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Original Contribution

Comparison of oral oxycodone and naproxen in soft tissue injury pain control: a double-blind randomized clinical trial☆,☆☆,★

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ABSTRACT

Objectives: This randomized clinical trial compares the efficacy and safety of oral oxycodone (an oral opioid) with naproxen (a nonsteroidal anti-inflammatory drug) in acute pain control in patients with soft tissue injury. It also evaluates the need for additional doses of analgesics in the first 24 hours of discharge from emergency department (ED).

Methods: Adult (>18 years old) patients with soft tissue injuries were enrolled in a teaching urban ED. Subjects were randomly allocated to receive a single dose of oral oxycodone (5 mg) or oral naproxen (250 mg). Pain scores and drugs' adverse effects were assessed before, 30 minutes, and 60 minutes after medication. Outcome: efficacy in pain control (reduction in pain scale >2 points) and safety (rate of side effects). The need for additional pain medication after discharge was assessed by follow-up phone call 24 hours after discharge.

Results: A total of 150 patients were enrolled. Pain scores were similar in oxycodone vs naproxen groups before (6.21 ± 0.9 in vs 6.0 ± 1.0), 30 minutes (4.5 ± 1.4 vs 4.4 ± 1.2), and 60 minutes (2.5 ± 1.3 in vs 2.6 ± 1.3) after medication, respectively. Twelve (16.0%) patients in oral oxycodone group and 5 (6.6%) patients in naproxen group needed more analgesics in first 24 hours after ED discharge. Adverse effects were more common in oxycodone group (statistically significant difference). The most common adverse effects in oxycodone group were nausea, (13.3%); vomiting, (8.0%); dizziness, (5.3%); drowsiness, 3 (4.0%); and pruritis, (2.7%).

Conclusion: Oral oxycodone is as effective as naproxen in soft tissue injury pain control but has a less favorable safety profile.

1. Introduction

Soft tissue injuries are common entities in the emergency departments (EDs). It is estimated that up to 10% of ED visits are due to soft tissue injuries [1]. Pain control is an essential component of management in such cases. In addition to patient's comfort, adequate pain control may expedite patient's return to normal physical activity by facilitating early controlled mobilization and exercise.

Healing after soft tissue injury starts with an inflammatory phase. Some of the elements of this inflammatory process are necessary for healing. Some investigators have suggested that inhibiting this inflammatory phase by anti-inflammatory drugs may impair the healing process. Therefore, it might be more appropriate to administer analgesics without anti-inflammatory properties to avoid impacting the inflammatory responses [2-5].

Oral oxycodone is an opioid with high oral bioavailability and predictable side effects. It is commonly used in patients whose pain does not respond to nonsteroidal anti-inflammatory drugs (NSAIDs) or acetaminophen alone [6-8].

The objective of this study was to compare the efficacy and safety of oral oxycodone with those of naproxen for treatment of pain in ED patients with soft tissue injury [9].

2. Methods

2.1. Study design

This study was a double-blind noninferiority randomized clinical trial. We enrolled a convenient sample of ED patients with soft tissue injuries. The study was conducted in a tertiary academic ED with annual census of 30 000. The study was approved by institutional ethics committee, and written informed consent was obtained from all patients. The trial was registered with the Iranian Registry of Clinical Trials (http://www.irct.ir, identifier: IRCT201112208104N3).

☆ Conflict of interest disclosure: All authors declare that they have no conflict of interest.
☆☆ Compliance with ethical requirements: This study was approved by institutional ethics committee, and written informed consent was obtained from all patients. Trial was registered at irct.ir (identifier: IRCT201112208104N3).
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Table 1
Baseline data of patients in 2 regimen groups

Variable	Oxycodone (n = 75)	Naproxen (n = 75)
Age, mean (±SD), y	34.1 (±10.7)	36.8 (±11.2)
Sex, n (%)		
Male	42 (56.0)	43 (57.3)
Female	33 (44.0)	32 (42.7)
Type of injury, n (%)		
Ligamentous and capsular sprain	32 (42.7)	39 (52.0)
Muscle strain	15 (20.0)	20 (26.7)
Contusion and bruising	14 (18.7)	4 (5.3)
Low back and lumbosacral injury	10 (13.3)	7 (9.3)
Intervertebral disk problems	4 (5.3)	5 (6.7)
Pain score at presentation, mean (±SD)	6.21 (±0.9)	6.0 (±1.0)

2.2. Study protocol

We included patients older than 18 years old with acute soft tissue injury and a pain numerical rating scale score between 3 and 7. We excluded patients with concurrent multitrauma or noninjury-related pain and known opioid or NSAIDs allergy; narcotics addiction (reported by either the patient or the family), history of chronic respiratory, renal, hepatic, or heart failure; patients who had received analgesics before their ED presentation; and pregnant patients and patients who were unable to understand or communicate because of language barrier or any other reason.

We used computer-generated randomization blocks of 4 to randomly assign patients to the 2 regimen groups. First group received 10-mg oxycodone (2 oxydone, 5-mg tablet; Raha Pharmaceutical Co, Tehran, Iran), orally with water. Second group received 250-mg naproxen (Naproxen-Sobhan, 250-mg tablet; Sobhan Daroo Co, Tehran, Iran), orally with water. Patients, physicians, nurses, and research assistants remained blinded to group assignment throughout the entire study. All study medications were prepared by a research assistant who was not involved in medication administration or data collection. We used sealed opaque envelopes to ensure allocation concealment.

We assessed pain scores (by numerical rating scale) and drugs' adverse effects (including nausea, vomiting, dizziness, headache, itching, flushing, hypotension, respiratory, or central nervous system depression) before, 30 minutes, and 60 minutes after medication administration. A telephone follow-up was made after 24 hours to ask about the additional analgesics use and adverse effects.

Our primary outcome measure was analgesics efficacy defined as a reduction in the mean pain score by more than 2 points at 30 and 60 minutes after medication administration. Our secondary outcome measure was drugs' adverse effects.

2.3. Data analysis

Descriptive statistics are presented as mean and SD. Student *t* test was used to compare the means of quantitative variables in 2 independent samples. The rate of adverse effects in each group was compared with χ^2 test. We considered $P < .05$ as significant. Our study was a noninferiority trial on continuous variable (pain score). We used the formula $n = 2 \times ([z_1\text{-}\alpha + z_1\text{-}\beta]/\sigma_0)^2 \times S^2$ for calculating the sample size. By considering $\alpha = .05$, $\beta = .20$, $P = .80$, $\sigma 0 = 3$, and $S = 6$, the sample size was calculated as 49 in each group. All data analyses were performed with SPSS, version 16 (SPSS, Inc, Chicago, IL).

3. Results

3.1. Basic characteristics of study patients

Baseline characteristics were similar in both groups (Table 1). Study subjects flow is illustrated as CONSORT diagram (Fig. 1).

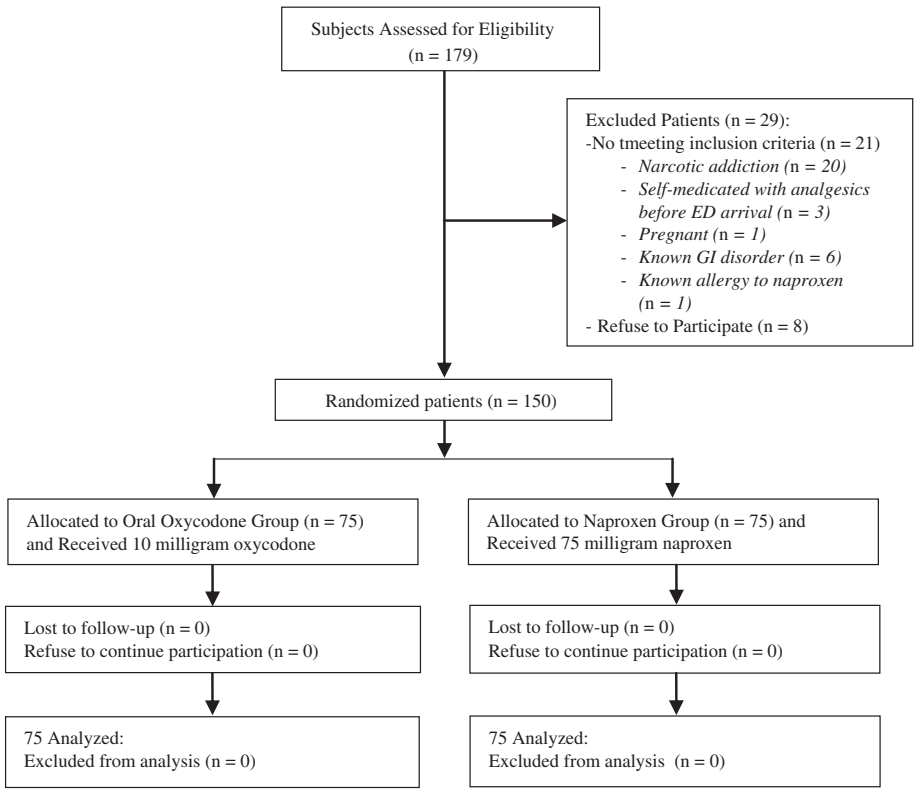

Fig. 1. CONSORT diagram showing participants flow in study.