A Comparative Assessment of Postoperative Analgesic Efficacy of Lornoxicam versus Tramadol after Open Reduction and Internal Fixation of Mandibular Fractures

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Abstract

Pain after any surgical procedure is inevitable but can be controlled by administration of analgesics in most cases. Postoperative pain after surgical treatment of mandibular fractures can be treated by nonsteroidal anti-inflammatory drugs (NSAIDs) and opioid analgesics. The purpose of this study is to critically compare the postoperative analgesic efficacy of small doses of intravenous TRAMADOL (opioid analgesic) versus LORNOXICAM (NSAID) in patients with mandibular trauma undergoing open reduction and internal fixation (ORIF) and to assess the presence of any adverse effects due to NSAID or opioid use. Forty adult ASA grade I–II patients with mandibular trauma, scheduled for ORIF under general anesthesia in the Department of Oral and Maxillofacial Surgery, College of Dental Sciences, Davangere, were selected for the study. The patients were randomly assigned into a tramadol group (Group T) and a lornoxicam group (Group L) and were administered intravenous tramadol 50 mg and intravenous lornoxicam 8 mg, respectively, at specific postoperative intervals. Pain intensity was quantitatively assessed at the 2nd, 4th, 6th, 12th, and 24th postoperative hours using a visual analog scale of 10 cm. Adverse effects of the analgesics were also recorded and compared. Both the drugs resulted in a significant decrease in pain intensity from 2nd to 24th postoperative hours, but better pain control was observed in Group L at 24th postoperative hour. Only two patients experienced nausea and vomiting in Group T and one patient experienced gastric acidity in Group L. The comparative results clearly demonstrate that pain control by intravenous lornoxicam is significantly better than by intravenous tramadol at 24th postoperative hour after ORIF of mandibular trauma. Side effects produced by both the drugs were minor and had no apparent effect on the study results.

Keywords

- lornoxicam
- tramadol
- Mandibular
- fracture
- pain
- ORIF

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Pain after any surgical procedure is inevitable and it is controlled by administration of analgesics in most cases. Causes of postoperative pain include surgical trauma, application of thermal and chemical stimuli to the wound, and often traction and manipulation of soft tissues.¹ Every attempt is made by the anesthetist and surgeon to eliminate postoperative pain without causing additional problems, such as depression of respiratory or cardiovascular system, disorders of gastrointestinal and visceral motility, coagulation anomalies, and drug tolerance and dependence.²

Two classes of drugs are available to treat postoperative pain: (1) nonsteroidal anti-inflammatory drugs (NSAIDs), which act by inhibition of prostaglandin synthesis to achieve analgesic and anti-inflammatory effects, and (2) narcotic analgesics, which act directly on opioid receptors in the central nervous system.³

NSAIDs are effective analgesics in a wide range of postoperative pain states and in some cases their analgesic effect is comparable to that produced by the opioids.⁴ NSAIDs have peripheral and central analgesic effect, anti-inflammatory properties, and relatively more tolerability than opioids.⁵

The purpose of this study is to critically compare the postoperative analgesic efficacy of small doses of intravenous TRAMADOL (opioid analgesic) versus LORNOXICAM (NSAID) in mandibular trauma patients undergoing open reduction and internal fixation (ORIF) under general anesthesia and to assess their adverse effects.

Methodology

A prospective study was done on 40 adult patients with mandibular trauma, scheduled for ORIF under general anesthesia in the Department of Oral and Maxillofacial Surgery, College of Dental Sciences, Davangere.

Inclusion Criteria

American Society of Anesthesiologists (ASA) grade I–II ***classified maxillofacial trauma patients with simple or compound mandibular fractures undergoing ORIF under general anesthesia were selected for the study.

Exclusion Criteria

1. Patients with additional midface or any other fractures.
2. Patients with history of hypersensitivity to tramadol or lornoxicam.
3. Patients with blood dyscrasias.

4. Patients with liver or kidney diseases.
5. Patients with history of peptic ulcer disease.
6. Patients with history of substance abuse.
7. Patients with head injury.
8. Pregnant or lactating females.
9. Patients from whom the informed consent cannot be obtained.

Method of Collecting Data

The first patient was randomly included in one group. Thereafter every patient fulfilling the inclusion criteria with an odd serial number was included in the same group and patients with even serial number were included in the other group. Each patient was assigned to a group irrespective of their age, sex, or fracture site after obtaining anesthesiologist's fitness for using either of the two drugs. All participants were given a covering letter including information such as the department behind the study, contact name and address of the researcher, the aims of the study, any potential benefits or harm resulting from the study, and what will happen to the information. Study was done after obtaining informed consent from the patients. Two groups were made and each group comprised 20 patients. Patients of one group (Group T) were administered intravenous tramadol 50 mg at the time of skin closure and the dose was repeated after 8 and 16 hours from the conclusion of the operation. Patients in the other group (Group L) were administered intravenous lornoxicam 8 mg in the same manner. Pain intensity was quantitatively assessed at the 2nd, 4th, 6th, 12th, and 24th postoperative hours. Pain was assessed using a visual analog scale of 10 cm with endpoints "no pain" and "pain could not be worse."⁶ Assessment of safety involved recording of adverse effects of the analgesic administered. Pain experienced among patients in Group T and Group L at different time intervals was compared using unpaired *t*-test for inter-group and ANOVA test for intra-group. The collected data were entered into the Microsoft excel sheet and were subjected to further statistical analysis using SPSS version 20. Ethical clearance was obtained from College of Dental Sciences, Davangere.

Results

All the patients enrolled completed the study.

► **Table 1** shows the distribution of patients in both groups based on age, sex, duration of surgery, and ASA grade. There

Table 1 Distribution of patients in both groups based on age, sex, duration of surgery, ASA grade

Variables	Subgroups	Group T, <i>n</i>	Group L, <i>n</i>
Gender	Male	17	18
	Female	3	2
ASA grades	I	15	17
	II	5	3
Age (y)		30.1 ± 7.8	29.9 ± 8.4
Duration of surgery (min)		50.15 ± 14.5	51.25 ± 16.7

Table 2 Comparison of the pain experienced among patients in Group T and Group L at different time intervals

Time interval	Group T, mean (SD)	Group L mean (SD)	t-Value	p-Value
2 h	2.45 (0.9)	2.25 (1)	0.644	0.52
4 h	2.50 (1.1) ^a	2.15 (0.9)	1.034	0.30
6 h	2.35 (1.3)	2 (0.8)	1.000	0.32
12 h	2 (1.2) ^a	1.60 (1.1)	1.073	0.29
24 h	2.10 (1.1)	1.45 (0.6)	2.285	0.028*
F-value	110.037	130.044	–	–
p-Value	<0.001**	<0.001**	–	–

Notes: Inter-group, unpaired *t*-test; intra-group, ANOVA test. *p* < 0.05—significant*; *p* < 0.001—highly significant**.

was statistically no significant difference observed between patients of both the groups with regard to these parameters.

► **Table 2** shows comparison of pain incidence between Group T and Group L. Though both the drugs resulted in a significant decrease in pain intensity from the 2nd to 24th postoperative hours, intravenous lornoxicam 8 mg resulted in significantly better pain control than intravenous tramadol 50 mg at 24th postoperative hour (*p* < 0.028).

There were no significant differences in both the groups with respect to the side effects and vital signs. Only two patients experienced nausea and vomiting in Group T and one patient experienced gastric acidity in Group L (► **Table 3**).

Discussion

A significant number of patients suffer from severe postoperative pain. This is in spite of great advances in the field of pain management including advances in techniques and analgesic agents.⁷ Postoperative pain prolongs the recovery time and adversely affects the patients outcome.⁸ Control of postoperative pain is an important factor affecting recovery and outcome.⁹ Consequences of severe postoperative pain may manifest as a cascade of endocrine-metabolic and inflammatory events that in turn may contribute to organ dysfunction, morbidity, increased hospital stay, and mortality.¹⁰

In this study, two analgesics, viz tramadol hydrochloride and lornoxicam, were critically compared for their postoperative analgesic efficacy in maxillofacial trauma patients undergoing ORIF under general anesthesia and were also assessed for presence of any adverse effects.

Tramadol hydrochloride is a centrally acting, synthetic analgesic developed to treat moderate to severe pain.² It has few gastrointestinal effects and causes minimal respiratory depression. Its potential to cause opiate-like dependence is less compared with morphine. On the other hand, lornoxicam (chlortenoxicam) is a NSAID. The cyclooxygenase inhibitory activity of lornoxicam is ~approximately 100 times more powerful than that of tenoxicam, and analgesic activity of lornoxicam is ~ approximately 10 times greater than that of either tenoxicam or piroxicam. It has a short plasma half-life compared with other NSAIDs leading to better tolerability profile.¹¹

In this study, pain intensity decreased over a period of 24 hours in both the groups. Pain control at 24th hour in the lornoxicam group was significantly better than in the tramadol group. However, no significant differences were noted at 2nd, 4th, 6th and 12th hours.

In a double-blind, randomized controlled study, Staunstrup compared the efficacy and tolerability of intramuscular lornoxicam and tramadol in 76 patients with moderate to unbearable postoperative pain. Lornoxicam produced a significantly greater improvement in total pain relief within 8 hours of treatment compared with tramadol. Also, significantly fewer patients reported one or more adverse events with lornoxicam than with tramadol.¹² Ozkan et al compared the efficacy of lornoxicam (Group L), paracetamol (Group P), and tramadol (Group T) by administering them 60 minutes before shockwave lithotripsy (SWL) in patients with urinary stone disease. Authors concluded that the need of additional analgesic decreased with intravenous lornoxicam in comparison with paracetamol and tramadol.¹³

Table 3 Cross-tabulation of side effects and vital signs in Group T and Group L

Variables	Sub-groups	Group T, N (%)	Group L, N (%)	Significance
Side effects	Nausea and vomiting	2 (10)	0 (0)	NS
	Gastric acidity	0 (0)	1 (5)	NS
Vital signs	Within normal limits	20 (100)	20 (100)	–

Abbreviation: NS, not significant.

Isik et al conducted a prospective, double-blind, randomized, clinical research to evaluate efficacy and adverse effects of preoperatively administered lornoxicam versus tramadol in adults, for post-tonsillectomy pain. Preoperative 8-mg lornoxicam was more effective than 50-mg tramadol with respect to early postoperative tonsillectomy pain in adult patients, and side effects were similar.¹⁴

The common side effects associated with tramadol are nausea, dizziness, drowsiness, sweating, vomiting, and dry mouth. The reported incidence is ~approximately 1.6 to 6.1%.¹⁵ In the tramadol group, only two (10%) patients had an episode of nausea and vomiting during the first 2 hours postoperatively. These patients were administered a single dose of intravenous ondansetron *stat*, following which no further episode of vomiting was reported. Because these are common post-general anesthesia sequelae, it is difficult to conclude that tramadol alone or in combination with general anesthesia had induced postoperative nausea and vomiting. Intraoperative parenteral antiemetic and H-1 blocker, as a regular protocol drugs in general anesthesia, can explain the insignificant number of these most common side effects of tramadol. A study by De Witte investigating impaired analgesic efficacy of tramadol by concurrent administration of ondansetron concluded that 5-HT₃ receptors play a key role in pain transmission at the spinal level and administration of 5-HT₃ antagonist like ondansetron can decrease the efficacy of tramadol. Hence, need of tramadol is increased with ondansetron administration for antiemetic prophylaxis.¹⁶ In this study, all the patients in both groups had received ondansetron as a routine general anesthetic drugs protocol at the time of induction. Therefore, ondansetron might have played a role in decreasing the postoperative analgesic efficacy of tramadol. In the lornoxicam group, only one (5%) patient reported with gastric acidity during the first 4 hours postoperatively. A single *stat* dose of intravenous ranitidine was administered, following which the symptoms relieved. This side effect could be possibly related to overnight starvation before surgery. Intraoperative parenteral ranitidine, as a regular protocol drugs in general anesthesia, can explain the insignificant number of these most common side effects of lornoxicam. Although this study shows better efficacy of lornoxicam over tramadol, similar studies with large sample sizes are needed to attest on results of this study.

Conclusion

Although both tramadol and lornoxicam were effective in controlling postoperative pain in patients with mandibular trauma undergoing ORIF under general anesthesia, the comparative results clearly demonstrate that pain control by

intravenous administration of lornoxicam is significantly better than intravenous administration of tramadol at 24th postoperative hour. However, the side effects produced by both the study drugs were minor and had no apparent effect on the study results. More conclusive investigation needs to be performed to attest to these aforementioned facts.

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