Effect of NSAID Use in the Acute Phase of Skeletally Immature Bone Healing: A Prospective, Randomized, Controlled Study

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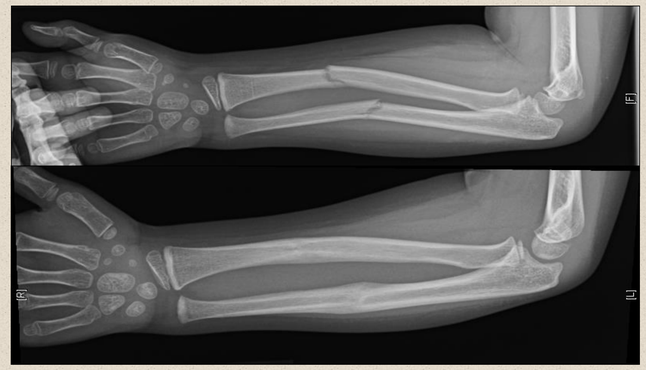
Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are effective in controlling both post-operative pain and pain associated with orthopaedic injuries. In the pediatric population, they can minimize the need for narcotic pain medications. There is little data on the effects these medications have on long bone healing in the skeletally immature patient with a fracture.



Objective

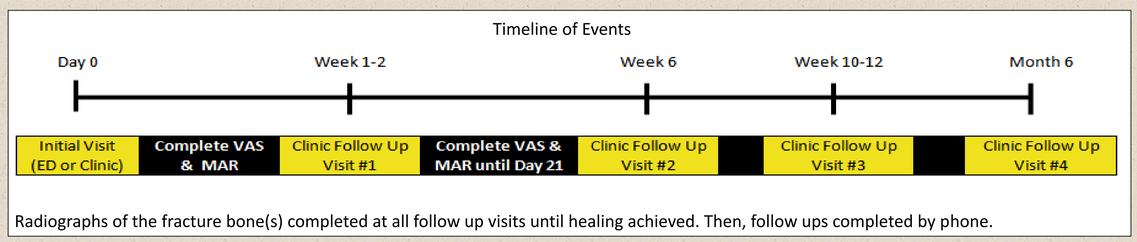
To compare time to union of fractures in skeletally immature patients administered NSAIDs for pain control during the acute phase of fracture healing with those administered acetaminophen for pain control.

Hypothesis

•The administration of NSAIDs to patients in the acute phase of bone healing will not results in delayed union or non-union as compared to patients who take acetaminophen for pain control during the same time period.

Materials and Methods

In this prospective, randomized, controlled study, skeletally immature patients with a long bone fracture were randomized to one of two groups for their post-fracture pain management: one group received acetaminophen (Control Group) and the other received ibuprofen (NSAID group). Both groups received oxycodone for breakthrough pain. The patients were followed clinically for fracture healing and were evaluated with physical exam, visual analog pain score and radiographs.



Radiographs of the fracture bone(s) completed at all follow up visits until healing achieved. Then, follow ups completed by phone.

Results

Eighty-one skeletally immature patients with long bone fractures were enrolled. Three were lost to follow up. Seventy eight patients completed 6 months of follow up (45 in the control group and 33 in the NSAID group). The groups were similar with regards to age, gender, height, weight and BMI (Table 1). No patients achieved healing by their two week follow up. By 6 weeks, 74% of the control patients had united fractures and 89% of the NSAID patients had healed fractures (p = 0.1). At the 12 week follow up, 97% of the control group fractures were healed and 100% of the NSAID group fractures were healed. All fractures were healed in both groups by 6 months (Figure 1). Healing was documented at a mean of 44 days in the control group and 42 days in the NSAID group (p = 0.58; power = 0.8). Oxycodone for breakthrough pain was used for an average of 2.5 days in the control group and 2 days in the NSAID group. There was no difference in pain scores between the two groups at any time point measured (Table 3).

Table 1: Patient Demographics

	Control group Mean (range)	NSAID group Mean (range)	p value	Power
Age	7.8 years (2-16)	7.6 years (1.5-16)	0.6	0.81
Male:Female	28:19	25:22		
Height	130 cm (88-175)	126 cm (80-176)	0.3	0.64
Weight	33.3 kg (13.5-76)	28.6 kg (10.9-70.3)	0.2	0.4
BMI	18 (12-27)	17 (13-27)	0.4	0.55

Table 2: Fracture Location

	Control Group	NSAID group
Humerus	10	4
Radius/Ulna	18	18
Distal Radius	10	5
Monteggia	1	-
Olecranon	1	-
Femur	2	2
Tibia	3	4
Total	45	33

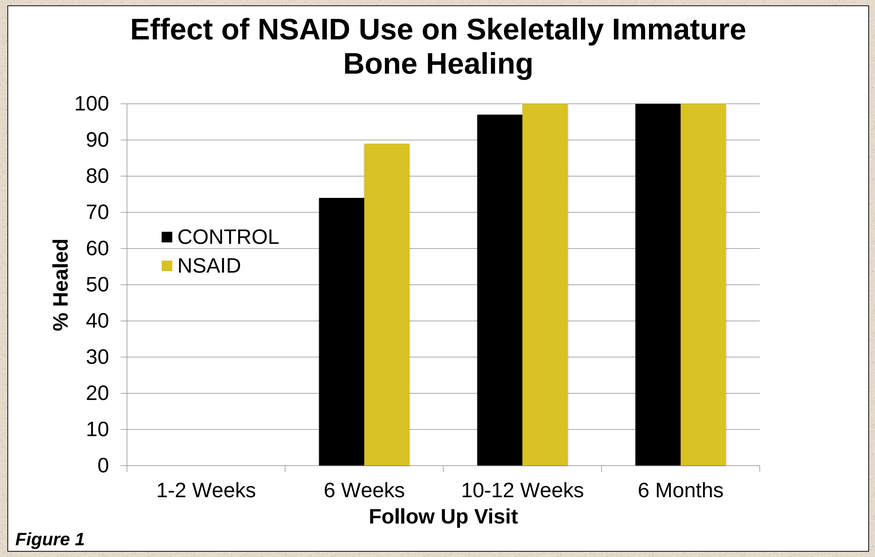


Figure 1

Table 3: Pain Scores

Time after injury	Control group Mean (range)	NSAID group Mean (range)	p value
1st 3 days after injury	3 (0.4-6)	2.6 (0.6-5.7)	0.3
1-2 week follow up	0.9 (0-8)	0.6 (0-6)	0.16
6 week follow up	0.02 (0-1)	0.06 (0-3)	0.6
10-12 week follow up	0 (0-0)	0 (0-0)	1
6 month follow up	0 (0-0)	0 (0-0)	1

Conclusions

The results of this study provide evidence that NSAID use does not impair long bone fracture healing in skeletally immature patients and can be a useful alternative for pain control in the acute fracture setting.

Funding

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The trial was registered with ClinicalTrials.gov (NCT02076321).