# How Much Opioid Do Kids Actually Need? A Prospective Study of Analgesic Prescribing and Postdischarge Opioid Use Among Pediatric Patients With Operative Fractures

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**Background:** Analgesic guidelines are lacking for most operative pediatric fractures, and little is known about postdischarge opioid use or pain control. We hypothesized that opioid/acetaminophen/non-steroidal anti-inflammatory drugs (NSAID) prescribing would vary, pain would be well controlled, and postdischarge opioid use would be low. **Methods:** This prospective cohort study included nonpolytraumatized patients aged 17 years and below with operative fractures at a level 1 trauma center from August 1, 2019 to March 31, 2021. Supracondylar humerus fractures were excluded since they have been studied extensively. Information regarding injury/surgery/ analgesics were collected. Discharged patients were called on postoperative days (POD) 1/3/5. Parents/guardians were asked about analgesic use and pain over the preceding 2 days. Complications, pain control, and opioid refills were recorded after first follow-up.

Results: All 100 eligible patients were included. Mean age was 10.1 years (range: 1.8 to 17.8 y). Common fracture types were humeral condyle/epicondyle (28%), radius/ulna (15%), and femoral shaft (13%). Opioids were prescribed to 95% of patients with mean 14 doses (range: 2 to 45). Acetaminophen/NSAIDs were prescribed to 74% and 60% of patients, respectively. Eleven patients were excluded from telephone follow-up (7 non-English speaking, 3 prohibitive social situations, 1 inpatient POD1 to 5). Telephone follow-up was completed for 87/89 eligible patients (98%). Mean pain scores declined from 3.7/10 POD1 to 2.4/10 POD5. Opioids were taken by 50% POD1, 20% POD5. Acetaminophen/NSAID was given before opioid 82% of the time. By POD5, mean total doses of opioid taken postdischarge was 2.3; mean proportion of prescribed opioid doses taken was 22%; and 97% of patients took  $\leq 8$  opioid doses postdischarge. Two patients were evaluated early due to poor pain control which improved with cast changes. Pain was well controlled or absent at follow-up in 97% of patients.

**Conclusions:** Pain is consistently well controlled after operative pediatric fractures. Nearly all were prescribed opioids, while acetaminophen/NSAIDs were inconsistently prescribed and used. Opioid prescriptions are written for 4 to 5 times the amount needed. Prescribing  $\leq 8$  doses of opioid is adequate for acute pain through POD5 in 97% of patients. Poorly controlled pain should prompt early evaluation for possible complications. **Level of Evidence:** Level II—prospective comparative study.

**Key Words:** opioid stewardship, pediatric fractures, pain control, analgesia, narcotics

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**C**ountless publications describe the epidemic proportions of opioid abuse in the United States, and efforts to improve opioid stewardship are ubiquitous. Opioid oversupply is a primary driver of misuse by patients and their friends and relatives.<sup>1</sup> Opioid prescribing practices of pediatric orthopaedic surgeons continue to vary widely and are driven by personal experience and anecdotal evidence, with significant variability in medication, dose, and duration.<sup>2</sup> The American Academy of Orthopaedic Surgeons information statement on this topic encourages individual practices to determine acceptable opioid prescribing ranges and limits for various musculoskeletal conditions and surgeries.<sup>3</sup> Some institutions have conducted quality improvement initiatives to established institutional opioid prescribing guidelines, but published opioid prescribing recommendations for operative pediatric fractures are lacking.

To our knowledge, only 2 studies have reported actual home opioid use by pediatric patients after fracture surgery. Both were published within the past 2 years and studied exclusively operative pediatric supracondylar humerus fractures. Both studies found that opioids continue to be overprescribed in spite of a modest need.<sup>4,5</sup> These studies were novel in that actual home opioid use was recorded, rather than only discharge opioid prescriptions as other studies have reported.<sup>6–8</sup> To our knowledge no study has evaluated postdischarge opioid use among operative pediatric fractures other than supracondylar humerus fractures.

We undertook this study to prospectively evaluate postdischarge opioid use and pain control among all other operatively treated pediatric fractures. We hypothesized that: (1) prescribing of opioids, acetaminophen, and

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L.G.K.: study design, data collection, statistical analysis, manuscript preparation. M.H.S.: study design, data collection, manuscript preparation. S.D.: data collection, manuscript preparation. M.R.S. and A.D.V.: study design, manuscript preparation.

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Non-steroidal anti-inflammatory drugs (NSAIDs) would be variable, (2) pain would be consistently well controlled, and (3) actual postdischarge opioid use would be low.

### METHODS

This was a prospective observational cohort study at an academic level 1 trauma center that serves as a tertiary referral center for the state. It was approved by the local institutional review board. From August 2019 through March 2021 all nonpolytraumatized patients aged 17 years and below with operative fractures were identified daily. Supracondylar humerus fractures (which have been studied extensively as noted above) were excluded to focus on all other fracture types. All potentially eligible patients were identified consecutively by screening the orthopaedic surgery consult list and relevant operating room schedules every day during the study period, and all eligible patients were offered enrollment. Demographic data, mechanism of injury, fracture type, surgical details, inpatient opioid use, and prescribed analgesics including morphine milliequivalents (MMEs) were collected on all patients. Discharge medications are typically prescribed by resident physicians at our institution, and no institution-wide protocol governed opioid prescribing to these patients during the study period. No new state legislation governing opioid prescribing was enacted during the study period.

All English-speaking patients were contacted by phone following discharge on postoperative day (POD) 1, 3, and 5. Patients were not contacted or informed of the study before discharge; the study was explained and verbal consent obtained at the beginning of the first telephone interview. All interviews were conducted by 3 trained researchers (1 resident and 2 medical students) using a scripted explanation of the study and standardized questions. During each call parents/guardians were asked about analgesic use, pain severity using a parental proxy 0 to 10 scale, and satisfaction with pain control over the preceding 2 days. Complications, pain control, and opioid refills were recorded after the first follow-up appointment. Study data were collected and managed using HIPAAcompliant Research Electronic Data Capture.<sup>9,10</sup>

Given non-normality of data, nonparametric tests were used to explore possible associations with total home opioid use (Kruskal-Wallis H tests for continuous and nondichotomous categorical independent variables, Wilcoxon rank sum/Mann-Whitney U tests for dichotomous independent variables). Analyses were performed using Stata SE version 16.1.

## RESULTS

One hundred nonpolytraumatized patients with any operative fracture other than supracondylar humerus fractures were identified and included. The 100 eligible patients had mean age 10.1 years (SD 4.1, range: 1.8 to 17.8 y) and included 60 males (60%) and 40 females (40%). Among included patients, 59% identified as White/Caucasian, 17% as Black/African American, and 24% as other races;

12% reported Hispanic/Latino ethnicity. The most common mechanisms were falls (62%), sports-related injuries (14%), and all-terrain vehicle accidents (10%, Table 1). Fracture types included 28 humeral condyle or epicondyle, 15 radius and/or ulna, 9 proximal femur, 13 femoral shaft, 7 distal femur, 4 tibial tubercle, 9 ankle, and a heterogenous group of 15 other fractures. Five pathologic fractures and 9 open fractures (all Gustilo-Anderson type 1) were included. Injuries were evenly divided between upper (51%) and lower extremities (49%). Types of surgeries included open reduction internal fixation (67%), closed or open reduction and percutaneous fixation (22%), and rigid or flexible

**TABLE 1.** Demographics, Injuries, and Surgeries Among 100

 Pediatric Patients With Operative Fractures

reliance rations with Operative Fractures	
Age [mean (SD, range)] (y)	10.1 (4.1, 1.8-17.8)
Sex [n (%)]	
Male	60 (60)
Female	40 (40)
Race [n (%)]	
White or Caucasian	59 (59)
Black or African American	17 (17)
Other	24 (24)
Ethnicity [n (%)]	
Hispanic or Latino	12 (12)
Non-Hispanic or Latino	88 (88)
Mechanism of injury [n (%)]	
Fall*	62 (62)
Sports-related <sup>†</sup>	14 (14)
All-terrain vehicle	10 (10)
Motor vehicle collision	2 (2)
Direct impact or crush	5 (5)
Gunshot wound	2 (2)
Atraumatic (pathologic fracture)	5 (5)
Fracture type [n (%)]	
Humeral condyle or epicondyle‡	28 (28)
Radius and/or ulna	15 (15)
Proximal femur	9 (9)
Femoral shaft	13 (13)
Distal femur	7 (7)
Tibial tubercle	4 (4)
Ankle	9 (9)
Other	15 (15)
Open fractures [n (%)]	9 (9)
Extremity [n (%)]	
Upper	51 (51)
Lower	49 (49)
Surgery type [n (%)]	
Open reduction internal fixation	67 (67)
Closed or open reduction and percutaneous	22 (22)
fixation	
Rigid or flexible intramedullary nails	11 (11)
Duration of surgery [mean (SD, range)] (min)	97 (55, 20-272)
Setting [n (%)]	
Inpatient (admission through emergency department)	55 (55)
Outpatient	45 (45)
Length of stay in hours among inpatient surgeries	[mean (SD)]
Preoperatively	16 (10)
Postoperatively	34 (37)
Total	52 (39)
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\*Including falls on trampolines, swings, skateboards, and bicycles.

†Including all injuries sustained during recreational or competitive athletics, contact, and noncontact mechanisms.

 $\$  Supracondylar humerus fractures were excluded as they have been studied extensively.

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intramedullary nails (11%). Four patients with pathologic fractures required more varied surgical treatment including acute casting with delayed internal fixation with customordered telescoping intramedullary nails, osteotomy, epiphysiodesis, fracture site biopsy, and open treatment of nonunion; these patients were included to describe the spectrum of pediatric fractures as comprehensively as possible. Mean duration of surgery was 97 minutes (SD 55, range: 20 to 272 min). Fifty-five inpatient surgeries (admitted through the emergency department) and 45 outpatient surgeries were included. Among inpatients, mean length of stay was 16 hours (SD 10) preoperatively and 34 hours (SD 37) postoperatively for mean total length of stay of 52 hours (SD 39).

Total in-hospital opioid use (in the postanesthesia care unit for outpatient surgeries, and from the emergency department through the entirety of the hospital stay for inpatient surgeries) was variable with mean 9.1 total doses (SD 7.2) among all patients and mean 0.2 doses per hour among inpatients (SD 0.1, Table 2). Opioids were prescribed at discharge to 95/100 patients with mean 14 doses (SD 10, range: 2 to 45). Oxycodone was the most commonly

**TABLE 2.** Analgesic Prescribing, Analgesic Use, and Quality of

 Pain Control by Postoperative Day (POD)

Opioid doses taken in-hospital and	9.1 (7.2)
postanesthesia care unit [mean (SD)]	
Opioid doses per hour during hospital admission [mean (SD)]*	0.2 (0.1)
Analgesics prescribed at discharge [n (%)]	
Onioid	95 (95)
Acetaminophen	74 (74)
NSAID	60 (60)
Opioid doses prescribed at discharge [mean	14(10, 2-45)
(SD, range)]	
Pain scores 0-10 [mean (SD)] <sup>†</sup>	
POD1	3.7 (2.6)
POD3	3.0 (2.3)
POD5	2.4 (2.2)
Opioid taken postdischarge, n (%, mean doses ta	ken, range)†
POD1	33/66 (50, 2.1, 1-6)
POD2	38/84 (45, 1.6, 1-7)
POD3	29/86 (34, 1.3, 1-4)
POD4	26/87 (30, 1.4, 1-4)
POD5	17/87 (20, 1.2, 1-2)
Acetaminophen/NSAID given before opioid, all timepoints	82%
Total doses of opioid taken POD1-5	2.3 (3.2, 0-19)
[mean (SD, range)] <sup>†</sup>	
Proportion of prescribed opioid doses taken POD1-5 [mean (SD, range)] <sup>†</sup>	22% (28%, 0%-100%)
Proportion who took $\leq 8$ opioid doses POD1-5 [n (%)] <sup>†</sup>	92/95 (97)
Parent/guardian satisfied with pain control (ves/n	o) [n (%)]†
POD1	64/66 (97)
POD3	84/86 (98)
POD5	85/87 (98)
Pain well-controlled or absent at first follow-up	96/99 (97)
[n (%)]§	
*Among 55 natients admitted perioperatively	

Among 55 patients admitted perioperatively

†Denominators reflect discharged patients contacted by phone. Doses averaged among only patients who took opioid at this timepoint.

‡Among the 95 patients prescribed an opioid at discharge.

§One patient was lost to follow-up.

prescribed opioid (98%) followed by hydrocodoneacetaminophen (2%). Mean standardized dosage was 32 MMEs/d (SD 17), which is equivalent to 21 mg of oxycodone per day, or 0.14 MMEs/dose/kg (SD 0.06). Acetaminophen was prescribed (not just recommended/ instructed) to 74% of patients and an NSAID to 60%.

Eleven patients were excluded from telephone followup (7 non-English speaking, 3 prohibitive social situations, 1 inpatient POD1 to 5). Telephone follow-up was completed for 87/89 eligible patients (98%). Data was collected from 239 completed phone interviews. Mean pain scores among only discharged patients (not those who remained inpatient) were 3.7/10 on POD1, 3.0/10 on POD3, and 2.4/10 on POD5. Opioids were taken by 33/66 (50%) of discharged patients called on POD1 (mean 2.1 doses taken among the 33 that took opioids), 38/84 (45%) on POD2 (mean 1.6 doses), 29/86 (34%) on POD3 (mean 1.3 doses), 26/87 (30%) on POD4 (mean 1.4 doses), and 17/87 (20%) on POD5 (mean 1.2 doses, Fig. 1). Acetaminophen or an NSAID was administered before an opioid 82% of the time. The proportion of parents/guardians satisfied with pain control was 97% to 98% at each timepoint.

The mean total opioid consumption postdischarge POD1 through POD5 was 2.3 doses (range: 0 to 19). The subset of pathologic fracture patients who required more extensive and varied surgical treatment had uniformly low postdischarge opioid requirements (range: 0 to 4 doses). The mean proportion of prescribed opioid doses taken postdischarge through POD5 was 22% (range: 0% to 100%). Ninety-seven percent of patients took  $\leq 8$  opioid doses postdischarge through POD5 (Fig. 2). Pain was well controlled or absent at first follow-up in 96/99 patients (97%).

Three patients took >8 doses of opioid postdischarge through POD5 (Fig. 2). One of these was a 12-year-old male with a sports-related distal femur fracture who was prescribed a refill after taking 13/20



**FIGURE 1.** Percent of discharged patients who took opioid pain medication on postoperative days (PODs) 1 through 5 (left vertical axis) and mean doses of opioid taken that day (right vertical axis).

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**TABLE 3.** Postdischarge Opioid Use Through Postoperative

Day 5 Among 95 Patients Who Were Prescribed Opioids, by

Age, Sex, Mechanism of Injury, Type of Fracture, Upper/Lower

Extremity, Type of Surgery, and Inpatient/Outpatient Setting





prescribed opioid doses by POD3, prompting early evaluation. This patient and one other with a distal femur fracture were evaluated early for poorly controlled pain which improved with cast changes; neither patient had further complications. Another outlier was 7-year-old female with a humeral condyle fracture due to a fall who was given 14 of doses of oxycodone through POD5 in spite of parent-reported pain scores of 2 to 4/10. The final outlier was an 11-year-old female with a sports-related physeal ankle fracture who took 11/30 prescribed doses of oxycodone with no apparent complications.

Total postdischarge opioid use was significantly associated with mechanism of injury (P = 0.04), with highest use after sports-related injuries (mean 4.6 doses compared with overall mean 2.3 doses). The youngest patients (2 to 5 y)took the least opioid postdischarge (mean 0.8 doses), but this was not statistically significant (P=0.10). Patients with humeral condyle or epicondyle fractures took the least opioid postdischarge of any fracture type (mean 1.5 compared with mean 2.6 among all others), but postdischarge opioid use was not significantly associated with fracture type (P=0.57). Postdischarge opioid use was associated with ethnicity (P = 0.03), with patients who identified as Hispanic/ Latino taking slightly less opioid postdischarge (mean 1.6 doses compared with mean 2.4 doses among non-Hispanic/ Latino patients). Postdischarge opioid use was not associated with sex (P=0.40), race (P=0.08), upper versus lower extremity (P=0.84), type of surgery (P=0.25), duration of surgery (P = 0.74), total or per-hour opioid doses given in the hospital and postanesthesia care unit (P=0.31 and 0.32), respectively), or inpatient versus outpatient setting (P = 0.31, Table 3).

## DISCUSSION

Despite efforts to turn the tide of opioid overprescribing, concrete evidence to guide prescribing after pediatric orthopaedic trauma surgery is scarce.<sup>2</sup> A 2017 systematic review found "no objective basis for prescription recommendations" in this population.<sup>11</sup> Improving nationwide opioid prescribing practices is particularly critical

	Mean Doses of Opioid Taken Postdischarge Through Postoperative Day 5	_
	[Mean (SD)]	P
Age (y)		
2-5	0.8 (1.0)	
6-9	2.2 (2.7)	0.10*
10-13	3.5 (4.2)	
14-17	2.0 (2.4)	
Sex		
Male	2.4 (3.1)	$0.40^{+}$
Female	2.2 (3.3)	
Race [n (%)]		
White or Caucasian	2.1 (2.2)	0.08*
Black or African	3.7 (4.8)	
American		
Other	2.0 (3.7)	
Ethnicity [n (%)]		
Hispanic or Latino	1.6 (4.0)	0.03*
Non-Hispanic or Latino	2.4 (3.0)	
Mechanism of injury		
Fall	1.9 (2.7)	
Sports-related	4.6 (5.2)	
All-terrain vehicle	2.8 (2.3)	
Motor vehicle collision	0.0 (0.0)	0.04*
Direct impact or crush	3.0 (1.2)	
Gunshot wound	2.0 (0.0)	
Atraumatic (pathologic	0.6 (1.3)	
fracture)		
Fracture type		
Humeral condyle or	1.5 (2.9)	
epicondyle		
Radius and/or ulna	3.0 (2.8)	
Proximal femur	2.1 (2.8)	
Femoral shaft	2.5 (1.8)	0.57*
Distal femur	3.9 (6.9)	
Tibial tubercle	2.5 (3.0)	
Ankle	3.2 (4.1)	
Other	1.9 (2.0)	
Extremity		
Upper	2.2 (2.8)	$0.84^{+}$
Lower	2.5 (3.5)	
Surgery type		
Open reduction internal	2.5 (2.9)	
fixation		
Closed or open reduction	1.9 (4.4)	0.25*
and percutaneous		
fixation		
Rigid or flexible	2.1 (2.2)	
intramedullary nails		
Setting		
Inpatient (emergency	2.4 (3.1)	0.31†
department admission)	× /	1
Outpatient	2.2 (3.3)	
×	× /	

\*Kruskal-Wallis H test for nondichotomous independent variables.

†Wilcoxon rank sum (Mann-Whitney U) test for dichotomous independent variables.

Statistically significant values presented in bold.

in pediatric patients, as prescription opioid use in adolescence increases risk of future opioid abuse.<sup>12</sup>

We undertook this study to determine use of opioids after discharge in a heterogenous group of common

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operative pediatric fractures. We found that opioids continue to be overprescribed, in spite of excellent pain control with minimal need for these potent medications. Ninety-seven percent of patients took  $\leq 8$  opioid doses postdischarge through POD5 with a mean of only 2.3 doses taken postdischarge. The mean pain scores were always < 4/10 even on POD1, and pain was well controlled or absent at first follow-up in 97% of patients. Patients with sports-related injuries may have higher opioid requirements but only marginally so with mean of 4.6 doses taken through POD5. Although age was not associated with postdischarge opioid use in our study, the relationship between mechanism of injury and opioid use may be confounded by age, as 80% of all sports injuries occurred in patients aged 10 years or older. Patients who identified as Hispanic or Latino took marginally less opioid postdischarge, but the clinical significance of this difference of <1 dose (1.6 vs. 2.4 doses) is dubious. We observed no other significant associations with postdischarge opioid requirement.

For nearly a decade some authors have advocated acetaminophen monotherapy for operative pediatric supracondylar humerus fractures based on adequate inpatient pain control,<sup>13</sup> but a recent study by Stillwagon et al<sup>4</sup> in this populations found that opioids continue to be overprescribed (mean 47 doses of opioid). They additionally found that 60% of patients took 3 or fewer doses of opioid postdischarge (1 in 4 taking none). Another recent prospective study of 81 operative pediatric supracondylar humerus fractures had similar findings and recommended prescribing no >7 doses of opioid.<sup>5</sup>

Three recent studies including other operative pediatric fractures have not reported actual opioid use postdischarge, but they have shown that these patients are consistently prescribed a mean of ~30 doses of opioid at discharge.<sup>6–8</sup> The mean of 14 opioid doses prescribed in our study offers some encouragement that prescribing practices may be improving. However, the mean of only 22% of prescribed doses actually taken in our cohort show that even this is 4 to 5 times the amount needed. Approximately 78% of the opioids we are still prescribing to pediatric fracture patients are not needed, and evidence suggests these typically remain "unlocked and undisposed."<sup>1</sup>

The primary motivator for excessive opioid prescribing postoperatively is presumably to avoid inadequate pain control after patients arrive home. This scenario historically required an additional clinic appointment or emergency department visit if an opioid was to be prescribed. The universal shift to e-prescribing of controlled substances obviates this dilemma. In our cohort, only 1 patient not prescribed an opioid at discharge later requested one due to inadequate pain control with nonopioids. This patient was e-prescribed 5 doses on POD2 without need for an additional visit and subsequently took only 2 doses.

It can be argued that 2 of the 3 outliers in this study who took > 8 opioid doses postdischarge through POD3 (excluding the patient who required a cast change) may have been given excessive opioids by their parents

primarily because of the substantial prescriptions they were given (up to 30 doses). Prescribing nonopioid analgesics along with very little opioid (or perhaps no opioid for some patients) is appropriate and may help set patient and parent expectations that pain control is seldom an issue and that frequent doses of opioids are not needed. Prescribing fewer doses of opioid will avoid excessive administration of opioid for mild pain, and it may also prompt earlier presentation of patients who may be experiencing severe pain due to a complication. Figure 2 suggests that providers would be justified in adopting a standard opioid prescription of no >8 doses, and standard prescriptions of 5 or even 3 doses for most patients would be very appropriate. Since the conclusion of this study, our institution has adopted a standard postoperative opioid prescription of 5 doses for pediatric fracture patients. This protocol is now consistently adhered to by our pediatric surgeons, but we have not yet studied adherence by other orthopaedic subspecialists who care for pediatric fractures on call. This will be an important quality improvement measure.

This study has a number of important limitations. Parental reporting of data from the preceding 1 to 2 days is susceptible to recall bias. However, by calling the caregivers of discharged patients on POD1, 3, and 5 we endeavored to minimize the effects of recall bias without the time commitment becoming onerous to participants. Parent-reported outcomes are susceptible to reporting and observer biases. However, parental reporting provided the most consistent measure of pain control in this study including children aged 1 through 17 years, and parental proxy pain scores have been shown to be a reliable surrogate, not differing significantly from patient-reported scores.<sup>14,15</sup> Selection bias is also a potential limitation, although its effects should be minimal, as all potentially eligible patients were identified consecutively and offered enrollment throughout the entire study period, and only 2 of 89 eligible patients declined to participate. The generalizability of this study may be limited by the exclusion of non-English speakers, as we did not have sufficient resources in this nonfunded study to employ an interpreter. However, our external validity is improved by the inclusion of 12% Hispanic/Latino patients whose caregivers could provide study data in English. Our results suggest that Hispanic/Latino patients may take marginally less opioid than other patients. In addition, we were not able to record a measure of patient or parent anxiety, which has been shown to influence opioid consumption.<sup>16,17</sup> This is an important consideration for these 100 families whose children suffered some degree of trauma. We did, however, exclude 3 patients with prohibitively complex social situations like family fatalities or custody battles, in which exceedingly high patient and/or parent anxiety may have affected perceptions of pain. We also did not inquire about known behavioral health problems such as autism spectrum disorders or about caretaker chronic pain or addiction. Finally, we did not collect data about immediate perioperative administration of ketorolac, local anesthesia, or regional blocks. Regional blocks are rarely if

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ever performed for pediatric fracture patients at our institution. The effects of perioperative ketorolac and local anesthetics, while helpful in the acute postoperative period, should be attenuated by the time of discharge from the hospital and certainly by POD5.

To conclude, pain is consistently well controlled in pediatric patients with operative fractures with minimal need for opioids postdischarge. At our academic center nearly all were prescribed opioids, while acetaminophen and NSAIDs were inconsistently prescribed and used. In spite of efforts to reduce overprescribing, opioid prescriptions are still written for 4 to 5 times the amount needed through POD5. When opioids are deemed necessary for these patients, prescribing no >8 doses is adequate for acute pain in 97% of patients; and poorly controlled pain should prompt early evaluation for possible complications.

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