

COMPARISON OF PARACETAMOL AND IBUPROFEN FOR THE ACUTE TREATMENT OF MIGRAINE IN CHILDREN AGED 6-12 YEARS

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Abstract

Background: Migraine is a prevalent condition in pediatric populations, significantly affecting quality of life. While various treatment options are available, the efficacy and safety of commonly used analgesics like paracetamol and ibuprofen remain debated.

Objective: This study aims to compare the effectiveness and safety of paracetamol and ibuprofen in the acute treatment of migraine in children aged 6-12 years.

Material and Methods: A total of 60 pediatric patients diagnosed with acute migraine were included in this prospective study conducted in the Department of Pediatrics at a tertiary care hospital. Patients were randomly assigned to receive either paracetamol (15 mg/kg) or ibuprofen (10 mg/kg). The primary outcome was the reduction in pain intensity measured on a visual analogue scale (VAS) after 2 hours. Secondary outcomes included side effects and the need for rescue medication.

Results: Ibuprofen was found to be significantly more effective than paracetamol in reducing pain intensity. Side effects were minimal and comparable between both groups.

Conclusion: Ibuprofen is more effective than paracetamol for the acute treatment of migraine in children aged 6-12 years, with a favorable safety profile.

Keywords: Migraine, Paracetamol, Ibuprofen, Pediatrics, Acute Treatment.

Introduction

Migraine is a common neurological disorder in children, characterized by recurrent attacks of moderate to severe headache, often accompanied by nausea, vomiting, and sensitivity to light and sound (1). According to the International Classification of Headache Disorders, migraines can begin in childhood, with a prevalence that increases with age, affecting approximately 5% of children aged 6 to 12 years (2). The impact of migraines on children's daily activities, academic performance, and overall quality of life can be substantial, necessitating effective treatment strategies.

Acute treatment of migraine attacks often involves the use of over-the-counter analgesics such as paracetamol (acetaminophen) and ibuprofen, a non-steroidal anti-inflammatory drug (NSAID). Both medications are commonly used in pediatric

populations; however, there is limited evidence regarding their comparative effectiveness in treating migraines in children.

Paracetamol is generally considered a first-line treatment for mild to moderate pain due to its analgesic and antipyretic properties (3). On the other hand, ibuprofen, with its anti-inflammatory effects, may provide additional benefits in pain relief due to its mechanism of action (4). Given the differences in pharmacodynamics and pharmacokinetics, this study aims to evaluate and compare the efficacy and safety of paracetamol versus ibuprofen for the acute treatment of migraine in children aged 6 to 12 years.

Aim and Objectives

Aim: To compare the effectiveness and safety of paracetamol and ibuprofen for the acute treatment of migraine in children aged 6-12 years.

Objectives:

1. To evaluate the reduction in pain intensity after 2 hours of treatment with either paracetamol or ibuprofen.
2. To assess the occurrence of side effects associated with each medication.
3. To determine the need for rescue medication after initial treatment.

Material and Methods

Study Design

This prospective randomized controlled trial was conducted in the Department of Pediatrics at a tertiary care hospital. Ethical approval was obtained from the hospital's institutional review board, and informed consent was collected from the parents or guardians of all participating children.

Participants

A total of 60 children aged 6 to 12 years who presented to the emergency department with acute migraine attacks were included in the study. Diagnosis was confirmed based on clinical criteria set by the International Classification of Headache Disorders (5).

Inclusion Criteria:

- Children aged 6-12 years.
- Diagnosis of acute migraine.
- Parental consent to participate in the study.

Exclusion Criteria:

- Children with contraindications to paracetamol or ibuprofen.
- Patients with a history of chronic headaches or secondary headaches.

- Patients receiving any prophylactic migraine treatment.
- Significant comorbid conditions affecting pain perception or treatment response.

Randomization and Treatment Protocol

Eligible participants were randomly assigned to receive either paracetamol (15 mg/kg, maximum dose 1000 mg) or ibuprofen (10 mg/kg, maximum dose 600 mg) as the initial treatment. Randomization was achieved using a computer-generated randomization list, ensuring blinding of the outcome assessors.

Data Collection

Clinical Assessment:

- Pain intensity was assessed using a 10-point visual analogue scale (VAS), where 0 indicates no pain and 10 indicates the worst pain imaginable.
- Pain intensity was recorded at baseline (before treatment) and at 2 hours post-treatment.

Side Effects:

- Side effects were monitored for 2 hours following treatment, including gastrointestinal disturbances, drowsiness, and any allergic reactions.

Rescue Medication:

The need for rescue medication (e.g., oral triptans) was recorded if pain relief was inadequate at the 2-hour assessment.

Statistical Analysis

Data were analyzed using statistical software. Descriptive statistics were used to summarize demographic characteristics. The difference in pain intensity between the two groups was evaluated using independent t-tests. The occurrence of side effects and the need for rescue medication were compared using chi-square tests. A p-value of <0.05 was considered statistically significant.

Results

Table 1: The demographic characteristics of the study population.

Characteristic	n (%)
Age (years)	
6-8 years	20 (33.3)
9-10 years	25 (41.7)
11-12 years	15 (25.0)
Male	30 (50.0)
Female	30 (50.0)
Duration of migraine	
Less than 24 hours	45 (75.0)
More than 24 hours	15 (25.0)

Table 1 provides an overview of the demographic characteristics of the study participants. The population was evenly split between males and females, with a majority aged between 9 and 10 years. Most children experienced migraines for less than 24 hours prior to treatment.

Table 2: The pain intensity reduction in both groups after 2 hours.

Group	n	Mean Pain Score at Baseline (\pm SD)	Mean Pain Score at 2 Hours (\pm SD)	Mean Reduction (\pm SD)	p-value
Paracetamol	30	7.8 \pm 1.2	4.5 \pm 1.3	3.3 \pm 1.5	<0.01
Ibuprofen	30	7.9 \pm 1.3	2.5 \pm 1.1	5.4 \pm 1.2	<0.01

Table 2 displays the pain intensity scores at baseline and after 2 hours for both treatment groups. Children receiving ibuprofen showed a significantly greater reduction in pain intensity compared to those treated with paracetamol, with a mean pain score reduction of 5.4 \pm 1.2 in the ibuprofen group versus 3.3 \pm 1.5 in the paracetamol group ($p < 0.01$).

Table 3: The occurrence of side effects and need for rescue medication.

Parameter	Paracetamol Group (n = 30)	Ibuprofen Group (n = 30)	p-value
Side Effects			
Gastrointestinal disturbances	2 (6.7%)	1 (3.3%)	0.66
Drowsiness	1 (3.3%)	2 (6.7%)	0.66
Allergic reactions	0 (0%)	1 (3.3%)	0.31
Need for Rescue Medication	6 (20.0%)	2 (6.7%)	0.04

Table 3 outlines the side effects experienced by patients in each treatment group. The incidence of side effects was low and comparable between the two groups. However, there was a significant difference in the need for rescue medication, with 20% of the paracetamol group requiring additional treatment compared to only 6.7% in the ibuprofen group ($p = 0.04$).

Discussion

The results of this study indicate that ibuprofen is significantly more effective than paracetamol in reducing pain intensity in children aged 6 to 12

years experiencing acute migraine attacks. This finding is consistent with previous studies that have compared the effectiveness of various analgesics for pediatric migraines (6).

Migraine is a complex disorder, and its management often requires a multimodal approach. The use of over-the-counter analgesics is common, but the efficacy can vary among individuals. Our study's results suggest that ibuprofen, with its anti-inflammatory properties, may provide superior pain relief compared to

paracetamol, which primarily acts as an analgesic and antipyretic (7).

The low incidence of side effects in both treatment groups further supports the safety of these medications in pediatric patients. Our findings align with those of previous studies indicating that both paracetamol and ibuprofen are generally well-tolerated in children (8).

The need for rescue medication was significantly lower in the ibuprofen group, suggesting that patients receiving ibuprofen experienced greater satisfaction with their initial treatment. This is particularly relevant in a clinical setting, as reducing the need for additional interventions can enhance patient comfort and improve overall treatment outcomes (9).

Limitations

This study has some limitations. The sample size, although adequate for preliminary comparisons, may not capture the full spectrum of response variability among pediatric patients with migraines. Additionally, the single-center design may limit the generalizability of the findings to other pediatric populations. Future studies should consider larger, multi-center cohorts to validate these findings.

Conclusion

In conclusion, ibuprofen demonstrates superior efficacy compared to paracetamol for the acute treatment of migraine in children aged 6 to 12 years, with a comparable safety profile. The significant reduction in pain intensity and lower need for rescue medication in the ibuprofen group

suggests that it may be a preferred option for managing acute migraine attacks in this age group.

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