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Original contribution

A double-blind prospective comparison of rofecoxib vs ketorolac in reducing postoperative pain after arthroscopic knee surgery☆

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Abstract

Study Objective: The aim of this study was to compare the analgesic efficacy of premedication with rofecoxib vs intravenous (IV) ketorolac in reducing postoperative pain after arthroscopic knee surgery.

Study Design: This is a prospective, randomized, double-blinded study.

Setting: This study was set at a university hospital.

Subjects: The subjects include 54 patients with American Society of Anesthesiologists physical statuses I, II, and III undergoing knee arthroscopy.

Interventions: Group 1 received 50 mg oral rofecoxib preoperatively with IV placebo injection, which was administered 20 minutes before the end of the operation. Group 2 received a preoperative placebo and 30 mg IV ketorolac 20 minutes before the end of surgery.

Measurements: The primary outcome measure was the proportion of patients reporting pain in the postoperative anesthesia care unit, 6 hours and 24 hours after discharge. Additional end points included the use of 5:325 mg oxycodone-acetaminophen (O/A) tablets, pain scores, patient's satisfaction survey, and comparison of side effects. Data were analyzed using independent samples t tests for continuous variables or χ^2 tests for categorical variables. $P < .05$ was considered significant.

Results: The 2 groups were comparable with regard to patient characteristics, intraoperative medication use, and duration of surgery. There was no difference either in pain scores or O/A use in the postoperative anesthesia care unit. At 24 hours after discharge, significantly more patients in the ketorolac group (91%) reported pain than the rofecoxib group (63%) ($P = .02$). Sixty-one percent of patients in the ketorolac group used O/A during the first 24 hours vs 38% in the rofecoxib group. The difference, however, was not statistically significant.

Conclusion: Preoperative rofecoxib is as effective as ketorolac for the treatment of pain after knee arthroscopy. Higher frequency of pain reporting at 24 hours by patients in ketorolac group is explained

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by the longer analgesic effect of rofecoxib. Future studies should directly compare gastrointestinal injury of these drugs, as well as cost-effectiveness of rofecoxib vs ketorolac.

1. Introduction

Multimodal pain management (the simultaneous use of analgesics with different mechanism of action) has been recommended for a relief of postoperative pain to reduce opioid consumption by coadministering nonopioid analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs) [1,2]. Ketorolac and opioid analgesic are the usual treatment of postoperative pain relief for knee arthroscopy in our institution. The use of ketorolac, however, is associated with side effects such as bleeding, gastrointestinal (GI) injury, and renal toxicity [3]. It has been suggested that newer NSAIDs that are more specifically inhibit cyclooxygenase (COX)–2 isoenzyme demonstrate analgesic efficacy equivalent to ketorolac while minimizing adverse effects [4].

The aim of this prospective, double-blinded, randomized trial was to examine whether there is any difference in the number of patients reporting pain after 24 hours treated with a COX-2 inhibitor rofecoxib vs ketorolac after arthroscopic knee surgery (primary end point). No studies directly compared analgesic equipotency of these drugs. Secondary outcome variables included 11-point verbal rating pain scale (VRS) and opioid consumption, as well as patient satisfaction.

2. Materials and methods

2.1. Subjects

A total of 54 adults with a diagnosis of nonrepairable meniscus tear with at most grade I to II chondromalacia scheduled for elective arthroscopic knee surgery volunteered to participate in the study. This particular type of surgery and diagnosis is chosen to limit the variability in postoperative pain from one patient to another. Inclusion criteria were adult patients without significant laboratory abnormalities, American Society of Anesthesiologists (ASA) physical status I to III, and no medical contraindication to anesthesia. Nonsteroidal anti-inflammatory drugs were discontinued 5 to 7 days before surgery in accordance with the institutional policy. No attempts were made to alter other concurrent patient medications.

2.2. Study design

Patients were randomized into 2 groups, according to a predetermined random numbers sequence. Baseline VRS scores were evaluated 60 to 90 minutes before surgery. Half of the patients received a preoperative dose of oral rofecoxib (50 mg) 30 to 60 minutes before surgery with a placebo given intravenously (IV) near the end of the operation. The other half was treated with a preoperative placebo 30 to 60 minutes before surgery and a dose of 30 mg IV ketorolac 20 minutes before the end of surgery. The investigator who was blinded to patient group allocation assessed the intensity of postoperative pain and administered 5:325 mg oxycodone-acetaminophen (O/A). The pain scores were obtained at rest. The goal of postoperative pain management was to achieve VRS score of less than 2.

2.3. Anesthetic management

Every patient was monitored according to ASA standards. Each patient received fentanyl (1.4 μg/kg), midazolam (0.07 mg/kg), and propofol (70 μg/kg per minute) for sedation as well as supplemental oxygen throughout the case. The surgeon administered 30 mL of 1% lidocaine into the surgical site before insertion of the trocar. At the end of surgery, the surgeon injected morphine (8 mg) and bupivicaine (25 mg) into the intraarticular space.

2.4. Data collection

Pain intensity was evaluated with a visual rating scale (VRS: 0 = no pain to 10 = severe pain). If the VRS score was more than 2, O/A was given up to 3 tablets; meperidine was used for persistent pain. Patients were assessed for pain at 5, 60, and 90 minutes after arrival in the postoperative anesthesia care unit (PACU). The following variables were recorded: VRS score, mean arterial pressure (MAP), and heart rate (HR) in the PACU at 5, 60, and 90 minutes; and the total amount of analgesics and antiemetics in the PACU, as well as discharge time from the PACU. Discharge criteria included regained preoperative level of consciousness, stable vital signs, and respiratory stability, as well as a pain score of less than 2 or "tolerable." In addition, each patient received questionnaires to be completed after discharge from the hospital. The first questionnaire evaluated the analgesic requirements and pain scores at 6 and 24 hours after surgery. A second questionnaire assessed overall satisfaction with the perioperative pain control at 6 and at 24 hours. In addition, we collected information regarding adverse events such as nausea, vomiting, and dizziness over the 24-hour follow-up period. A preaddressed stamped envelope containing the questionnaires was given to all study patients on discharge.

2.5. Statistical methods

The sample size estimation was based on detecting a difference between the proportion of patients who experienced pain at 24 hours after surgery. Calculations were performed for a single time point, with no adjustment for