Need for pharmacological analgesia after cast immobilisation in children with bone fractures: an observational cross-sectional study

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ABSTRACT

Background Bone fractures are a common reason for children and adolescents to seek evaluation in the ED. Little is known about the pain experienced after cast immobilisation and discharge from the ED and its optimal management. We aimed to investigate the administration of pharmacological analgesia in the first days after cast immobilisation and to identify possible influencing variables.

Methods A prospective observational cross-sectional study was conducted at the ED of the children's hospital, Institute for Maternal and Child Health of Trieste, Italy, from October 2019 to June 2020. Patients aged 0–17 years with bone fractures were included. The primary outcome was the administration of analgesia during the 10 days following discharge, while secondary outcomes were the associated variables, including age, gender, fracture type and location, the mean limitation in usual activities and the frequency of re-evaluation at the ED for pain. Data were recorded through a questionnaire, completed by caregivers and collected by the researchers mainly through a telephone interview. The primary endpoint was evaluated as the ratio between the number of children who took at least one analgesic dose and the total enrolled children, while X^2 or Fisher's exact tests were used to assess secondary outcomes.

Results During the study period, 213 patients, mean age 10 years (IQR: 8–13), were enrolled. Among them, 137 (64.3%) did not take any analgesic during follow-up. Among children who were administered analgesia, 22 (28.9%) received it only on the first day, and 47 (61.8%) for less than 5 days. One hundred and sixty one patients (75.6%) did not report any limitation in usual activities because of pain. The administration of analgesia was not related to the child's age, gender or fracture site. Displaced fractures were associated with significantly more frequent analgesia being taken (OR 5.5, 95% CI 1.4 to 21.0).

Conclusion Although some studies recommend scheduled analgesic treatment after discharge for bone fractures, this study would suggest analgesia on demand in children with non-displaced fractures, limiting scheduled analgesia to children with displaced fractures.

Key messages

What is already known on this subject

⇒ Bone fractures are a significant source of pain and a common reason for children and adolescents to seek evaluation in the ED. They are generally managed with immobilisation and analgesic therapy, consisting non-steroidal anti-inflammatory drugs and/or opioids. While previous studies have demonstrated the efficacy of scheduled analgesia after discharge from the ED, no prospective study specifically assessed the requirement for pain relief at home.

What this study adds

⇒ In this single-centre, observational study, during the 10 days following fracture cast immobilisation, 64.3% of children did not require pharmacological analgesia. Only a minority of children displayed severe functional impairment. The need for analgesia was significantly associated with the presence of a displaced fracture (OR 5.5; 95% CI 1.4 to 21.0). These results suggest that on-demand analgesia is suitable for children with non-displaced fractures, while patients with displaced fractures would likely benefit from a scheduled analgesic treatment.

INTRODUCTION

Bone fractures are a significant source of pain and a common reason for children and adolescents to access the ED. One-third of children suffer at least one fracture by age 17 years.[1]

Appropriate pain management in children is still an issue in several clinical settings,[2 3] and the harmful effects of inadequate treatment are well known.[4 5]

Only a minority of children with bone fractures require hospitalisation.[6] In most cases, fractures can be managed with immobilisation and standard analgesic therapy.[7] Several drugs are available to manage pain in children with bony injuries, including non-steroidal anti-inflammatory drugs (NSAIDs) and opioids.[8] While several studies investigated the severity of pain and the effectiveness of analgesic therapy in the ED in children with fractures,[9–12] only limited data are available on the amount of pain these children experience after cast immobilisation and discharge from the ED.[13] A single retrospective series showed that some children experienced pain and needed analgesia in the days

following discharge.[14] Based on this occurrence, two trials tested the effectiveness of scheduled administration of ibuprofen or acetaminophen in the first 3 days after discharge, finding overall low levels of pain, efficiently treated with both acetaminophen and ibuprofen[7]; interestingly in one of the studies, the 7% of the analysed sample did not take any dose of analgesic.[15] Nevertheless, there are no prospective data on the need for analgesia after cast immobilisation to children and adolescents with bone fractures.

As a result, recommendations about pain management at home mainly rely on physicians' personal experience, and risks standardised guidelines that ignore the age of the child and the type of fracture. In order to provide more specific advice to families on what to expect and how to support children, and to avoid a simplified 'one-size-fits-all' approach, a prospective study was undertaken. The aim was to investigate the need for administration of analgesia in the first 10 days following cast immobilisation and identify possible influencing variables.

METHODS

A prospective observational cross-sectional study was performed at the paediatric ED of a tertiary level, university teaching children's hospital (Institute for Maternal and Child Health, Trieste, Italy), from October 2019 to June 2020. Written informed consent for anonymous data collection was obtained from the accompanying caregivers of enrolled children.

Based on our experience, we expected that nearly half of the patients would not use any analgesic in the 10 days after cast immobilisation: thus, fixing alpha=0.05, with a precision of 7%, that is, the maximum acceptable error of the sample estimate for the proportion, the enrolment of 200 children in the study was judged necessary.[16]

Patients aged 0–17 years with bone fractures requiring cast immobilisation were considered eligible. Patients with polytrauma, pathological fractures, fractures treated with the application of either bandages or splints (including thumb spica splints or radial/ulnar gutter splints), ongoing analgesic treatment for any baseline condition or cognitive impairment were excluded. At the study institute, all children with acute traumatic musculoskeletal injuries are evaluated in the ED, and following radiological imaging, a paediatric orthopaedic consultation is requested, even for cast application.

On discharge from the ED following cast immobilisation, caregivers of participating children were provided with standardised instructions for pain management. They were advised to observe carefully for pain in their children and to administer oral ibuprofen 10 mg/kg, maximum every 8 hours as needed for pain, but they were free to administer another analgesic, according to their preference. Rescue therapy in case of ibuprofen failure was also prescribed (acetaminophen 20 mg/kg, maximum every 6 hours). Analgesic dosing for both ibuprofen and acetaminophen was chosen according to institutional guidelines and in line with international recommendations,[17] in order to provide the maximum dose of 30 mg/kg/day of ibuprofen and 80 mg/kg/day of acetaminophen, which are considered safe for children needing consecutive administrations of these drugs for several days. Families were advised to return to the ED in case of untreatable pain or any doubts regarding the cast.

A questionnaire was provided to participants, assessing the administration of analgesia and any limitation in daily activities related to pain during the day of discharge and the next 9 days. Parents were instructed to complete the questionnaire day by day. Data were obtained by collecting the questionnaire responses through a telephone survey 10 days after discharge from the ED, or collecting the questionnaire itself during the scheduled appointment to remove the cast. Children whose families could not be contacted by telephone or did not return the questionnaire at the scheduled visit were considered lost to follow-up.

The questionnaire was developed specifically for this study. It included the following items: number of analgesic drug doses administered each day, need for any other analgesic different from that prescribed, limitation in the child's daily activities related to pain (sleeping, eating, playing and school attendance—beyond restricted participation in Physical Education or any other school activity) and the need for further re-evaluation at the ED for fracture-related pain. Limitation of a child's daily activities was assessed through the caregivers' judgement using a Likert scale with four levels of limitation marked from none to complete. Limitation was not evaluable for activities that were not suitable for that child at baseline (eg, school attendance for preschool-aged patients), or were limited by factors different from the fracture itself (eg, concurrent infection or school closure).

The study's primary outcome was the administration of analgesia in children with cast immobilisation for fractures in the 10 days following discharge from the ED.

Secondary outcomes were the variables associated with analgesia administration at home, including age, gender, fracture type and location, mean limitation in usual activities and frequency of re-evaluation at the ED for pain.

Continuous variables were reported as median and IQR, while categorical variables were recorded as numbers and percentages. The primary endpoint was evaluated as the ratio between the number of children who took at least one analgesic dose in the first 10 days following discharge and the total enrolled children. X^2 or Fisher's exact tests were used to determine the association between the administration of analgesia and gender, fracture type and site. Wilcoxon Mann-Whitney non-parametric test evaluated the difference in age distribution between those who did take and who did not take analgesics. A logistic regression model was applied to assess the administration of analgesia in the first 10 days following ED discharge. All independent variables were included in the multivariable model and selected through a stepwise method, adjusting the model by age and gender. Statistical analysis was conducted using SAS software, V.9.4 (SAS Institute).

Patient and public involvement

No patient or parental involvement was sought.

RESULTS

Two hundred and fifty-five patients were considered for participation in the study. Three children were excluded due to the presence of exclusion criteria (two had pathological fractures and one was receiving an analgesic treatment for a chronic condition), and in two cases the parents declined participation in the study. Therefore, a total of 250 children were enrolled. The telephone survey was performed on 198 patients (79.2%). Fifteen completed questionnaires were returned at the scheduled orthopaedic appointment for cast removal. Thirty-five (14.0%) patients could not be contacted by telephone and did not return the completed questionnaire on the scheduled visit. Thus, a total of 37 (14.8%) patients were lost to follow-up, with data from 213 children (85.2%) available for analysis (figure 1).

The median age of the enrolled patients was 10 years (IQR: 8–13 years). One hundred thirty-one (61.5%) were male. The

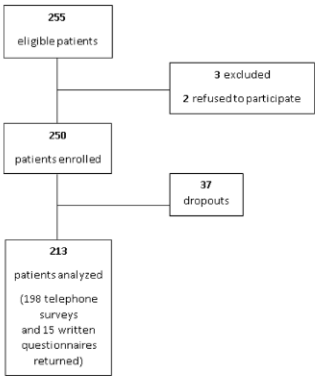

Figure 1 Summary of participant flow. Three children were excluded (two pathological fractures, one receiving analgesic treatment for a chronic condition). Thirty-seven patients were lost to follow-up.

type and site of fractures are presented in table 1. Two hundred one (94.4%) fractures were non-displaced and 12 (5.6%) were displaced, that is, requiring manual reduction before cast immobilisation.

Figure 2 summarises the trend in the number of analgesic doses administered during the days of follow-up.

During follow-up, 137 (64.3%, 95% CI 57.9% to 70.7%) children were not administered any analgesic and 76 (34.7%) received at least one dose of analgesia. Among children who were administered analgesia, 22 (28.9%) received it only on the first day, and 47 (61.8%) for less than 5 days. Four children (5.3%) received medication for more than 5 days. When analgesia was administered, the median number of daily doses was 2 (IQR 1–4). Fifty (65.8%) children were administered ibuprofen, while 24 patients (31.6%) used acetaminophen and 2 (2.6%) ketoprofen.

Table 1 Distribution of children who received and did not receive analgesia

	Children who received analgesia	Children who did not receive analgesia	Total	P value
Patients, n (%)	76 (34.7)	137 (64.3)	213	
Age years, median (IQR)	11 (8.5–14)	10 (7–13)	10 (8–13)	0.16
Female, n (%)	27 (35.5)	55 (40.2)	82 (38.5)	0.51
Site of fracture, n (%)				0.34
Arm	32 (42.1)	42 (30.7)	74 (34.7)	
Hand	24 (31.6)	46 (33.6)	70 (32.9)	
Leg	13 (17.1)	30 (21.9)	43 (20.2)	
Foot	7 (9.2)	19 (13.9)	26 (12.2)	
Fractured bone, n (%)				
Humerus	4 (5.3)	7 (5.1)	11 (5.2)	1.00*
Humerus+radius	–	1 (0.7)	1 (0.5)	1.00*
Radius	13 (17.1)	20 (14.6)	33 (15.5)	0.63
Radius+ulna	14 (18.4)	8 (5.8)	22 (10.3)	0.004
Ulna	1 (1.3)	6 (4.4)	7 (3.3)	0.43*
Scaphoid	5 (6.6)	6 (4.4)	11 (5.2)	0.49
Trapezium	1 (1.3)	–	1 (0.5)	0.36*
Sesamoid	–	1 (0.7)	1 (0.5)	0.46*
Metacarpal	4 (5.3)	10 (7.3)	14 (6.6)	0.77*
Hand finger phalanx	14 (18.4)	29 (21.2)	43 (20.2)	0.63
Femur	–	2 (1.5)	2 (0.9)	0.54*
Patella	1 (1.3)	1 (0.7)	2 (0.9)	1.00*
Tibia	6 (7.9)	5 (3.6)	11 (5.2)	0.18
Fibula	6 (7.9)	23 (16.8)	29 (13.6)	0.07
Calcaneus	–	1 (0.7)	1 (0.5)	0.46*
Navicular	–	1 (0.7)	1 (0.5)	0.46*
Cuneiform	1 (1.3)	–	1 (0.5)	0.36*
Metatarsal	6 (7.9)	16 (11.7)	22 (10.3)	0.48
Type of fracture, n (%)				0.01*
Non-displaced	67 (88.2)	134 (97.8)	201 (94.4)	
Displaced	9 (11.8)	3 (2.2)	12 (5.6)	

*Fisher's exact test.

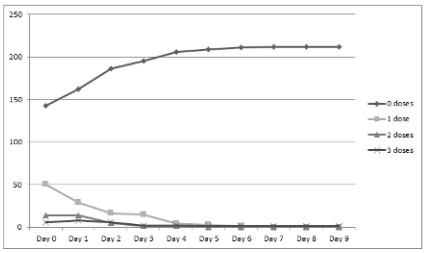

Figure 2 Distribution of children according to the number of analgesic drug doses received during each day after cast immobilisation (n=213).

Figure 3 summarises the entity of impairment in usual activities during follow-up. No limitation was reported for 161 (75.6%) patients. Any reported impairment showed a progressive improvement day after day.

Six children were re-evaluated in ED due to pain: four underwent cast replacement, while in two cases the previous instructions on analgesia were confirmed.

Between children who were and were not administered analgesia, there was no difference in age, gender and fracture site. Adjusting for age and sex, a strong association between receiving analgesia and type of fracture was found for displaced fracture versus non-displaced fracture (OR 5.5; 95% CI 1.4 to 21.0). Figure 4 shows the day-by-day distribution of children who did not take analgesics according to the presence or absence of fracture displacement.

DISCUSSION

To date, few studies have examined the need for analgesia after fracture reduction and immobilisation in children. In our prospective study, we found that after cast immobilisation, only a minority of children were administered analgesia or displayed a limitation in baseline activities. Among those who required medication, it was rare for analgesia to be given after 5 days. Median duration of analgesia was 2 days. The vast majority of patients used ibuprofen, as recommended by the clinician, while only a few children received other analgesic drugs, namely acetaminophen and ketoprofen. Few patients sought re-evaluation in the ED for pain and the clinical characteristics of these children did not differ from those of the remaining population. The need for analgesia was associated with the type of fracture, but not age, site or gender.

In two previous clinical trials, shedding some light on the need for analgesia by comparing medication usage in children, parents were allowed to administer pain medication as needed. A randomised controlled trial by Poonai and colleagues, comparing ibuprofen and oral morphine in children with fracture after discharge,[18] found that 26.8% of enrolled patients did not take any analgesic, as the pain was not severe enough to require treatment. Drendel and colleagues compared the efficacy of ibuprofen and acetaminophen with codeine in children with arm fractures during the first 3 days after discharge from the ED and found that 7% did not take any dose of analgesic; among those who took at least one dose, the median number of doses

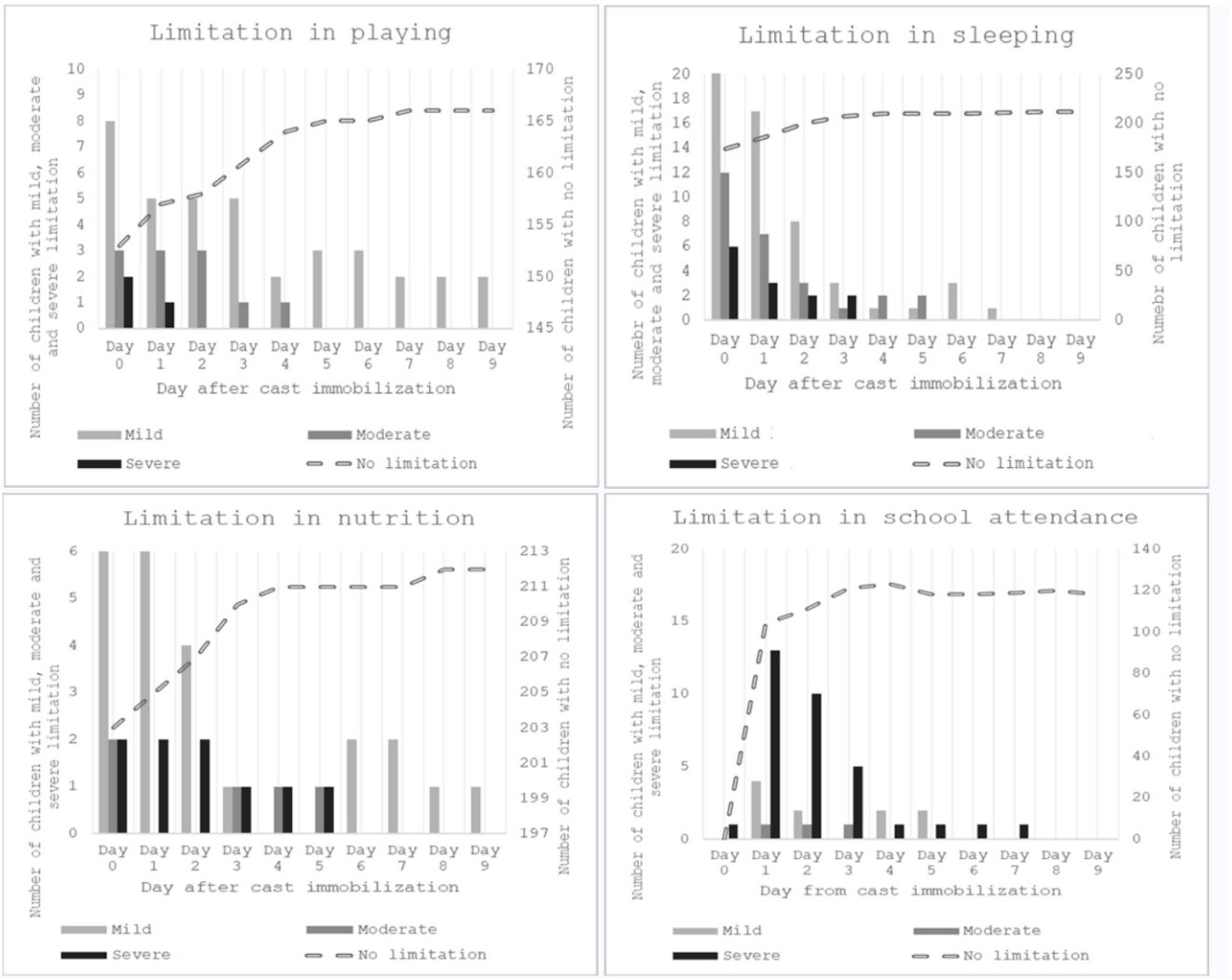

Figure 3 Limitation in usual daily activities during follow-up.

administered was 4.[15] The same study also demonstrated that the degree of functional impairment significantly decreased from the day of the injury to the third following day (60% vs 29.4%). An earlier retrospective study by Drendel and colleagues[14] specifically addressed the administration of as-needed analgesia and the degree of functional impairment in children with isolated extremities fractures, and therefore provides results more comparable with our findings. The present study, however, differs from these prior studies as it specifically addresses the need for analgesia prospectively.

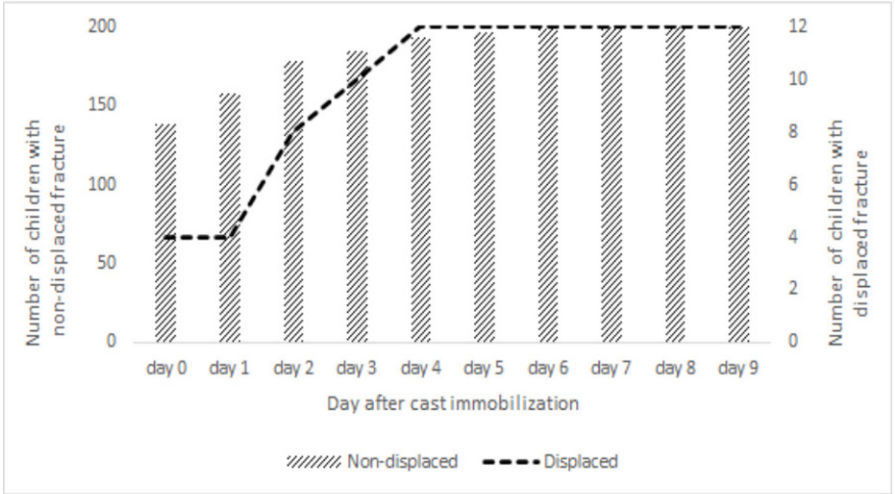

Figure 4 Distribution of children who did not take analgesics according to the presence or absence of bone displacement.

The proportion of children receiving analgesia and the frequency of limitations in the present study cohort was lower, compared with both studies by Drendel and colleagues[14 15] and the study by Poonai and colleagues[18] (34.7 vs 93%, 93.9% and 73.2%, respectively). In the subgroup of children who received at least one analgesic dose in this study, the median duration of analgesia administration was 2 days, consistent with the study by Drendel and colleagues.[14] However, the median number of analgesic doses administered in children who received analgesia was 2, whereas in the studies by Drendel and colleagues it varied from 4[15] to 5.[14] This difference does not appear to be due to the proportion of patients with displaced fractures which was similar across studies (5.6% in this study vs 6.7% in the previous study).[14] Neither of the two studies showed any difference in the need for administration of analgesia by fracture site although in the study by Drendel and colleagues, children with fractures of the lower limbs displayed higher frequency of impairment rate.[14]

The limitation in baseline activities was also lower than in Drendel and colleagues' study[14]: sleep was reported as reduced in 19.7% of patients in this study vs 44.7%; school attendance was limited in 8.4% of the enrolled children vs 28.8%; play activities were affected in 6.6% of cases vs 59.2%, and feeding was impaired in 4.7% of patients vs 16.2%.

Although undertreatment of pain in children has undoubtedly been a relevant issue in previous decades, the risks of overtreatment, related to a non-evidence-based approach, should not be underestimated.

In this study, most of the enrolled children benefited from ibuprofen or acetaminophen, confirming previous findings on the effectiveness of NSAIDs on musculoskeletal pain from traumas or fractures.[8] A well-fitted cast likely contributed to pain relief by decreasing movement and the risk of minor trauma. While several guidelines and discharge instructions advise regular pain relief to 'get ahead of the pain',[2] this study suggests that a scheduled analgesic treatment should be reserved for children with displaced fractures.

LIMITATIONS

This study has some limitations. A possible source of bias was the manner of data collection, consisting of a telephone survey and a written questionnaire, to which patients, caregivers, or child-led parents responded and were subjected to recall bias. Furthermore, the questionnaire we used to collect the data was specifically developed for the purpose of the study and not validated. Although several validated questionnaires exist to investigate the degree of disability and the quality of life in the paediatric population, we preferred to provide families with a brief tool, summarising the questions addressing both the disability and the analgesics administration, in order to facilitate the completion of the questionnaire during each day of follow-up.

In the study hospital, plaster casting is performed by paediatric orthopaedics rather than ED staff, and children with torus and buckle fractures are cast. Both these practices may have influenced the study results, decreasing the number of children needing pharmacological analgesia. While we did not assess children's self-reported pain, the administration of analgesics at home largely depended on parental choice, and we did not consider the number of analgesic doses administered in the ED. Finally, we were not able to analyse data from the children who were lost to follow-up, so we cannot rule out a possible selection bias.

The lack of pain measurement was undoubtedly a significant limitation, and it can be speculated that some of these children may have experienced pain that has not been adequately assessed and treated. However, it should be considered that in this study, the impairment rate was consistently lower than that reported by the only retrospective study of children receiving scheduled treatment,[15] suggesting that even when present, pain would not have been severe. Remarkably, in this study, parents were alerted and made aware of pain issues, and generally Italian children have been reported to overexpress their pain.[19] From a pragmatic perspective, we assumed that the administration of analgesics and the limitation of daily activities acted as the best proxy measures to detect the presence of pain in our population.

This study was not designed to provide information about the use of pharmacological analgesia in single sites of fractures according to the presence or absence of bone displacement. Future studies are needed to clarify this issue.

CONCLUSION

Although previous studies recommend scheduled analgesic administration during the days following a fracture,[7] our findings suggest that this could be reserved to patients with displaced fractures, while children with non-displaced fractures would equally benefit from on-demand pharmacological analgesia.

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Contributors GC conceptualised and supervised the work and is the guarantor of the work. DD, MR, VDC and MRLG recruited participants. AB performed patients' follow-up and collected the questionnaires. MG was responsible for the statistical analysis of data. LCW wrote the first draft of the manuscript. EB revised and edited the final version of the manuscript. All the authors approved the final version of the manuscript and take full responsibility for its contents.

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