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Research Article

COMPARATIVE ANALYSIS OF TRAMADOL AND LORNOXICAM FOR POST-OPERATIVE PAIN RELIEF IN ENT SURGICAL PROCEDURES: A RANDOMIZED CONTROLLED TRIAL

Dr Payal Bhattacharya[1], Dr P Prashanth Kumar[2]*

[1]Associate Professor, Department of ENT, Gayatri Vidya Parishad Institute of Health Care & Medical technology, Vishakapatnam, Andhra Pradesh, India.
[2]Associate Professor, Department of ENT, Gayatri Vidya Parishad Institute of Health Care & Medical technology, Vishakapatnam, Andhra Pradesh, India.

ABSTRACT

This prospective, randomized, double-blind controlled trial aimed to assess the analgesic efficacy of tramadol compared to lornoxicam in postoperative pain management for patients undergoing ear, nose, and throat (ENT) surgical procedures. Two hundred and forty ASA class I-II patients, who had undergone elective ENT surgery under general anesthesia, were randomly allocated to three groups. Group L received 8 mg lornoxicam IV, Group T received 1 mg/kg tramadol IV, and Group C received IV saline after anesthesia induction pre-surgery. Postoperative pain, evaluated using the visual analogue scale (VAS), demonstrated significantly higher scores in Group C compared to Groups L and T at 30 minutes, and 1, 2, 4, and 6 hours postoperatively, with no significant difference between Groups L and T. Surgeon-assessed intraoperative blood loss did not differ significantly among the three groups. The most common adverse events in all groups were nausea and vomiting, with a significantly higher incidence in the placebo group than in the other two groups. Tramadol 1 mg/kg exhibited comparable efficacy to lornoxicam 8 mg in providing postoperative pain relief for ENT surgery patients. Both medications reduced the need for postoperative opioids, thereby minimizing associated adverse effects.

Key words:-Ear, Nose, Throat, Tramadol, Lornoxicam, Pain Relief

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INTRODUCTION

Postoperative pain represents a significant concern, leading to undesirable consequences such as excessive analgesic use, prolonged hospitalization, dietary intolerance, and subsequently, a diminished quality of life [1]. While systemic opioids are traditionally employed for postoperative pain management, their potential side effects, including respiratory depression, sedation, ileus, urinary retention, and itching, restrict their use, particularly following surgeries involving the upper respiratory pathway [2].

Corresponding Author
Dr. P Prashanth Kumar

Numerous studies highlight the effectiveness of pre-emptive analgesia in perioperative pain management. Non-steroidal anti-inflammatory drugs (NSAIDs) have gained widespread use as an effective and well-tolerated postoperative analgesic regimen, offering advantages with fewer adverse effects [3-5].

NSAIDs exert their analgesic effects through peripheral anti-inflammatory actions, primarily by diminishing prostaglandin synthesis through the inactivation of cyclooxygenase. This peripheral action of NSAIDs indirectly inhibits central neural sensitization,

leading to a reduction in the amplification of pain [6]. Lornoxicam (Xefo), belonging to the non-selective NSAID oxicam group, stands out as a potent analgesic with anti-inflammatory properties. Lornoxicam achieves its effects by inhibiting cyclooxygenase, thereby decreasing prostaglandin synthesis. Notably, lornoxicam exhibits rapid elimination, with a plasma half-life ranging from 3 to 5 hours. This short plasma half-life may contribute to the observed reduced incidence of adverse effects associated with lornoxicam use.

Lornoxicam has demonstrated effectiveness in both preventing and treating postoperative pain, as supported by various studies [7-14]. Tramadol, on the other hand, is a synthetic centrally acting analgesic with a structural resemblance to codeine and morphine. Functioning as a weak μ-opioid receptor agonist, tramadol induces analgesia by inhibiting monoamine reuptake, specifically targeting serotonin and norepinephrine, in the synapses of the descending inhibitory pain pathways [15]. Tramadol has a plasma half-life of approximately 6-7 hours.

While tramadol's potency is weaker than morphine, it comes with a lower risk of dependency and respiratory depression. Nevertheless, some side effects, including nausea, vomiting, sweating, dizziness, and a potential reduction in the seizure threshold, are associated with tramadol use [16]. Numerous studies have consistently affirmed the efficacy of tramadol in managing perioperative pain [17-20].

METHODS

This prospective, randomized, double-blind comparative study was conducted, involving 240 ASA physical status I-II healthy adult patients aged 18-45 years, encompassing both sexes, and scheduled for elective ear, nose, and throat (ENT) surgical procedures. The study obtained approval from the ethical committee, and participants provided informed written consent. Exclusion criteria comprised known hypersensitivity to medication drugs, coagulation disorders, bronchial asthma, pregnancy, lactation, significant cardiac, kidney, or liver dysfunction, peptic ulcer, alcohol abuse, active bleeding for any cause, and the use of any analgesic medications within 24 hours pre-operatively or antiplatelet medication within the past 2 weeks.

All patients underwent routine pre-operative evaluation and standard laboratory studies as per the hospital's protocol. Visual analogue scales (VAS) were introduced to patients during the pre-operative visit. Prior to the operation, patients fasted overnight and received oral pre-anesthetic medication, including midazolam at 0.05 mg/kg and ranitidine 150 mg. They were randomly assigned to three equal groups using a computer-generated randomization scheme: Group L received 8 mg lornoxicam (XefoR) IV, Group T received tramadol (ContramalR) 1 mg/kg IV, and Group C received saline after anesthesia induction before the start of surgery.

Upon arrival at the operative theater, standardized monitoring techniques, including electrocardiogram (ECG), pulse oximetry (SpO_2), capnography, non-invasive blood pressure monitoring, body temperature, and neuromuscular transmission (TOF; transmission with four stimulators), were applied. A standardized anesthetic technique was administered to all patients, involving induction with propofol (2-3 mg/kg IV), fentanyl (2 ug/kg IV), and cisatracurium (0.15 mg/kg IV) to facilitate tracheal intubation. Anesthesia was maintained with 50% oxygen in air and 1.5-2% sevoflurane. Neuromuscular blockade was sustained with intermittent boluses of cisatracurium as needed. Patients were mechanically ventilated to maintain end-tidal carbon dioxide tension at 35-40 mmHg.

After induction of anesthesia before the commencement of surgery, Group L patients received 8 mg lornoxicam intravenously diluted to 10 mL, Group T patients received 1 mg/kg IV tramadol intravenously diluted to 10 mL, and Group C patients received 10 mL of normal saline IV. An independent observer, not involved in any other aspect of the study, prepared, covered, and coded the study medications. The administration of study drugs was carried out by an anesthesiologist not participating in anesthesia management or follow-up to maintain the double-blind nature of the study. The attending anesthesiologist, surgeon, and data collection personnel were all blinded to patient group assignments and the nature of the study medication.

All patients in each group received strict fluid replacement adhering to standard fluid administration guidelines during anesthesia. Surgeons, throughout the surgery, followed a standardized protocol for local anesthetic administration, utilizing 1% lidocaine with epinephrine (1:100,000) for bleeding and pain control. Insufficient analgesia, defined as a more than 15% increase in blood pressure or heart rate from the pre-operative value, was treated with intermittent doses of fentanyl (0.5 ug/kg IV) if necessary. No other sedatives or opioids were administered during the operation. For the control of postoperative nausea and vomiting, dexamethasone (0.2 mg/kg IV, maximum 16 mg) was administered. All procedures were conducted by the same three surgeons, each with over 5 years of clinical experience, using a consistent surgical technique for each type of surgery.

Upon completion of the surgery, anesthesia was terminated, and 100% oxygen was administered. Direct visual inspection of the oral cavity was conducted, followed by the aspiration of secretions and blood clots. Residual neuromuscular relaxation was reversed using neostigmine (40 ug/kg) and atropine (20 ug/kg) slowly via the intravenous route. Extubation was performed in an awake state after the return of protective airway reflexes.

Intraoperative blood loss was approximately estimated by surgeons, visually assessing the blood volume in suction bottles and counting swabs using the Five-Point Scale (0 = no bleeding, 1 = bleeding as usual, 2 = bleeding more than usual, 3 = profuse, 4 = excessive, and 5 = excessive and continuous).

Additionally, the total consumption of rescue analgesics within the first 24 hours postoperatively was calculated. Sedation levels during the post-anesthesia care unit (PACU) stay were evaluated using a Four-Point Sedation Scale (0 = eyes open spontaneously, 1 = eyes open to speech, 2 = eyes open when shaken, and 3 = unrousable at arrival to the PACU) at 30 minutes, 1 hour, and 2 hours by a nurse unaware of the study drug used. Adverse events in the initial 24 hours postoperative were both treated and recorded for each patient, encompassing respiratory depression (respiratory rate $\leq$ 10), desaturation (SpO2 $\leq$ 92%), nausea, vomiting, bleeding, allergic reactions, urinary retention, and any abnormal gastrointestinal manifestations. Ondansetron (4 mg) was administered intravenously as a rescue antiemetic.

Statistical Analysis

A priori power analysis was conducted based on mean post-operative morphine consumption data obtained from a pilot study involving 30 patients who received a placebo (five tonsillectomy cases, five septoplasty cases, and five septorhinoplasty cases; none of which were included in the current study). To achieve a minimum of 80% power ($\alpha = 0.05$) in detecting a 50% reduction in total post-operative morphine consumption, a sample size of 80 patients per study group was estimated. The data analysis was performed using SPSS version 17 (Chicago, IL, USA). Numerical data were presented as mean ± SD, along with numbers and percentages. Parametric data were compared using analysis of variances (ANOVAs) followed by the Tukey posthoc test for pairwise comparisons. The Kruskal-Wallis test was employed for non-parametric data (when indicated). Categorical data were compared using the Chi-square test, with a significance level set at 0.05.

RESULTS

A total of 240 patients were assessed for eligibility in this study, and all 240 patients, with 80 in each group, provided consent and were successfully enrolled, with no dropouts. There were no significant differences among the three groups in terms of age, gender, weight, ASA class, duration of surgery, and anesthesia ($P > 0.05$) [Table 1].

Visual analogue scale (VAS) pain scores were significantly higher in Group C compared to Groups L and T at 30 minutes and 1, 2, 4, and 6 hours postoperatively ($P < 0.05$). However, there was no significant difference in the pain score between Group L and Group T ($P > 0.05$) [Figure 2]. The time to the first analgesic requirement was significantly longer in Group L (92.62 ± 24.23 min) and Group T (88 ± 21.43 min) compared to Group C (42.82 ± 25.61 min) ($P = 0.011$), with no difference between Group L and Group T ($P > 0.05$) [Table 2]. Postoperative morphine consumption was significantly lower in Group L (5.2 ± 2.5 mg) and Group T (5.0 ± 2.0 mg) compared to Group C (7.4 ± 2.3 mg) ($P = 0.001$), with no statistical difference between Group L and Group T ($P > 0.05$) [Table 2].

The need for morphine was significantly higher in Group C compared to the other two groups ($P = 0.016$), with no statistical difference observed between Group L and Group T ($P > 0.05$) [Table 2]. Nausea and vomiting were the most common side effects across all three groups, and their incidence was significantly higher in Group C compared to the other two groups ($P = 0.002$) [Table 2]. There were no significant differences among the three groups in terms of recovery times or mean sedation scores in the post-anesthesia care unit (PACU) ($P > 0.05$) [Table 2]. Surgeon-assessed intraoperative blood loss scores showed no significant differences between the three groups ($P > 0.05$) [Table 3]. Additionally, no instances of prolonged excessive post-operative bleeding requiring surgical intervention were observed in any patient.

Table: 1 Demographic characteristics

	Group L	Group T	Group C	*P*
Number (n)	80	80	80	
Age (years)	28.36±7.72	27.20±6.35	27.83±8.76	0.332
Weight (kg)	70.69±12.61	71.26±14.24	69.92±11.93	0.413
Sex (M/F)	34/46	32/48	32/48	0.394
ASA physical status I/II	52/28	52/28	50/30	0.662
Duration of anesthesia (min)	103.18±21.42	105.57±18.34	107.01±23.60	0.321
Duration of surgery (min)	114.26±16.93	111.68±15.37	113.72±14.61	0.450
Type of surgery				
Tonsillectomy	24(60)	22(55)	22(55)	0.821
Septoplasty	32(80)	34(85)	32(80)	0.756
Septorhinoplasty	24(60)	24(60)	26(65)	0.723

Table 2: Recovery parameters and post-operative data

	Group L	Group T	Group C	*P*
Time to spontaneous eye opening(min)	6.09±3.45	5.76±4.29	5.89±3.79	0.751
Time to orientation (min)	8.23±2.70	8.14±1.72	7.90±2.62	0.824
Time to an Aldrete score >9	22.53±6.72	23.15±5.80	22.17±6.13	0.723
Intraoperative fentanyl consumption (ug/kg)	3.76±0.38	3.84±0.42	3.72±0.35	0.820
Time to first request of rescue analgesic(min)	91.62±24.23	87±21.43	41.82±25.61*	0.011
Total morphine consumption (mg)	5.1±2.5	5.2±2.0	7.6±2.3*	0.001
Morphinen (%)	5(12.5)	8(20)	15(37.5) *	0.016
Total paracetamol consumption (mg)	2246±185	2303±204	3500±312*	0.042
Post-operative sedation score	1.8±0.6	1.9±1.2	1.7±0.8	0.673
Post-operative nausea/vomiting (n)	16/10	18/12	30/22*	0.002
Rescue antiemetic n (%)	12(30)	14(35)	24(60) *	0.004

Table 3: Intraoperative blood loss as estimated by the surgeon

Intraoperative bleeding score	Group L	Group T	Group C	*P*
No bleeding	8(20)	6(15)	6(15)	0.520
Bleeding as usual	56(140)	60(150)	58(145)	0.456
Bleeding more than usual	16(40)	14(35)	16(40)	0.378
Profuse	0(0)	0(0)	0(0)	—
Excessive	0(0)	0(0)	0(0)	—
Excessive and continuous	0(0)	0(0)	0(0)	—
Intraoperative blood loss (mL)	99.65±37.62	100.36±36.01	102.45±29.98	0.548

DISCUSSION

In this double-blind, placebo-controlled study, the analgesic efficacy of intravenous lornoxicam 8 mg and tramadol 1 mg/kg, administered after anesthesia induction, was found to be comparable. This was clinically evident through lower pain scores within the initial 6 hours, an extended time until the first analgesic request, and a decrease in post-operative narcotic analgesic consumption (morphine) among patients undergoing ear, nose, and throat (ENT) surgical procedures. Numerous clinical trials have previously established the pre-emptive analgesic effects of lornoxicam at a dose of 8 mg.

Various studies in the literature have employed different doses of lornoxicam and tramadol for post-operative pain management across various surgical procedures. Additionally, a meta-analysis has been conducted to assess the risk of post-operative hemorrhage linked to NSAID administration after tonsillectomy, revealing that NSAID consumption did not impact the incidence of post-operative bleeding. In the present study, patients were closely monitored for perioperative bleeding, and it was determined that there was no noteworthy increase in bleeding, as assessed by the ear, nose, and throat (ENT) surgeons.

CONCLUSION

Tramadol at a dose of 1 mg/kg demonstrated similar efficacy to lornoxicam at 8 mg in providing post-operative pain relief for patients undergoing ear, nose, and throat (ENT) surgical procedures. Both medications contributed to a decreased need for post-operative opioids, consequently mitigating the associated adverse effects of opioid use.

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