 72 hours), postoperative opioid consumption, PONV, rescue analgesia, and intraoperative anesthetic/opioid requirements.

Objectives

1. Compare postoperative pain scores (VAS) at 2, 6, 12, 24, 36, 48 and 72 hours between OFA and OBA groups.
2. Compare total postoperative opioid (morphine via epidural or IV) consumption in the first 72 hours.
3. Compare the incidence of postoperative nausea and vomiting (PONV) between groups.

Materials and Methods

Study Design and Setting

This was designed as a prospective, randomized, parallel-group clinical trial conducted in the Department of Anaesthesia, Sree Mookambika Institute of Medical Sciences (SMIMS). The study compared two anaesthetic techniques—opioid-based anaesthesia (OBA) and opioid-free anaesthesia (OFA)—in patients undergoing elective oncologic surgeries. Approval was obtained from the Institutional Ethics Committee prior to initiation, and the trial was registered in accordance with national clinical trial registry guidelines. Written informed consent was taken from all participants.

Study Population

Inclusion criteria

- Adult patients aged 18–70 years.
- American Society of Anesthesiologists (ASA) physical status I–III.
- Patients scheduled for elective open or laparoscopic oncologic surgery under general anaesthesia with thoracic epidural analgesia.
- Patients willing to participate and provide written informed consent.

Exclusion criteria

- ASA physical status IV–V.
- Chronic opioid or benzodiazepine users.

- History of chronic pain syndrome or psychiatric illness interfering with pain assessment.
- Contraindications to epidural catheterization (e.g., coagulopathy, local infection, patient refusal).
- Known hypersensitivity to any study drug (opioids, ketamine, lidocaine, magnesium, bupivacaine, NSAIDs, acetaminophen).
- Severe hepatic, renal, or cardiac dysfunction.

Sample Size

The sample size was calculated using postoperative pain scores (VAS at 24 hours) reported in earlier studies comparing OFA and OBA. Based on an expected mean difference of approximately 4 units with a pooled standard deviation of 2, the effect size was estimated to be large. At a power of 80% and alpha of 0.05, the minimum required sample size was 10 patients per group. To improve robustness, allow subgroup analysis, and account for possible dropouts, a final sample of 30 patients per group (total n = 60) was planned.

Randomization and Allocation

Patients fulfilling eligibility criteria were randomly assigned into one of the two groups (OFA or OBA) in a 1:1 ratio. Randomization was performed using a computer-generated random sequence and allocation was concealed in sealed opaque envelopes, which were opened immediately prior to induction. The anaesthesiologist performing the induction was aware of the group allocation, but the observer recording postoperative outcomes was blinded to group assignment.

Preoperative Preparation

All patients underwent standard preoperative evaluation, including medical history, physical examination, baseline laboratory investigations, ECG, and chest X-ray. The Visual Analogue Scale (VAS; 0 = no pain, 10 = worst pain imaginable) was explained to each patient during the pre-anaesthetic visit. Patients were instructed to fast as per ASA guidelines. Standard premedication included oral ranitidine 150 mg and alprazolam 0.25 mg the night before surgery.

Anaesthetic Technique

Monitoring

Standard monitoring included continuous ECG, non-invasive blood pressure, pulse oximetry, end-tidal CO₂, and entropy monitoring to maintain depth of anaesthesia between 40–60. Temperature and urine output were also recorded. A thoracic epidural catheter was inserted at the T9–T10 interspace under aseptic precautions before induction. A test dose of 2 ml of 0.5% bupivacaine was administered to confirm placement.

Group A: Opioid-Based Anaesthesia (OBA)

- Induction: Lidocaine 1 mg/kg IV, fentanyl 100 µg IV, propofol 2 mg/kg IV, and rocuronium 0.6 mg/kg IV.
- Maintenance: Sevoflurane 0.7–1 MAC in 50% oxygen-air mixture with pressure-controlled ventilation (6–8

ml/kg tidal volume, PEEP 5 cm H₂O). Fentanyl boluses (50–100 µg IV) were administered as required for hemodynamic stability.

- Epidural analgesia: 0.25% bupivacaine 2–3 ml intermittently every 30–45 minutes.

Group B: Opioid-Free Anaesthesia (OFA)

- Pre-induction: Dexamethasone 0.1 mg/kg IV and paracetamol 1 g IV.
- Induction: Lidocaine 1 mg/kg IV, propofol 2 mg/kg IV, ketamine 0.5 mg/kg IV, and rocuronium 0.6 mg/kg IV.
- Maintenance: Continuous infusion of lidocaine (2 mg/kg/h), ketamine (0.2 mg/kg/h), and magnesium sulfate (15 mg/kg/h after loading dose). Sevoflurane 0.7–1 MAC in 50% oxygen-air mixture was used for hypnosis.
- Epidural analgesia: 0.25% bupivacaine 2–3 ml intermittently every 30–45 minutes.

Intraoperative Management

All patients were mechanically ventilated with standard ventilator settings. A nasogastric tube and urinary catheter were inserted. Intraoperative hemodynamic parameters (HR, MAP, SpO₂, EtCO₂) were recorded at baseline and every 5 minutes. Anaesthesia was titrated to maintain MAP within ±20% of baseline.

At the end of surgery, all patients received IV metamizole 2 g. Neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. Patients were extubated after recovery of spontaneous breathing and transferred to the post-anaesthesia care unit (PACU).

Postoperative Analgesia Protocol

- All patients were monitored in the PACU for at least 2 hours, followed by transfer to the surgical ward
- Pain scores (VAS at rest) were assessed at 2, 6, 12, 24, 36, 48, and 72 hours postoperatively
- If VAS was 4–6, IV metamizole 1 g was administered; if VAS ≥7, morphine 2 mg diluted in saline was given via epidural catheter
- Rescue analgesia with IV paracetamol 1 g was available if required
- Postoperative nausea and vomiting (PONV) was recorded, and ondansetron 4 mg IV was administered if present

Outcome Measures

Primary Outcome

- Postoperative pain scores (VAS) at multiple time points within the first 72 hours

Secondary Outcomes

- Total morphine consumption in the first 72 hours
- Incidence of PONV
- Number of patients requiring rescue analgesia
- Total intraoperative fentanyl requirement
- Total intraoperative bupivacaine administered via

epidural.

- Hemodynamic stability (variation in MAP and HR from baseline).

Statistical Analysis

Data was analyzed using SPSS version 26.0 (IBM, Chicago, USA). Continuous variables were tested for normality using Shapiro–Wilk test. Normally distributed data were expressed as mean $\pm$ SD and compared using independent Student's t-test. Non-normally distributed data were expressed as median (IQR) and compared using Mann–Whitney U test. Categorical variables were compared using Chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant.

Results

Table 1: Baseline demographics & clinical characteristics (n = 30 per group)

Variable	OBA (n=30)	OFA (n=30)	p-value
Age (years), mean $\pm$ SD	58.2 $\pm$ 7.4	58.6 $\pm$ 9.8	0.78
Gender (F / M)	15 / 15	16 / 14	0.85
BMI (kg/m ²), mean $\pm$ SD	25.26 $\pm$ 2.03	24.83 $\pm$ 1.6	0.002
ASA I / II / III	as recruited	as recruited	—
Duration of surgery (min), mean $\pm$ SD	150 $\pm$ 30	150 $\pm$ 30	—

Table 2: Postoperative pain (VAS, mean $\pm$ SD) — 2 to 72 hours (n = 30 per group)

Time after surgery	OBA (mean $\pm$ SD)	OFA (mean $\pm$ SD)	ANOVA / t-test p-value
2 h	8.30 $\pm$ 1.03	4.90 $\pm$ 2.60	< 0.0001
6 h	5.60 $\pm$ 0.90	5.40 $\pm$ 1.10	0.18
12 h	7.40 $\pm$ 0.90	3.10 $\pm$ 2.40	< 0.0001
24 h	8.10 $\pm$ 0.90	3.60 $\pm$ 2.10	< 0.0001
36 h	6.35 $\pm$ 1.20	4.30 $\pm$ 1.70	0.0012
48 h	4.70 $\pm$ 0.80	3.45 $\pm$ 1.60	0.0009
72 h	3.75 $\pm$ 0.80	2.65 $\pm$ 1.90	0.0065

Table 3: Postoperative morphine requirements (first 72 h) — all patients (n = 30 per group)

Metric	OBA (n=30)	OFA (n=30)	p-value
Patients who received morphine (n, %)	30 / 100%	14 / 47%	< 0.0001
Mean morphine dose (mg) — all patients, mean $\pm$ SD	6.60 $\pm$ 1.3	1.30 $\pm$ 1.6	< 0.0001
Median (IQR) morphine (mg)	6 (6–8)	0 (0–2)	—
Range (mg)	4–8	0–4	—

Table 4: Intraoperative analgesic/anesthetic consumption & rescue analgesia (n = 30 per group)

Variable	OBA	OFA	p-value
Intraop fentanyl (μ g), mean $\pm$ SD	382.25 $\pm$ 106.3	0	< 0.0001
Total intraop epidural bupivacaine (mg), mean $\pm$ SD	26.37 $\pm$ 2.6	24.50 $\pm$ 4.3	0.09
Patients requiring additional postop analgesic (n, %)	17 / 57%	11 / 37%	0.12
Mean number of rescue doses per patient (among those needing)	1.8 $\pm$ 0.6	1.4 $\pm$ 0.5	0.04

Table 5: Postoperative Nausea & Vomiting (PONV) and safety outcomes (n = 30 per group)

Outcome	OBA (n=30)	OFA (n=30)	p-value
Nausea (any), n (%)	18 / 60%	0 / 0%	< 0.0001
Vomiting (any), n (%)	18 / 60%	0 / 0%	< 0.0001
Major adverse events (e.g., respiratory depression)	0	0	—
Mean PACU stay (min), mean $\pm$ SD	120 $\pm$ 30*	100 $\pm$ 25*	0.03

Discussion

The present prospective randomized study evaluated the efficacy of opioid-free anaesthesia compared with conventional opioid-based anaesthesia in patients undergoing oncologic surgery, focusing on postoperative pain trajectory, opioid consumption, postoperative nausea and vomiting, rescue analgesic requirement, and recovery parameters. The findings of this study demonstrate that OFA provided superior postoperative analgesia at several time points, significantly reduced postoperative opioid consumption, and markedly decreased the incidence of PONV without compromising intraoperative hemodynamic stability or safety. Postoperative Pain Scores. In the present study, postoperative pain scores were significantly lower in the OFA group at 2, 12, 24, 36, 48, and 72 hours postoperatively, while pain scores at 6 hours were comparable between groups. These findings suggest that OFA offers sustained analgesic benefits beyond the immediate postoperative period.

Similar observations were reported by Beloeil et al.[5], who demonstrated lower postoperative pain scores in patients receiving opioid-free anaesthesia using dexmedetomidine and lidocaine during major abdominal surgery. The authors attributed improved analgesia to synergistic inhibition of central sensitization and attenuation of nociceptive transmission at multiple levels of the pain pathway.

Likewise, Bugada et al.[7] reported improved pain control in the first 48 hours following cancer surgery with OFA, emphasizing the role of NMDA antagonism by ketamine and membrane-stabilizing effects of lidocaine. The sustained reduction in pain scores observed in the present study up to 72 hours may be explained by the multimodal analgesic regimen combining ketamine, lidocaine, magnesium sulfate, paracetamol, and thoracic epidural analgesia, which collectively reduce hyperalgesia and opioid-induced pain amplification.

Postoperative Opioid Consumption

A key finding of the present study was the significant reduction in postoperative morphine requirement in the OFA group. While all patients in the OBA group required postoperative morphine, less than half of the patients in the OFA group required opioid rescue, with a substantially lower mean morphine dose. These findings are consistent with those of Forget et al.[6], who reported significantly reduced postoperative opioid consumption in patients receiving lidocaine-based multimodal analgesia. Similarly, Soffin and YaDeau[8] demonstrated that opioid-sparing and opioid-free techniques significantly decrease postoperative opioid exposure without worsening pain outcomes. In oncologic patients, minimizing opioid exposure may have additional benefits. Experimental evidence suggests that opioids can suppress natural killer cell activity and modulate tumor-promoting pathways. Lucia et al.[9]. highlighted a potential association between reduced perioperative opioid use and improved oncologic outcomes, although causal relationships

remain under investigation. The marked reduction in opioid requirement observed in the present study supports the feasibility of OFA as an opioid-minimizing strategy in cancer surgery.

Postoperative Nausea and Vomiting (PONV)

The incidence of postoperative nausea and vomiting was significantly higher in the OBA group, whereas no patient in the OFA group experienced nausea or vomiting. This striking difference underscores one of the most consistent advantages of opioid-free anaesthesia. Similar findings have been reported by Gan et al.[10], who identified perioperative opioid use as one of the strongest independent predictors of PONV. Lavand'homme and Estebe[11] also reported near-complete elimination of PONV with OFA protocols, particularly when combined with prophylactic antiemetics and avoidance of volatile opioid boluses. The absence of PONV in the OFA group in the present study may be attributed to the complete avoidance of opioids, use of dexamethasone, and stable intraoperative hemodynamics, all of which are known to reduce emetogenic stimuli.

Rescue Analgesia Requirement

Although the proportion of patients requiring rescue analgesia did not differ significantly between groups, the mean number of rescue doses was significantly lower in the OFA group. This indicates that pain episodes, when present, were less intense and more easily controlled in patients receiving OFA. Comparable results were reported by Arnet et al.[12], where fewer rescue analgesic interventions were required in the OFA group despite similar baseline characteristics. This finding supports the concept that OFA improves the quality of analgesia rather than merely delaying opioid administration.

Intraoperative Analgesic Requirements and Hemodynamic Stability

As expected, intraoperative fentanyl consumption was significantly higher in the OBA group, while no opioids were administered in the OFA group. Total epidural bupivacaine consumption was comparable between groups, suggesting that differences in postoperative outcomes were primarily attributable to systemic analgesic strategy rather than regional technique. Importantly, no major adverse events or clinically significant hemodynamic instability were observed in either group. These findings align with those of Abebe et al.[13], who demonstrated that OFA provides hemodynamic stability comparable to opioid-based techniques when appropriately titrated.

Recovery Parameters

Patients in the OFA group had a shorter PACU stay compared with the OBA group. Faster recovery may be attributed to reduced opioid-related sedation, absence of PONV, and improved pain control. Kehlet and Wilmore[14], in their work on enhanced recovery pathways, emphasized that opioid minimization is a key factor in accelerating postoperative

recovery and reducing hospital stay.

Clinical Implications

The results of the present study support the growing body of evidence favoring opioid-free anaesthesia as an effective and safe alternative to conventional opioid-based techniques in oncologic surgery. The demonstrated benefits in pain control, opioid reduction, and PONV prevention are particularly relevant in cancer patients, where enhanced recovery and opioid stewardship are of paramount importance.

Strength and limitations

The study's strengths lie in its prospective randomized design, which minimizes selection bias and enhances internal validity. By employing standardized anaesthetic protocols and objectively assessing postoperative pain for 72 hours, it effectively compares analgesic efficacy. The incorporation of key outcomes, including opioid consumption and recovery parameters, offers a thorough evaluation of opioid-free anaesthesia in oncologic surgery; conducting the study in a real-world tertiary care setting enhances the findings' applicability. Limitations include a single-centre focus, modest sample size, lack of anaesthesiologist blinding leading to potential bias, and absence of long-term outcome assessments. Despite these drawbacks, the study presents significant evidence for opioid-free anaesthesia as a viable alternative in oncologic procedures.

Conclusion

The present study demonstrates that opioid-free anaesthesia is a safe and effective alternative to conventional opioid-based anaesthesia in patients undergoing oncologic surgery. Opioid-free anaesthesia was associated with significantly lower postoperative pain scores at multiple time points, a marked reduction in postoperative opioid requirements, and a substantially lower incidence of postoperative nausea and vomiting, without compromising intraoperative hemodynamic stability or patient safety. The reduced need for rescue analgesia and shorter recovery duration further support its role in enhancing postoperative recovery. These findings suggest that a multimodal opioid-free anaesthetic approach can improve postoperative outcomes and promote opioid stewardship in oncologic surgical patients, and may be considered as part of routine perioperative pain management protocols in appropriately selected patients.

Conflict of Interest

None

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