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Peritonsillar infiltration of lidocaine Hcl versus intravenous pre-incisional lornoxicam in reducing post-tonsillectomy pain: this is a prospective, randomized, double-blinded, placebo-controlled study

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Abstract

Background: Tonsillectomy is one of the most common procedures in otorhinolaryngology practice where analgesics are required for pain-relief especially in children. To compare the efficacy of using peritonsillar infiltration of lidocaine Hcl versus intravenous preincisional lornoxicam in reducing post tonsillectomy pain.

Results: Prospective, randomized, double-blinded, placebo-controlled study. Ninety-nine patients from age 12 to 18 years old, prepared for tonsillectomy. Patients were randomly subdivided into three groups as 33 patient in each group to receive either lidocaine (group 1), lornoxicam (group 2), or saline as a placebo (group 3). Anesthesia was induced using intravenous fentanyl and propofol, while endotracheal intubation was facilitated with rocuronium and maintenance by halothan. Intraoperative bleeding, pain scores, interval until first order for analgesic. The postoperative complications including bleeding, hypoxia, nausea, and vomiting also were observed. Pain scores at rest were significantly lower in group 2 than groups 1 and 3 at all observation times. Similarly, pain scores were lower in group 2 during the first 5 postoperative hours. The mean time for rescue analgesic was 276 min in group 2, 91 min in group 1, and about 60 min in group 3. No significant differences were noted for intraoperative bleeding.

Conclusion: The use of lornoxicam 16 mg at preoperative phase gave good control of immediate post tonsillectomy pain.

Level of evidence: 3b

Keywords: Tonsillectomy, Blood loss, Lidocaine, Lornoxicam, Nonsteroidal anti-inflammatory drugs

Background

One of the most common procedures in otorhinolaryngology practice is tonsillectomy. However, the recovery time from the surgery is a painful feeling. The pain increases during swallowing leading to poor nutrition and delay in returning to normal activities especially in children. That is why the provision of good analgesia leads to less physiologic derangement and may decrease morbidity. So, in children, analgesics are very important for postoperative pain relief. The drugs that are usually prescribed include non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, and opioids [1].

The use of NSAIDs may lead to increased postoperative bleeding [2]. Although the analgesic mechanism of action (i.e., inhibition of prostaglandin synthesis) is the

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same as all available NSAIDs, the analgesic effects relative to side effects may vary from a drug to a drug [3].

Lornoxicam is a nonselective NSAID, with analgesic, anti-inflammatory, and antipyretic effects [4]. Lornoxicam has a short half-life of 3 to 5 h [5]. At preincisional phase intravenous administration of lornoxicam decrease postoperative pain after different types of surgery, and it reduces the need for postoperative rescue pain medication [6–11]. Lidocaine Hcl has been used as a local anesthetic. It has a rapid onset and intermediate duration. That helps easy recovery and control of pain in the immediate postoperative time [12].

This study targets to compare the efficacy of using peritonsillar infiltration of lidocaine Hcl versus intravenous preincisional lornoxicam in reducing post tonsillectomy pain.

Methods

This is a prospective, randomized, double-blinded, placebo-controlled study. The study protocol was approved by the local ethics committee, and written informed consent was signed from all patients' parents or first degree relatives.

This study includes 99 patients aged from 8 to 18 years. They were arranged for elective tonsillectomy due to chronic tonsillitis. Patients were excluded from the study if they had a history of significant cardiac, pulmonary, hepatic, renal, and hematologic disease or hypersensitivity to any of the drugs used in the study were excluded. The patients were randomly allocated to three equal groups of 33 patients.

Table 1 Observation criteria

Observation	Criteria	Points
Blood pressure	±10% preoperative value	0
	>20% preoperative value	1
	> 30% preoperative value	2
Crying	Not crying	0
	Crying but responds to loving care	1
	Crying and does not respond to loving care	2
Movement	None	0
	Restless	1
	Thrashing around	2
Agitation	Asleep or calm	0
	Mild agitation	1
	Hysterical	2
Verbalization of pain	Asleep or state no pain	0
	There is pain but can't localize	1
	Can localize pain	2

Table 2 Age and sex distribution among studied patients in three groups

		Group 1		Group 2		Group 3		*p*-value
Age	Mean ± SD	14.48 ± 2.67		14.9 ± 2.34		15.9 ± 2.43		0.06 (NS)
	Range	8–18		9–17		14–18		
Sex	Male	23	69.7%	18	54.55%	25	75.76%	0.2 (NS)
	Female	10	30.3%	15	45.55%	8	24.24%	

NS No statistically significant difference. No statistically significant difference was noted between three groups

Group 1 received 20 ml intravenous saline and 4 ml lidocaine Hcl peritonsillar infiltration at pre-incisional phase. Group 2 received 8 mg intravenous lornoxicam on 20 ml saline and 4ml saline peritonsillar infiltration at pre-incisional phase and group 3 received 20 ml intravenous saline and 4ml saline peritonsillar infiltration at pre-incisional phase. Peritonsillar infiltration was done in both sides in a fan like manner from the upper to the lower pole using a spinal needle.

Bipolar tonsillectomy technique was used in all patients. The blood loss during the operation, heart rate, mean arterial blood pressure, the first time of asking rescue analgesic, the amount of rescue analgesic used during the first 12 and 24 postoperative hours, the first time of drinking and eating, nausea, vomiting, and needing anti-vomiting drug during the first 24 h were recorded.

Intraoperative blood loss was assessed by visual estimation of the blood volume in swabs and suction bottle. After surgery, postoperative pain was evaluated at rest and during swallowing using observation criteria score (Table 1), verbal rating scale (VRS) with (no pain=0, mild pain = 1, moderate pain = 2, severe pain =3), patient's or parents' satisfaction, and first time asking rescue analgesic (*acetaminophen*). The first examination was done immediately after the patient was transferred to the ward, which was 15 min postoperatively. Observation was then made at 30 min and 1, 4, 16, and 24 h after surgery.

Statistical analysis

Data collected were handled by using SPSS version 21 (SPSS Inc., Chicago, IL, USA). Qualitative data expressed

Table 3 Observation criteria score in different time points (mean ± SD)

Observation criteria score	Group 1	Group 2	Group 3	*p*-value
15 min	2.69±0.6	3 ± 0	3 ± 0	2.69 ± 0.6
30 min	3 ± 0.6	2.15 ± 0.3	4 ± 0	0.001*
1 h	2.9 ± 0.7	2.27 ± 0.5	4 ± 0	0.001*
4 h	3.42 ± 0.6	2.4 ± 0.5	3 ± 0	0.001*
16 h	3.12 ± 0.9	2.15 ± 0.4	4 ± 0	0.001*
24 h	2.48 ± 0.7	2.5 ± 0.5	3 ± 0	0.001*

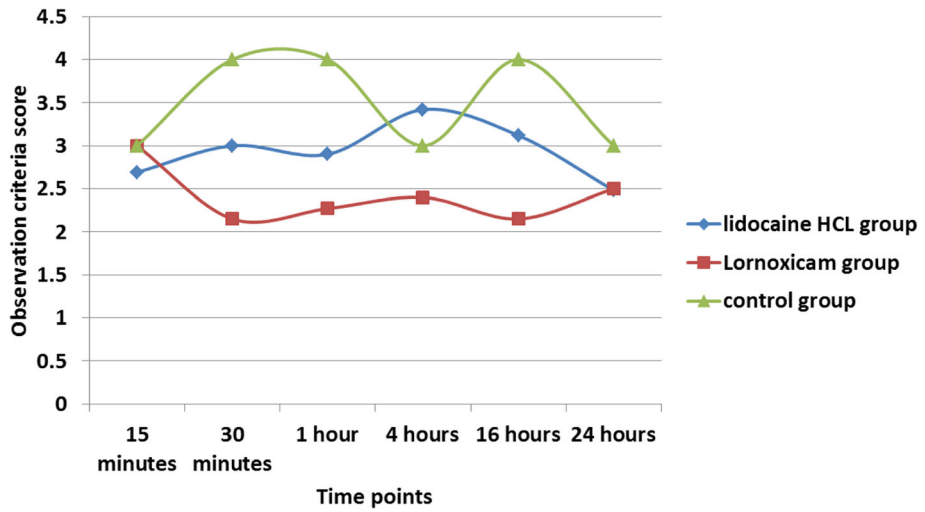

Fig 1 Group 2 (lornoxicam group). Group 2 (lornoxicam group) showed lower observation criteria score compared to group I (lidocaine HCL group) and group 3 (control group)

as numbers and percentages while quantitative data expressed as means ± SD. The Student *t* test was used to compare the significance of difference for quantitative variables that follow normal distribution.

Results

The study groups were almost similar in age and sex distribution (Table 2). The observed criteria of the patients in group 2 (lornoxicam) showed that those patients had the lowest painful criteria in all times of recording among all groups, followed by group 1 (lidocaine) and the maximum pain. Group 2 (Lornoxicam group) showed lower observation criteria score compared to group 1 (lidocaine HCL group) and group 3 (control group) (Table 3, Fig. 1).

This result was supported by the verbal rating scale)VRS) which rated the postoperative pain is the least using the preoperative lornoxicam (Fig. 2). Both measures showed statistically significant values.

The times asking rescue analgesic were the longest in group 2 (276.7 ± 35.3 min) followed by group 1 (91.9 ± 34.6 min) then group 3 (59.2 ± 33.2 min) (Fig. 3).

Group 2 (lornoxicam group) showed longer time to first rescue analgesia rating scale compared to group 1 (lidocaine HCL group) and group 3 (control group).

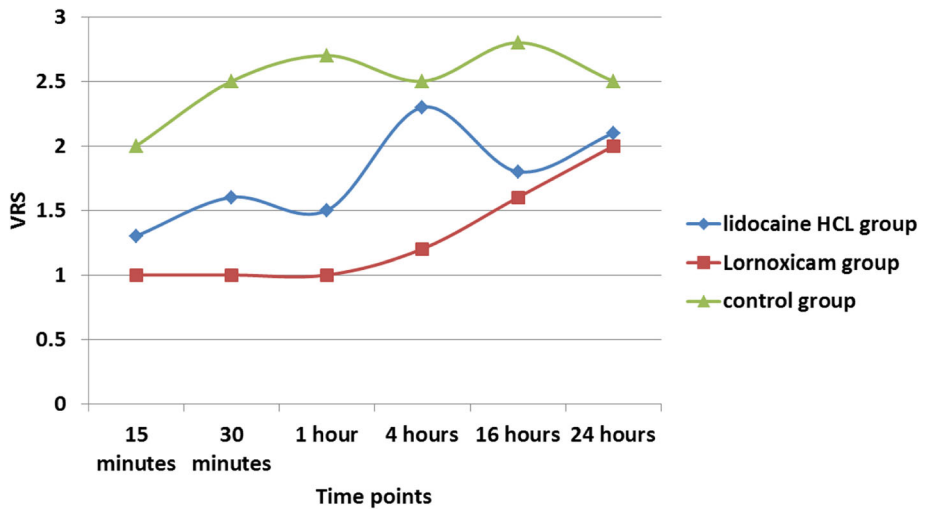

Fig 2 Verbal rating scale in different time points among studied patients in three groups. Verbal rating scale in group 2 is significantly lower than the other groups in comparing to others

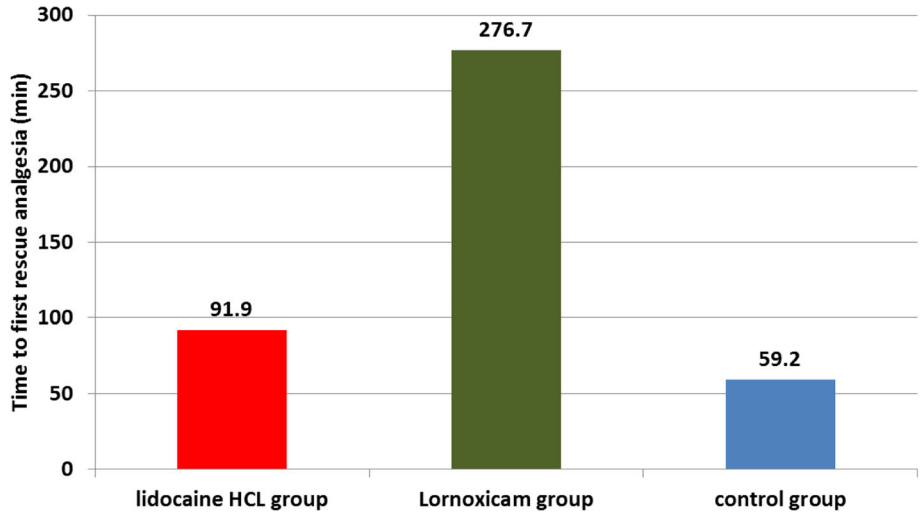

Fig 3 Time to first rescue analgesia. Group 2 (Lornoxicam group) showed longer time to first rescue analgesia rating scale compared to group 1 (lidocaine HCL group) and group 3 (control group)

There were no significant differences between the study groups regarding the operation time (Table 4) or amount of blood loss (Fig. 4).

Intraoperative blood loss was not significantly different between the three groups.

Discussion

One of the most important targets for patients who underwent tonsillectomy is to provide safe and effective analgesia and good pain management. Some methods of pain control can cause post-tonsillectomy complications [13].

Lornoxicam is NSAID with highly potent short-acting analgesic properties [4]. It exerts its analgesic effect by inhibition of cyclooxygenase (COX) I and II, leading to a release of endogenous dynorphin and beta-endorphin [14, 15]. It has a good tolerability profile and longer duration of effect than other NSAIDs [10, 16], a central effect that seems to be independent of anti-inflammatory effects.

Lornoxicam has no effect on body temperature, respiratory rate, heart rate, blood pressure, ECG, and spirometry.

Due to these properties and its availability as a parenteral form, lornoxicam may be favorable for acute perioperative pain management, particularly in patients for whom perioperative oral administration is undesirable [17].

Table 4 Intraoperative time among studied patients in three groups

		Group 1	Group 2	Group 3	*p*-value
Op	Mean ± SD	23.6 ± 2.4	23.8 ± 2.2	23.3 ± 2.9	Not significant

Operative time was not significantly different between the three groups

Eight and 16 mg were the selected dose of IV lornoxicam used in clinical trials [6–11, 16, 18–20]. In this study, we used was 8 mg because the study group was young. The least dose gave effective pain control in most of the patients. Lornoxicam 16 mg may produce more potent analgesia and of longer duration [16, 19, 20], but better reserved for older patients.

In this study, preoperative lornoxicam 8 mg gave effective immediate postoperative analgesia. This is a good effect of lornoxicam on postoperative pain relief which was clinically evident by decreased pain scores, a longer time to another analgesic request with a reduction in the first 24-h analgesic consumption. This significant reduction in analgesic consumption was achieved by preincisional lornoxicam.

Lidocaine is a local analgesic, usually applied by submucosal infiltration in combination with epinephrine to achieve local vasoconstriction and get a double effect, to obtain homeostasis and get a longer reduction of postoperative pain in most surgeries [21].

In 2003, Irfan said that no matter the injection was lidocaine or normal saline, the difference in postoperative pain was not statistically significant [12].

In this study, there was about 30-min difference between the lidocaine and the saline group in asking for rescue analgesia, with the upper hand for the lidocaine.

Conclusion

At preoperative, lornoxicam 8 mg gave potent pain relief in the immediate period following tonsillectomy since preoperative lornoxicam prevented the need for

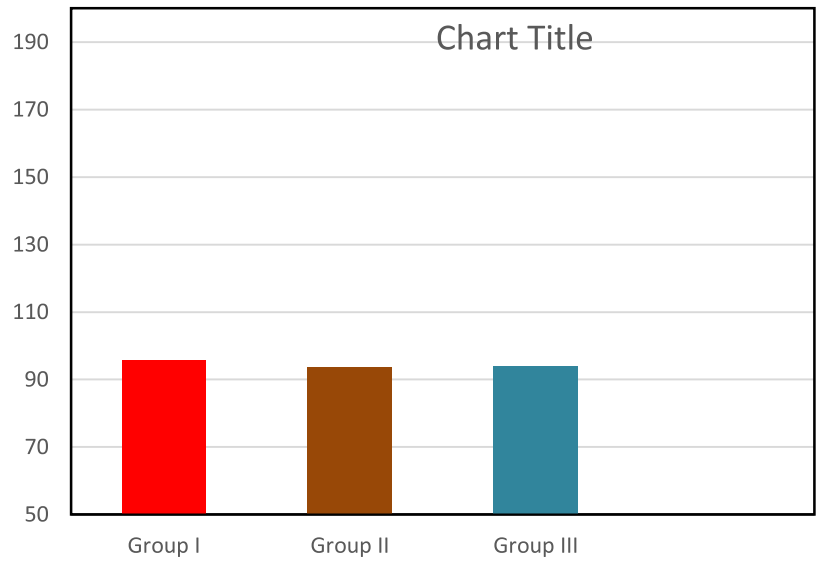

Fig 4 Intraoperative blood loss. Intra-operative blood loss was not significantly different between three groups

postoperative analgesia especially during the first postoperative 4 h and decrease the total dose of rescue medication needed during the first postoperative 24 h. There was no incidence of bleeding during the perioperative observation period, and no need of excessive sedation or respiratory depression was noted among the study patients.

Abbreviations

ml: Milliliter; NSAIAD: Non-steroidal anti-inflammatory drugs; VRS: Verbal rating scale; COX: Cyclooxygenase

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s43163-021-00161-2.

Additional file 1.

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None
This is study adheres to CONSORT guidelines.
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Retrospectively registered

Authors' contributions

RZ analyzed and interpreted the patients' data regarding otorhinology examination and scoring system. EH was responsible for collecting the data, follow-up of patients, and analysis of the results. Il was responsible for collecting the data, the follow-up of patients, and printing the results. MB was responsible for the analysis of the statistical section and performed the discussion, and all authors contributed in writing the manuscript and read and approved the final manuscript.

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Availability of data and materials

Not applicable

Declarations

Ethics approval and consent to participate

Local ethics committee (Faculty of Medicine Suez Canal University under the number 333 date of approval - September 2017).
Informed written consent to participate in the study was provided by all participants and their parent or legal guardian in the case of children under 16. And all participants included in the study have been informed about the procedures to be done and the expected results.

Consent for publication

Written informed consent for the publication was obtained from the participants and from their parent or legal guardian in the case of children under 16.

Competing interests

The authors declare that they have no competing interests.

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