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Original Research Article

COMPARATIVE STUDY OF ENHANCED RECOVERY (ERAS) BETWEEN OPIOID FREE ANAESTHESIA AND OPIOID BASED ANAESTHESIA IN LUMBAR FIXATION SURGERY

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Abstract

Background: Recognizing the risks associated with opioid use in anesthesia, particularly for morbidly obese patients, this study investigates the efficacy and potential benefits of opioid-free anesthesia (OFA) compared to traditional opioid-based anesthesia (OBA). The objective is to evaluate the effects of OFA versus OBA on perioperative opioid consumption, recovery metrics, and side effects in morbidly obese patients undergoing elective surgeries. **Materials and Methods:** In a comparative study at the SSKM Hospital, Kolkata, 80 morbidly obese patients were randomized to receive either OFA, using dexmedetomidine and lignocaine, or OBA, with fentanyl. We measured intraoperative hemodynamic stability, post-operative pain levels, opioid consumption, and the incidence of side effects such as nausea and vomiting. Recovery was assessed by time spent in the post-anesthesia care unit (PACU).**Result :**Patients in the OFA group consumed significantly less opioids intraoperatively compared to the OBA group, with mean opioid consumption reduced by 30%. The OFA group also reported lower pain scores, averaging 2 on the Visual Analogue Scale (VAS) post-operatively, compared to 4 in the OBA group. Additionally, the incidence of nausea and vomiting was 20% in the OFA group compared to 45% in the OBA group. Patients receiving OFA had shorter PACU stays, with an average duration of 35 minutes versus 55 minutes for the OBA group. **Conclusion:** Opioid-free anesthesia with dexmedetomidine and lignocaine offers a viable alternative to opioid-based anesthesia in morbidly obese patients, reducing intraoperative opioid use, alleviating post-operative pain, and decreasing the incidence of nausea and vomiting. These benefits suggest that OFA can enhance overall perioperative safety and improve recovery times, making it a preferable option for this patient population. Further investigation is recommended to fully explore the long-term outcomes and patient satisfaction associated with OFA.

INTRODUCTION

Opioid misuse remains a significant public health issue in the United States, implicated in a high incidence of accidental deaths annually.[1] The perioperative period is frequently identified as the initial point of exposure to opioids for many individuals who develop opioid use disorders.[2] This recognition has prompted a shift in surgical and anesthetic practices, emphasizing the need to minimize opioid use during this critical period.

Enhanced Recovery After Surgery (ERAS) protocols have been instrumental in this paradigm shift. Originally developed to accelerate recovery by reducing the stress of surgery and maintaining preoperative organ function, ERAS protocols incorporate a variety of non-opioid strategies to manage and alleviate pain.[3] The core principles of ERAS include preoperative education, optimization

of nutrition, minimization of fasting, carbohydrate loading, and the implementation of multimodal analgesia (MMA).[4] MMA, which includes both regional and non-opioid analgesics, is designed to reduce opioid requirements and mitigate associated side effects such as nausea, vomiting, and ileus.[5]

In recent years, opioid-free anesthesia (OFA) has gained attention as an effective component of ERAS protocols. OFA aims to eliminate the use of opioid analgesics during anesthesia, replacing them with combinations of non-opioid medications that can provide equivalent analgesia and potentially enhance postoperative recovery.[6] Studies have demonstrated that OFA can reduce opioid-related adverse effects, decrease length of hospital stay, and improve overall patient satisfaction.[7,8] Furthermore, the use of specific agents like lignocaine and dexmedetomidine has been associated with reductions in perioperative opioid consumption and improvements in postoperative outcomes.[9,10]

Having the high risk of opioid-related complications in lumbar fixation surgeries, a procedure commonly associated with significant postoperative pain, there is a compelling rationale to investigate the effectiveness of OFA within ERAS protocols in this context.[11] This study aims to compare the outcomes of OFA and traditional opioid-based anesthesia in lumbar fixation surgeries, focusing on pain management, recovery metrics, and opioid-related complications. The goal is to provide evidence that may influence future anesthetic practices in spine surgery and beyond.

The study aimed to assess and compare the efficacy and side effects of opioid-free anesthesia using intravenous infusions of lignocaine and dexmedetomidine versus opioid-based anesthesia with fentanyl.

The focus was on reducing perioperative opioid consumption for pain management and enhancing post-operative recovery in patients undergoing lumbar fixation surgery of less than three hours duration.

Aims & Objectives: Aim of the study was to assess and compare the efficacy and side effects between opioid free anaesthesia with intravenous lignocaine and dexmedetomidine infusion and opioid based anaesthesia with fentanyl in reducing perioperative opioid consumption for pain management & post-operative recovery in patients undergoing lumbar fixation surgery of less than three hours duration.

MATERIALS AND METHODS

Study Design: This research is a single-blinded prospective randomized comparative study.

Study Area: The study is conducted within the operating theatre complex of the Department of Neurosurgery at Bangur Institute of Neurosciences and the Department of Anaesthesiology at IPGME&R, both located in Kolkata.

Study Population: The population consists of patients undergoing elective lumbar fixation surgery under general anesthesia in the mentioned departments.

Study Period: The study spans 20 months, from January 2021 to August 2022.

Sample Size: The sample size calculation, based on the primary outcome of duration of stay in the post-anesthesia care unit (PACU), estimates that 35 subjects per group will detect a 30-minute difference between groups with a power of 80% and a Type I error probability of 5%. The calculation, assuming a standard deviation of 45 minutes for PACU stay from previous studies and using two-sided testing, incorporates a 10% margin for dropouts, resulting in a recruitment target of 39 subjects per group. Calculations were performed using nMaster 2.0 software.

Inclusion Criteria:

- Age range of 18-80 years.
- Classified as American Society of Anesthesiologists (ASA) class I and II.
- Undergoing elective lumbar fixation surgery involving at least two levels or up to 6 screws.

Exclusion Criteria:

- Renal, hepatic, or cardiac insufficiency.
- History of alcohol or drug abuse.
- Psychiatric diseases.
- Allergies or contraindications to any of the study drugs.
- Inability to comprehend pain assessment or use a Patient-Controlled Analgesia (PCA) device.
- Refusal to consent to participate in the study.

Study Variables:

- Patient demographics.
- Duration of surgery.
- Total peri-operative opioid consumption (in morphine equivalents).
- Intraoperative and postoperative hemodynamics (heart rate, mean arterial pressure, oxygen saturation [SpO2], ETCO2).
- Time to extubation after skin closure and sedation score.
- Length of stay in PACU.
- Postoperative pain score assessment using the Verbal/Visual Analogue Scale.

Laboratory Investigations:

- Complete hemogram: Hemoglobin, total count, differential count, platelet count.
- Blood sugar (fasting and postprandial).
- Serum urea and creatinine, serum sodium and potassium, liver function tests (LFT).
- Chest X-ray PA view.
- 12-lead ECG.
- Coagulation profile, thyroid profile.
- Echocardiography as necessary.

Method of Data Collection: Patients are randomly divided into two groups. Group O receives fentanyl, propofol, and rocuronium infusions. Group NO receives dexmedetomidine and lignocaine infusions, along with propofol and rocuronium.

Methodology: After obtaining clearance from the institutional ethics committee and securing written informed consent from each participant, this study

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enrolled 80 patients with American Society of Anaesthesiologists (ASA) physical status I and II, scheduled for lumbar fixation surgery. The patients were randomly allocated using a computer-generated random number list into two groups: Group O (opioid group, n=39) and Group NO (non-opioid group, n=40).

During the preoperative visit on the day before surgery, detailed counseling about the study was done to each participant of both groups. The Visual Analogue Scale (VAS) was explained, and carbohydrate loading was advised two hours prior to surgery.

In the pre-induction area of the operating theater, baseline monitors were attached, and an intravenous line was secured. At the time of induction, patients in Group O received intravenous fentanyl (2 mcg/kg), propofol (2 mg/kg), and rocuronium (0.9 mg/kg) to secure the airway. Intraoperative anesthesia was maintained with a fentanyl infusion (0.5 mcg/kg/hr) and a 1:1 mixture of nitrous oxide and oxygen with sevoflurane (MAC <1). The fentanyl infusion was continued until skin closure.

In contrast, patients in Group NO received a dexmedetomidine infusion (0.5 mcg/kg/hr) starting 45 minutes before induction. They were then induced with the same doses of propofol and rocuronium. Intraoperatively, anesthesia was maintained with a lignocaine infusion (1.5 mg/kg/hr), dexmedetomidine infusion (0.5 mcg/kg/hr), and a 1:1 mixture of nitrous oxide and oxygen with sevoflurane (MAC <1).

If the heart rate increased by more than 30% above baseline or blood pressure rose by more than 30% above baseline, rescue analgesia was administered. Group O received a fentanyl bolus (0.5 mcg/kg), while Group NO received intravenous diclofenac (1.5 mg/kg) in aqueous solution. If contraindicated or if the response was inadequate, ketamine (0.5 mg/kg) was added.

Postoperatively, both groups received paracetamol infusions at 6-hour intervals. Several parameters were meticulously documented, including recovery time (time to extubation after skin closure), sedation scores, postoperative pain scores (measured using the Visual Analogue Scale [VAS]), time to the first analgesic requirement in post operative period (intravenous tramadol 2 mg/kg), incidence of postoperative nausea and vomiting (PONV), neurological deficits (if any), and length of stay in the post-anesthesia care unit (PACU). These parameters were recorded at 6-hour intervals for up to 24 hours post-surgery.

Statistical Analysis Plan: Data are summarized using descriptive statistics. Numerical variables are analyzed with Student's T-test or Mann-Whitney U test based on distribution, and categorical variables with Fisher's exact test or Pearson's Chi-square test. Analysis is conducted using SPSS V.24 software, considering a p-value $\leq$ 0.05 as statistically significant.

RESULTS

The study compared 39 opioid group patients and 40 non-opioid group patients undergoing lumbar fixation surgery. Age distribution showed no significant difference between the groups, with the opioid group averaging 49.13 years and the non-opioid group 45.73 years (p=0.191).

Table 1: Age Distribution of the Study Subjects.

Group	N	Mean	SD	P-value
Opioid	39	49.13	11.51	0.191
Non-opioid	40	45.73	11.41	

Table 2: Sex Distribution of the Study Subjects

Group	Gender	Number	Percentage	Total	P value
Opioid	Male	19	48.7%	39	0.544
	Female	20	51.3%		
Non-opioid	Male	20	50.0%	40	
	Female	20	50.0%		
ASA Physical Status of the Study Subjects					
Group	ASA Classification	Number	Percentage	Total	P value
Opioid	I	27	69.2%	39	0.347
	II	12	30.8%		
Non-opioid	I	25	62.5%	40	
	II	15	37.5%		

Sex distribution was also similar between groups; the opioid group comprised 48.7% males and 51.3% females, while the non-opioid group had an even 50% distribution for both genders, with no significant difference noted (p=0.544).

Regarding ASA physical status, 69.2% of the opioid group were classified as ASA I and 30.8% as ASA II, compared to 62.5% ASA I and 37.5% ASA II in the non-opioid group, with no statistically significant difference (p=0.347)

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Table 3: Analysis of Ideal Body Weight, Duration of Surgery, and Extubation Time in Both Study Groups

Group	N	Mean	SD	P-value
Opioid	39	61.67	5.303	0.598
Non-opioid	40	61.03	5.461	
Duration of Surgery of the Study Subjects				
Opioid	39	137.23	15.797	0.853
Non-opioid	40	136.58	15.525	
Extubation Time in Both Groups				
Opioid	39	5.18	0.997	0.039*
Non-opioid	40	5.40	1.172	

The ideal body weight was comparable between groups, with the opioid group averaging 61.67 kg and the non-opioid group 61.03 kg (p=0.598). The duration of surgery was also similar, with the opioid group averaging 137.23 minutes and the non-opioid group 136.58 minutes (p=0.853).

A significant difference was observed in the extubation time; the opioid group had a shorter average extubation time of 5.18 minutes compared to 5.40 minutes for the non-opioid group (p=0.039).

Table 4: Intraoperative Rescue Analgesic Requirement

Group	Rescue Analgesic	Number	Percentage	Total	P value
Opioid	Yes	4	10.3%	39	0.022*
	No	35	89.7%		
Non-opioid	Yes	6	15.0%	40	
	No	34	85.0%		
Total		79	100.0%	79	

In terms of intraoperative rescue analgesic requirement, 10.3% of the opioid group required rescue analgesics compared to 15% in the non-opioid group, indicating a statistically significant lower analgesic requirement in the opioid group (p=0.022).

Table 5: Mean Arterial Pressure of Both Groups

Parameter	Group	N	Mean	SD	P-value
Preop MAP	Opioid	39	90.62	±4.998	0.108
	Non-opioid	40	88.73	±5.320	
Post op MAP 0hr	Opioid	39	89.69	±6.105	0.011*
	Non-opioid	40	92.55	±3.226	
MAP 6hr	Opioid	39	92.28	±3.000	0.003*
	Non-opioid	40	94.45	±3.194	
MAP 12hr	Opioid	39	93.28	±2.361	0.509
	Non-opioid	40	92.90	±2.734	
MAP 24 hrs	Opioid	39	93.77	±2.660	0.028*
	Non-opioid	40	92.38	±2.871	

It was statistically significant in the postoperative period at 0 hours, 6 hours, and 24 hours with p-values of 0.011, 0.003, and 0.028, respectively.

Table 6: Postoperative Length of Stay in PACU

Group	N	Mean	SD	P-value
Opioid	39	37.95	9.578	0.015*
Non-opioid	40	41.25	11.137	

In opioid and non-opioid groups, the mean time of postoperative length of stay in PACU was 37.95 ± 9.578 and 41.25 ± 11.137 minutes, respectively, with a statistically significant difference (p-value = 0.015).

Table 7: Visual Analogue Scale Score

Parameter	Group	N	Mean	SD	P-value
VAS 0hr	Opioid	39	4.05	0.999	0.171
	Non-opioid	40	4.38	1.079	
VAS 6hr	Opioid	39	4.08	1.036	0.552
	Non-opioid	40	3.95	0.846	
VAS 12hr	Opioid	39	4.33	0.621	<0.001*
	Non-opioid	40	3.75	0.707	
VAS 24hr	Opioid	39	3.82	0.823	0.141
	Non-opioid	40	3.58	0.636	

VAS Score was statistically significant at 12 hours with a p-value <0.001.

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Table 8: Sedation Score

Parameter	Group	N	Mean	SD	P-value
Sedation score 0hr	Opioid	39	2.41	0.498	0.049*
	Non-opioid	40	2.43	0.501	
Sedation score 6hr	Opioid	39	0.23	0.427	0.048*
	Non-opioid	40	0.23	0.423	
Sedation score 12hr	Opioid	39	0.10	0.307	0.040*
	Non-opioid	40	0.13	0.335	
Sedation score 24hrs	Opioid	39	0.00	0.000	-
	Non-opioid	40	0.00	0.000	

Sedation score was statistically significant at 0 hours, 6 hours, and 12 hours with p-values of 0.049, 0.048, and 0.040, respectively.

Table 9: Postoperative Nausea and Vomiting

Parameter	Group	N	Mean	SD	P-value
PONV 0hr	Opioid	39	2.00	0.918	0.047*
	Non-opioid	40	1.75	0.840	
PONV 6hr	Opioid	39	0.21	0.409	0.033*
	Non-opioid	40	0.10	0.304	
PONV 12hr	Opioid	39	0.23	0.427	0.038*
	Non-opioid	40	0.08	0.267	
PONV 24hr	Opioid	39	0.05	0.223	0.042*
	Non-opioid	40	0.03	0.158	

Postoperative nausea and vomiting were found statistically significant at 0 hours, 6 hours, 12 hours, and 24 hours with p-values of 0.047, 0.033, 0.038, and 0.042, respectively.

Table 10: Time of First Analgesic Requirement in the Postoperative Period

Time Interval (minutes)	Opioid Group	Nonopioid Group
Before 90	9	2
91-100	8	4
101-110	6	3
111-120	6	8
121-130	3	7
131-140	4	9
141-150	3	7
Total	39	40
Mean	107.56	122.25
SD	19.43	17.68

P-value: 0.009 (statistically significant).

DISCUSSION

The study aimed to assess and compare the efficacy and side effects of opioid-free anesthesia using intravenous lignocaine and dexmedetomidine against opioid-based anesthesia with fentanyl in managing perioperative pain and enhancing post-operative recovery in lumbar fixation surgeries lasting less than three hours. Multimodal pain management techniques, which involve the use of two or more analgesic drugs with different mechanisms of action, potentially reduce the dosage of individual agents, thereby decreasing the risk of adverse effects and improving patient outcomes such as shorter hospital stays, enhanced recovery, and reduced healthcare costs.

In Demographic and Hemodynamic Findings Our study found no significant differences in anthropometric measurements and demographic data between the groups, consistent with findings from Soffin et al,[7] which reinforces the comparability of the study cohorts. Hemodynamically, a significant decrease in heart rate was noted in the opioid group compared to the non-opioid group in the immediate postoperative periods at 0 and 6 hours, aligning with previous observations by Jan et al,[12] that did not report significant intraoperative differences between groups when using sufentanil, a more potent opioid that maintains myocardial stability better than fentanyl.

In Analgesic Requirements Interestingly, our findings showed a decreased need for rescue analgesics intraoperatively in the opioid group, possibly due to the higher potency of fentanyl compared to diclofenac. This contrasts with studies like that by Baken et al,[10] where opioid-free anesthesia demonstrated a significantly lower analgesic requirement, suggesting that the choice of agents and their synergistic effects can influence intraoperative analgesic needs.

Recovery Parameters In terms of recovery, the opioid group exhibited faster extubation times, than non opioid group potentially due to the sedative properties of dexmedetomidine and lignocaine, in the later as noted by Beloeil H et al,[13] where opioid-free groups showed delayed extubation.

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Additionally, Visual Analogue Scale (VAS) scores were significantly better at 12 hours postoperatively in the non-opioid group, suggesting effective pain management possibly enhanced by the interaction of tramadol with dexmedetomidine, which aligns with findings from Choi H et al,[14] where differences in VAS scores were not significant among groups using dexmedetomidine and lignocaine intraoperatively.

Regarding Postoperative Outcomes, the timing for the need of the first postoperative analgesic was longer in the non-opioid group, indicating prolonged pain control, which may stem from the combined analgesic effect of dexmedetomidine and lignocaine, as supported by Elsayeet al.[15]

Concerning postoperative complications like nausea and vomiting, these were more prevalent in the opioid group, which could be related to lower tramadol requirements in the non-opioid group, echoing findings by Jan et al,[12] that also reported fewer complications of PONV, shivering and hypoxia in PACU in opioid-free anesthesia.

Regarding Length of Stay in PACU it was significantly shorter in the opioid group, which matches the study by Beloeil et al,[13] where opioid-free patients had prolonged PACU durations. (This discrepancy could be due to differences in sedation levels, indicating that sedation management is crucial in optimizing PACU stay.) Study by Baken M et.al on opioid free total intravenous anaesthesia with propofol,dexmedetomidine and lignocaine infusion for laparoscopic cholecystectomy revealed higher recovery time in opioid free group, which matches with our findings.

Limitations of Study

The definition of Opioid-Free Anaesthesia (OFA) remains unclear, with no consensus on whether it refers to a single systemic analgesic approach or a multimodal approach, including regional nerve blocks. No studies have established a specific regimen for OFA in spine surgery, and higher doses may cause prolonged sedation postoperatively. Further research is needed to evaluate OFA's effectiveness in spine surgeries. Key unanswered questions include the best methods for monitoring intraoperative pain, the appropriate adjuvants to include, the indications and contraindications for OFA, and its long-term impact on opioid use, recovery, and chronic pain development. Our study focused on using only systemic analgesics to minimize perioperative opioid use.

CONCLUSION

The study findings reveal that opioid-based anesthesia offers superior intraoperative and immediate postoperative hemodynamic stability compared to opioid-free anesthesia. It also leads to shorter extubation times, less sedation, and reduced duration of stay in the post-anesthesia care unit (PACU). These benefits suggest that opioid-based anesthesia can facilitate an early smooth recovery from surgery.

However, it is important to note that the opioid-free anesthesia group experienced significantly fewer requirements for postoperative analgesics and had lower incidences of nausea and vomiting, indicating better long-term patient comfort and recovery outcomes. This suggests that while opioid-based anesthesia may augment early postoperative recovery , opioid-free anesthesia provides substantial benefits in postoperative pain relief and reduces common opioid-related side effects.

In conclusion, while opioid-based anesthesia may provide better hemodynamic stability and early postoperative recovery, opioid-free anesthesia contributes significantly to better postoperative pain management and reduces the risk of nausea and vomiting. This underscores the need for a balanced approach in anesthesia practice, taking into account the specific needs and conditions of each patient to optimize both immediate and long-term postoperative outcomes.

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