

Research Article

Egyptian Society of Anesthesiologists

Egyptian Journal of Anaesthesia

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Preincisional peritonsillar vs. intravenous lornoxicam for posttonsillectomy analgesia: A clinical and platelet aggregometry comparative study

Hala Saad Abdel-Ghaffar^{a,*}, Jehane Ahmed Sayed^a, Mohamed Amir Fathy^b, Hanan Galal Abdel-Azeem^c, Mohamed Ahmed Mahmoud Salem^d

^a Anesthesia and Intensive Care Department, Faculty of Medicine, Assiut University, Egypt

^b Pediatric Department, Faculty of Medicine, Assiut University, Egypt

^c Clinical Pathology Department, Faculty of Medicine, Assiut University, Egypt

^d Ear Nose and Throat Surgical Department, Faculty of Medicine, Assiut University, Egypt

Received 12 October 2011; revised 19 December 2011; accepted 19 December 2011 Available online 31 January 2012

KEYWORDS

Pediatric; Tonsillectomy; Analgesia; NSAIDS; Lornoxicam **Abstract** *Background:* Lornoxicam is a fairly new short-half oxicam with an improved tolerability profile. Our objective was to investigate the safety and efficacy of intravenous and peritonsillar infiltration of 8 mg lornoxicam on pain relief in children undergoing tonsillectomy. *Methods:* In a double-blinded, placebo-controlled trial, 60 children were randomized into three

groups: intravenous group (n = 20), received lornoxicam 8 mg iv., infiltration group (n = 20) received lornoxicam 8 mg peritonsillar infiltration, and placebo controls (n = 20). The verbal rating pain scale, time to first postoperative analgesic request, total analgesic consumption during 1st 24 h postoperative, platelet aggregometry before, 15 min, 2 and 24 h after study drug administration, intraoperative blood loss, postoperative bleeding, and adverse effects were evaluated.

* Corresponding author. Tel.: +20 01003812011; fax: +20 0882333327.

E-mail addresses: hallasaad@yahoo.com (H.S. Abdel-Ghaffar), Jehane. Alloul@yahoo.com (J.A. Sayed), Amir63@yahoo.com (M.A. Fathy), Hanahgalal2000@yahoo.com (H.G. Abdel-Azeem), drsalem70@ yahoo.com (M.A.M. Salem).

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Peer review under responsibility of Egyptian Society of Anesthesiologists. doi:10.1016/j.egja.2011.12.005



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Results: The time to first postoperative analgesic request was significantly prolonged in intravenous (318.75 \pm 67.37 min) and infiltration (214.50 \pm 43.06 min) groups compared with placebo group (66.75 \pm 26.95 min). A significantly lower mean postoperative VRS scores and significantly reduced 1st day postoperative diclofenac consumption were recorded in iv. group (44.73 \pm 9.31 mg), compared with infiltration (69.80 \pm 38.71 mg) and placebo (87.8 \pm 24.40 mg) groups. An increased intraoperative blood volume losses and intraoperative bleeding complains were observed in infiltration group (34.25 \pm 11.93 ml), rather than in iv. (28.85 \pm 10.01 ml) and placebo (24.75 \pm 8.70 ml) groups. The (%) of platelet aggregation with ADP, collagen, and arachidonic acid was significantly reduced 15 min and 2 h after study drug administration with highest decreases in iv. group compared with infiltration and placebo groups. No patients reported postoperative bleeding or GIT adverse effects in the study.

Conclusion: Intraoperative preincisional intravenous lornoxicam enhanced postoperative analgesia after tonsillectomy in children. In comparison, the analgesic efficacy of locally applied lornoxicam was inferior to intravenous administration and was associated with increased incidence of intraoperative bleeding.

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1. Introduction

Postoperative pain is one of the most troublesome aspects after tonsillectomy. Despite the use of various types of analgesics, the recovery period can be quite painful. Opioid-based vs. NSAIDS-based analgesic regimens is still a focus of continuous debate. Non-selective NSAIDS are claimed to cause increased incidence of perioperative bleeding caused by platelet function inhibition and gastrointestinal toxicity [1–3]. Although the mechanism of analgesic action (i.e., inhibition of cyclooxygenase enzyme COX I and II, leading to decreased prostaglandin synthesis) is the same as all available NSAIDS, the analgesic efficacy relative to side effects may vary from agent to agent [4]. When used short term at the lowest effective dose, NSAIDS may provide for analgesic benefit without significant toxicity [5].

Lornoxicam (Chlorotenoxicam, Xefo[®]) is a potent nonselective NSAID of the oxicam class with analgesic, antiinflammatory, and antipyretic properties [6]. It is rapidly eliminated with a short plasma elimination half life of 3–5 h [7]. This short plasma half life may in part be responsible for the lornoxicam's reduced incidence of adverse effects [7]. We designed this prospective study to demonstrate the postoperative analgesic efficacy and adverse effects of a single intraoperative dose of lornoxicam 8 mg given before the start of surgery in tonsillectomy patients (8–18 years). Two routes of administration were used in comparison, intravenous vs. peritonsillar infiltration.

2. Patients and methods

This study was approved by the Local Research Ethics Committee in the Faculty of Medicine, Assiut University, Egypt. After obtaining an informed written parental consent, 60 ASA physical status I–II patients aged 8–18 years and scheduled for elective tonsillectomy due to recurrent or chronic tonsillitis were included in the study. Excluded from the study, patients with known hypersensitivity to medication drugs, coagulation disorders, thrombocytopenia, bronchial asthma, significant cardiac, renal, pulmonary or hepatic disease, peptic ulcer, previous peritonsillar abscess formation, active bleeding for any cause, and patients received any analgesic medications within 24 h preoperative or antiplatelet medication within the past 2 weeks.

Using an online research randomizer (http://www.randomizer.org), patients were randomly allocated to three groups of 20 patients each to receive lornoxicam 8 mg iv. (intravenous group), or peritonsillar infiltration (infiltration group), or saline (placebo group), after induction of anesthesia before the start of the surgery.

The fasted unpremedicated patients received a standardized anesthetic technique that included induction with propofol 2–3 mg/kg iv. and atracurium besylate 0.5 mg/kg iv. to facilitate endotracheal intubation. Anesthesia was maintained with isoflurane in oxygen/air mixture. Patients were mechanically ventilated in ventilation parameters that maintain an end-tidal $CO_2 \sim 32-35$ mm Hg. Monitoring included electrocardiography (ECG), non-invasive blood pressure, peripheral arterial oxygen saturation (SaO₂%), and end-tidal carbon dioxide (EtCO₂).

After induction of anesthesia before the start of the surgery, patients in the placebo group received 10 ml of normal saline iv. and 4 ml saline by peritonsillar infiltration (2 ml each side). The lornoxicam intravenous group patients received iv. 8 mg lornoxicam diluted to 10 ml plus 4 ml saline by peritonsillar infiltration. The lornoxicam infiltration group patients received 8 mg lornoxicam diluted to 4 ml and infiltrated pericapsularly through the tonsillar bed and peritonsillar tissues in a fanwise direction from the superior to inferior poles of the fossa (2 ml each side), using a 25-gauge spinal needle over a syringe, Plus 10 ml saline iv. The attending anesthesiologist, surgeon and data collection personal were blinded to patient group assignment and to the nature of the study medication. Saline 0.9% was used for diluting study drugs, while Lactated Ringer's solution was used for fluid maintenance and deficit replacement.

An intravenous antibiotic and dexamethasone 0.2 mg/kg were administered. At the end of the surgery, anesthesia was discontinued and neuromuscular relaxation was reversed using neostigmine $40 \mu \text{g/kg}$ and atropine $20 \mu \text{g/kg}$ slowly intravenous, and patients were turned aside in the recovery position. Extubation performed awake after the return of protective airway reflexes. Patients were transported to PACU, where they discharged to the ward after attaining an Aldrete and Kroulik

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