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Original contribution

Preoperative lornoxicam for pain prevention after tonsillectomy in adults

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Abstract

Study Objective: To evaluate the efficacy of preoperative lornoxicam on postoperative pain management following tonsillectomy.

Design: Prospective, randomized, double-blinded, placebo-controlled study.

Setting: King Fahd University Hospital.

Patients: 40 adult, ASA physical status I and II patients scheduled for tonsillectomy.

Interventions: Patients were randomly allocated to two groups to receive either intravenous (IV) lornoxicam 16 mg (Group L) or saline as control (Group C) preoperatively. Anesthesia was induced using IV fentanyl and propofol, while endotracheal intubation was facilitated with rocuronium, and maintenance was accomplished using nitrous oxide and sevoflurane.

Measurements: Pain scores at rest and on swallowing, intraoperative bleeding, interval until first request for rescue diclofenac suppository, and total diclofenac dose given in the first 12 and 24 hours postoperatively were recorded. The frequency of postoperative complications including bleeding, hypoxia, nausea and vomiting also were observed.

Main Results: Pain scores at rest were significantly lower in Group L than Group C at all observation times. Similarly, pain scores on swallowing were lower in Group L during the first 4 postoperative hours. The maximum verbal pain scale (VPS) in the control group was 7 (5.75 - 8 median, interquartile range) and in the lornoxicam group, it was 4 (4 - 5 median, interquartile range) ($P < 0.001$). The total diclofenac dose during the immediate postoperative 12 hours was significantly lower in Group L than Group C (65 ± 24 mg vs. 20 ± 25 mg, respectively; $P < 0.001$). No significant differences were noted for intraoperative bleeding. The frequency of postoperative nausea and vomiting was similar in both groups.

Conclusion: Preoperative 16 mg lornoxicam was effective for immediate postoperative pain relief after tonsillectomy in adults.

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1. Introduction

Tonsillectomy is a frequently performed procedure in adults, often on an outpatient basis [1]. The preoperative use of nonsteroidal anti-inflammatory drugs (NSAIDs) is a reasonable alternative, as they reduce postoperative pain and have an analgesic sparing effect. However, NSAIDs may also contribute to increased perioperative bleeding [2]. Although the mechanism of analgesic action (ie, inhibition of prostaglandin synthesis) is the same as all available NSAIDs, the analgesic efficacy relative to side effects may vary from agent to agent [3].

Lornoxicam is a nonselective NSAID of the oxicam class, with analgesic, anti-inflammatory, and antipyretic effects [4]. It is rapidly eliminated and has a short plasma elimination half-life of three to 5 hours [5]. Preoperative intravenous (IV) administration of lornoxicam reduces postoperative pain after various types of surgery, and it reduces the need for postoperative rescue pain medication [6-11]. We hypothesized that preoperative administration of IV lornoxicam 16 mg would provide postoperative analgesia without increasing perioperative blood loss after tonsillectomy in adults.

2. Materials and methods

2.1. Participants

Following King Fahd University Hospital Research Ethics Committee approval and written, informed consent, 40 adult, ASA physical status I and II patients, who were greater than 18 years of age, and were scheduled to receive general anesthesia for elective tonsillectomy due to chronic tonsillitis, were included in the study. Patients were excluded from the study if they weighed more than 150% of their ideal body weight; had a history of significant cardiac, pulmonary, hepatic, renal, or hematologic disease; had chronic drug or alcohol abuse or hypersensitivity to any of the drugs used in the study; bronchial asthma; peptic ulcer; or pregnancy. Subjects with obstructive sleep apnea or those who received any analgesic drugs one day before surgery also were excluded.

Patients were randomly allocated, using an online research randomizer (http://www.randomizer.org), to two groups of 20 patients each to receive either 16 mg of lornoxicam IV (Group L) or saline IV (Group C) 30 minutes before induction of anesthesia.

2.2. Interventions

Monitoring included electrocardiography (ECG), non-invasive blood pressure, peripheral pulse oximetry (SpO_2) and a train-of-four (TOF) neuromuscular monitor. An entropy sensor was placed according to the manufacturer's specifications and passed the initial impedance check. The spectral entropy plug-in module calculated state entropy and response entropy variables. Thirty minutes before induction of anesthesia, the control group (Group C) received 20 mL of 0.9% IV saline. The lornoxicam group (Group L) received IV lornoxicam 16 mg (Xefo) diluted to 20 mL. The injections differed in appearance (placebo is clear and lornoxicam is yellow), so to maintain observer blindness, the syringes were covered and the medications were prepared and administered by a different provider who was not involved in the study.

Anesthesia was induced with IV fentanyl 1.0 μg/kg and propofol 2.0 mg/kg; tracheal intubation was facilitated with IV rocuronium 0.6 mg/kg. Anesthesia was maintained with nitrous oxide and sevoflurane adjusted to maintain state entropy as measured by spectral entropy around 50%. Patients were mechanically ventilated to maintain end-tidal carbon dioxide concentration ($ETCO_2$) between 30 and 35 mmHg. Patients received an infusion of Ringer's acetate solution 10 mL/hr. On completion of the procedure, the neuromuscular block was reversed with neostigmine 2.5 mg and glycopyrrolate 0.4 mg. Patients received hypotonic oral rehydration solution after surgery until they were able to tolerate oral fluids. The tonsillectomies were performed by a senior consultant surgeon who was unaware of patient group allocation. For rescue analgesia, patients received diclofenac sodium 50 mg rectally at their request. No other analgesic medication was permitted during the first 24 hours.

2.3. Outcomes and assessments

Intraoperative blood loss was assessed by visual estimation of the blood volume in swabs and suction bottle. After surgery, an anesthesiologist who was blinded to patient group allocation assessed patient pain at rest and during swallowing using an 11-point verbal pain score (VPS), with 0 = no pain and 10 = worst pain imaginable. The first assessment was performed immediately after the patient was transferred to the ward, which was 30 minutes postoperatively. Observation was then made at 1, 2, 3, 4, 12 and 24 hours after surgery. In addition, the highest VPS was recorded for every patient. Oxygen saturation, respiratory rate (RR), and sedation on a 5-point scale (1 = fully alert; 2 = sleepy; 3 = sleepy, but easily arousable and reacting to verbal questions; 4 = fully asleep, reacting only to forceful handling; and 5 = fully asleep, reacting only to painful stimulus) [12] were recorded at the same intervals postoperatively. The interval until the first request for analgesia, total dose of diclofenac given during the first 12 and 24 hours postoperatively, and all adverse events were recorded for each patient.

2.4. Statistics

Sample size was based on a pilot study of 10 patients, which showed highest VPS scores of 7 ± 3 after tonsillectomy. A reduction of 3 in VPS was thought to be clinically