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October 2017

Oral Analgesics Utilization for Children With Musculoskeletal Injury (OUCH Trial): An RCT

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Abstract

BACKGROUND: Musculoskeletal injuries (MSK-Is) are a common and painful condition among children that remains poorly treated in the emergency department (ED). We aimed to test the efficacy of a combination of an anti-inflammatory drug with an opioid for pain management of MSK-I in children presenting to the ED.

METHODS: In this randomized, double-blinded, placebo-controlled trial, we enrolled children between 6 and 17 years presenting to the ED with an MSK-I and a pain score >29 mm on the visual analog scale (VAS). Participants were randomly assigned to oral morphine (0.2 mg/kg) + ibuprofen (10 mg/kg) (morphine + ibuprofen) or morphine (0.2 mg/kg) + placebo of ibuprofen or ibuprofen (10 mg/kg) + placebo of morphine. Primary outcome was children with VAS pain score <30 mm at 60 minutes postmedication administration.

RESULTS: A total of 501 participants were enrolled and 456 were included in primary analyses (morphine + ibuprofen = 177;

morphine = 188; ibuprofen = 91). Only 29.9% (morphine + ibuprofen), 29.3% (morphine), and 33.0% (ibuprofen) of participants achieved the primary outcome ($P = .81$). Mean VAS pain reduction at 60 minutes were -18.7 (95% confidence interval [CI]: -21.9 to -16.6) (morphine + ibuprofen), -17.0 (95% CI: -20.0 to -13.9) (morphine), -18.6 (95% CI: -22.9 to -14.2) (ibuprofen) ($P = .69$). Children in the morphine + ibuprofen group ($P < .001$) and in the morphine group ($P < .001$) experienced more side effects than those in the ibuprofen group. No serious adverse event was reported.

CONCLUSIONS: Combination of morphine with ibuprofen did not provide adequate pain relief for children with MSK-I in the ED. None of the study medication provided an optimal pain management because most of children did not reach a mild pain score (NCT02064894).

Accepted August 4, 2017.

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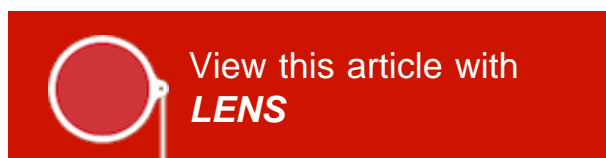
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[Current Issue](#)

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