



# Paracetamol vs Ibuprofen for the Acute Treatment of Migraine Headache in Children: A Randomized Controlled Trial



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## AIM

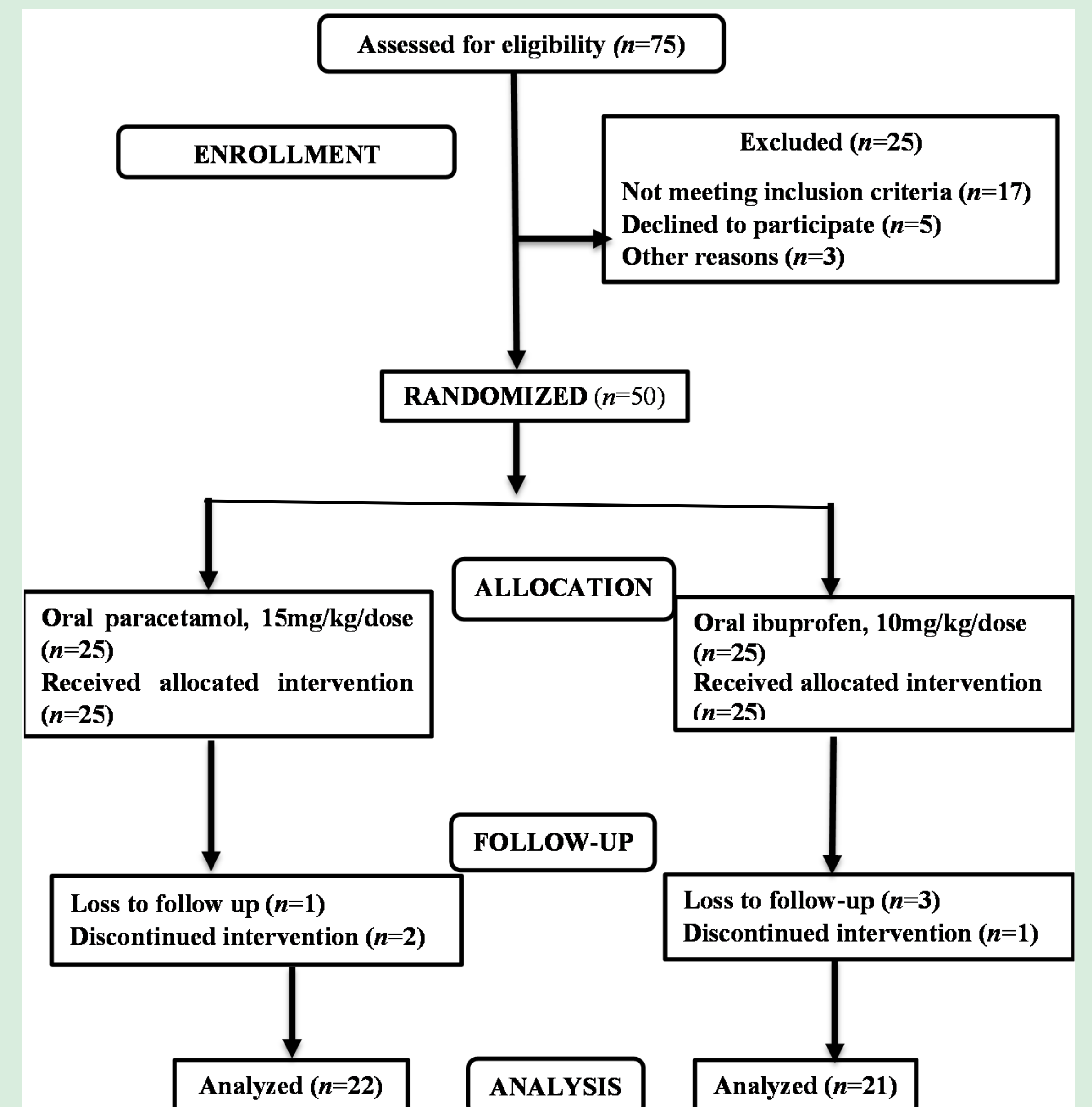
To compare the Efficacy of oral Paracetamol and oral Ibuprofen for acute treatment of migraine headache in children.

## OBJECTIVE

To compare the number of children achieving Pain-freedom at 2 hours after either oral Paracetamol or Ibuprofen for acute treatment of migraine headache.

## METHODS

- **Methods:** We included 50 children (aged 6 to 12 years) with Migraine without aura as per International Classification for Headache Disorders (ICHD-3) criteria, after IEC clearance and informed written consent. Patients were randomized by block randomization to the two study groups, with one group (n=25) receiving oral paracetamol and the other group (n=25) oral ibuprofen, at home, during an episode of acute migraine headache.
- The study drugs were dispensed in a blinded fashion, and the outcome assessor and the statistician were unaware of the group allocation.
- Pain-freedom (score of zero in an 11-point Visual analogue pain scale) and Pain-relief ( $\geq 2$  point reduction from baseline in 11-point VAS) two hours after the study drug were the main outcome measures.
- All analyses were Intention-to-treat.



## RESULTS

- 43 children (22 PCM group, 21 IBP group)
- Similar at baseline (Table 1)

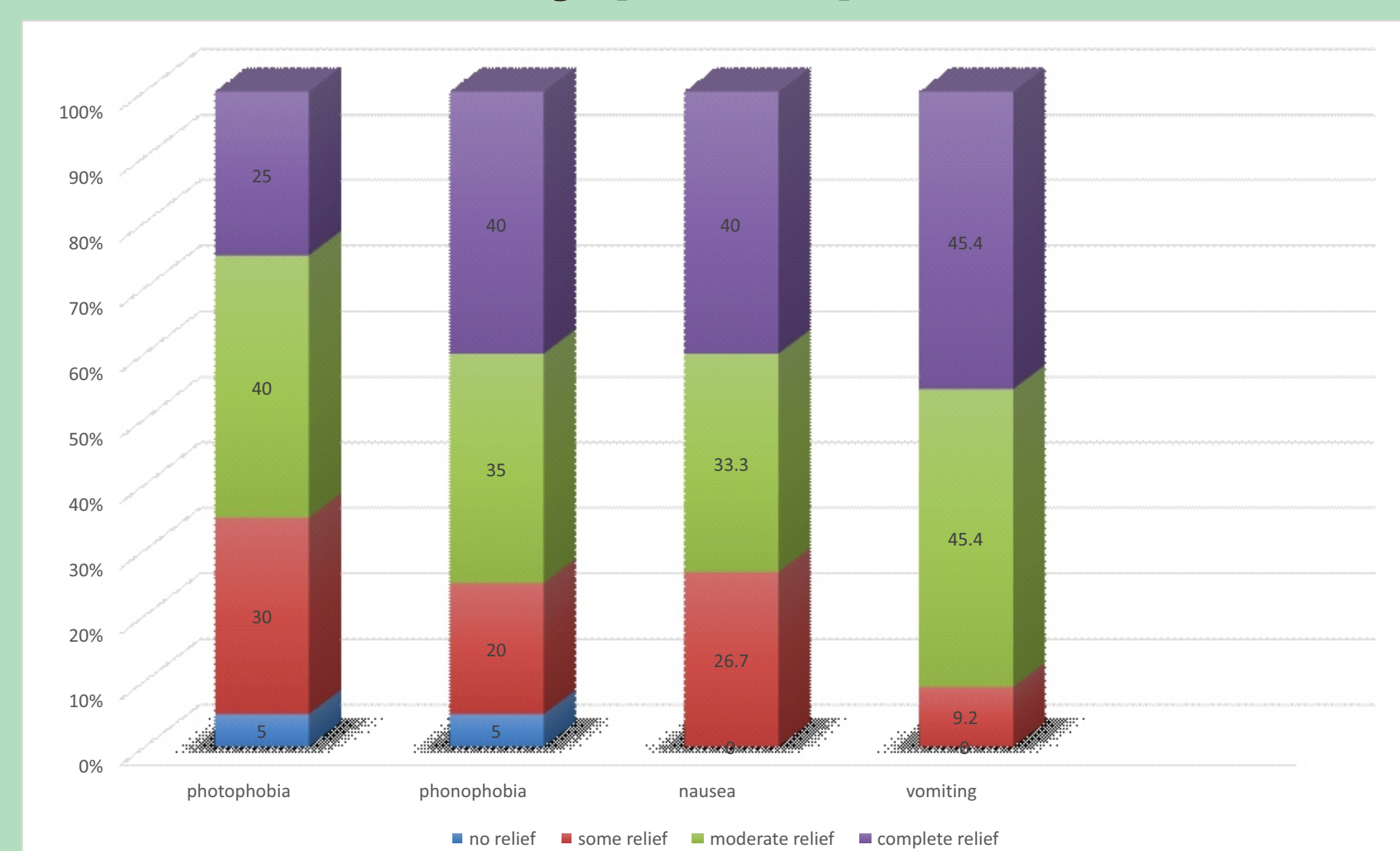
### 2-hour after the study drug

- 15 (34.9%) children achieved Pain-freedom
- 40 (93%) children achieved pain-relief.
- 10 (23.2%) had a mild drug side-effect

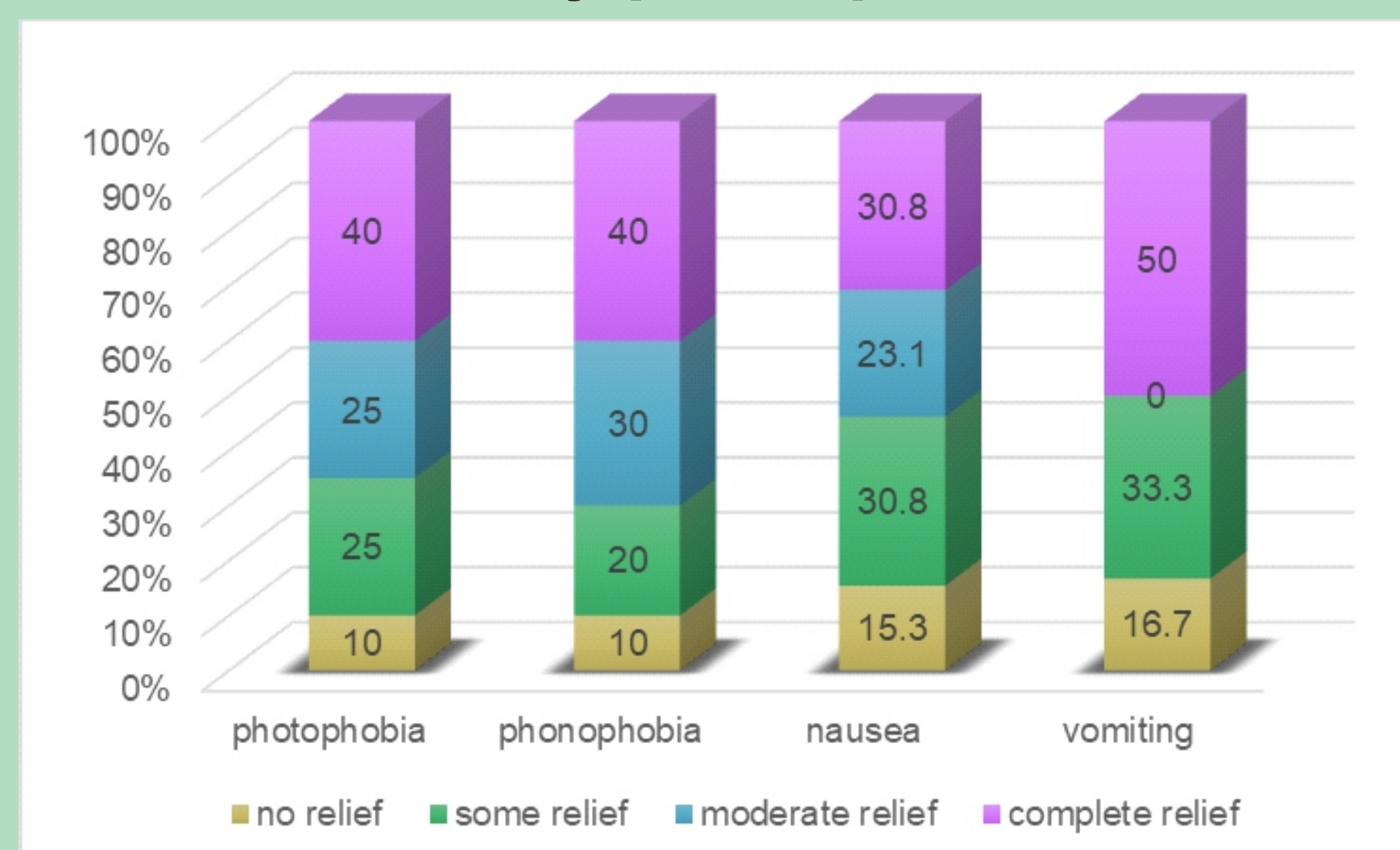
Paracetamol vs. Ibuprofen: Similar Outcomes (Table 2)

- Pain-freedom (32% vs 28%, P=0.77)
- Pain-relief (80% vs 80%, P=0.86)
- Drug side-effects (13.6% vs 33.3%; P=0.11)

### Effect of Ibuprofen on the associated symptoms among study participants.



### Effects of the Paracetamol on the associated symptoms among study participants



### Drug side-effects reported by the study participants (N=43)

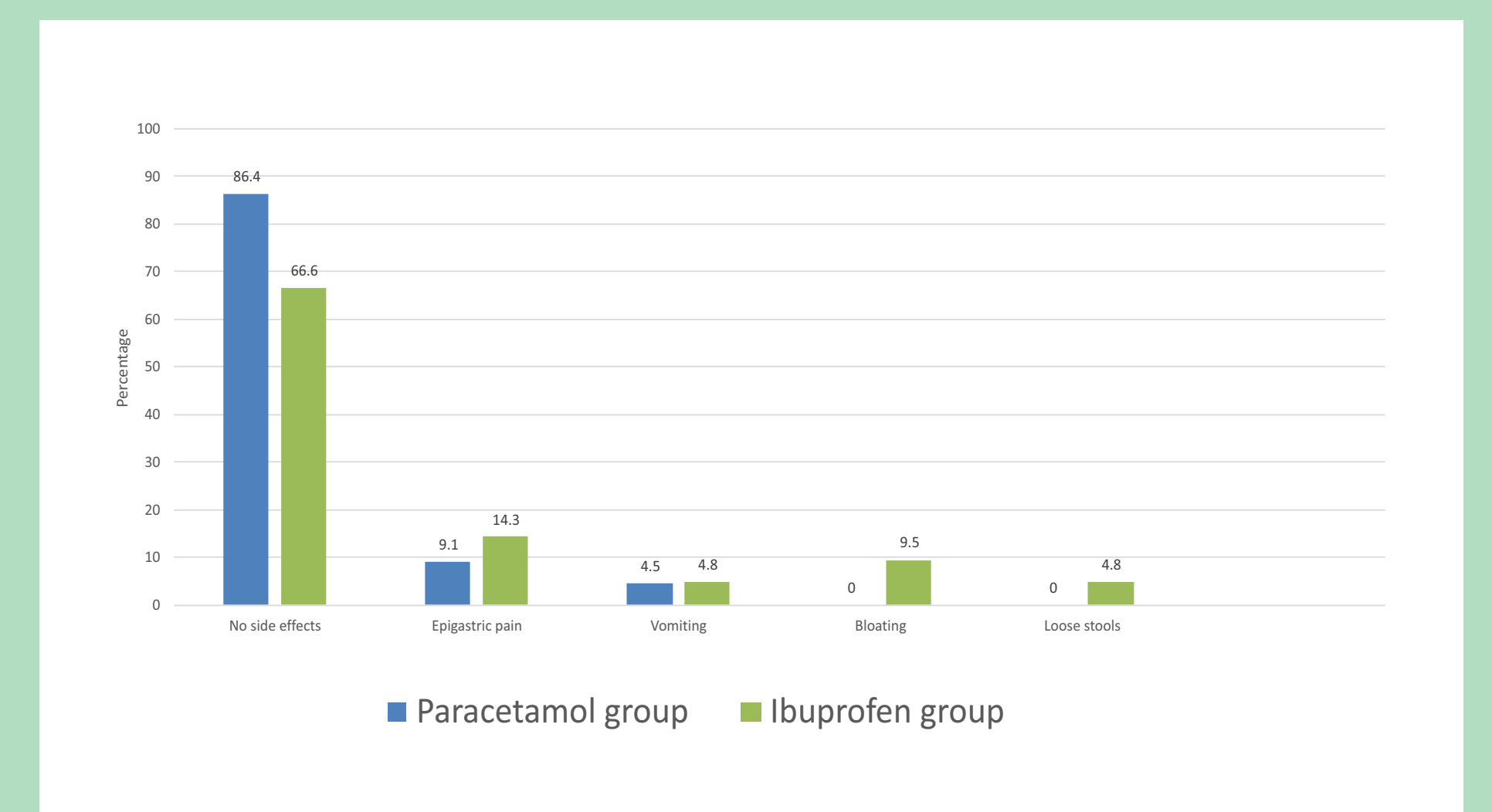


Table I Baseline Characteristics of the Study population (N=50)

Characteristics	Paracetamol group (n=25)	Ibuprofen group (n=25)	P value
Female gender, no. (%)	12 (48)	9 (36)	0.10
Age, y, mean (SD)	9.9 (1.56)	9.8 (1.59)	0.82
Disease characteristics			
Disease duration, mo	12 (8,24)	12 (8,24)	0.19
Episodes in last month	4 (3,5.75)	4 (3,5)	0.19
Headache location <sup>†</sup> , no. (%)			
B/ B/L temporofrontal	14 (56)	15 (60)	0.89
U/ U/L temporofrontal	10 (40)	10 (40)	
°O Occipital <sup>‡</sup>	1 (4)	0	
Duration of each episode, h	5.5 (3.5,8)	6 (3,8)	0.66
No. of school absences <sup>§</sup> , d	1.5 (1,2)	1 (1,2)	0.39
Family history, no. (%)	5 (20)	6 (24)	0.87
Associated features <sup>@</sup> , no. (%)			
Photophobia & Phonophobia	23 (92)	24 (96)	0.62
Nausea	14 (56)	17 (68)	0.40
Vomiting <sup>&amp;</sup>	6 (24)	12 (48)	0.09

All values are in median (IQR), unless otherwise specified; <sup>†</sup>Location of headache in a typical episode; <sup>‡</sup>Co-occurring with bitemporal headache; <sup>§</sup>In the last 3 months; d=days, h=hours; mo=months; <sup>@</sup>Many children had more than one associated symptoms; <sup>&</sup>All patients with vomiting also had associated nausea.

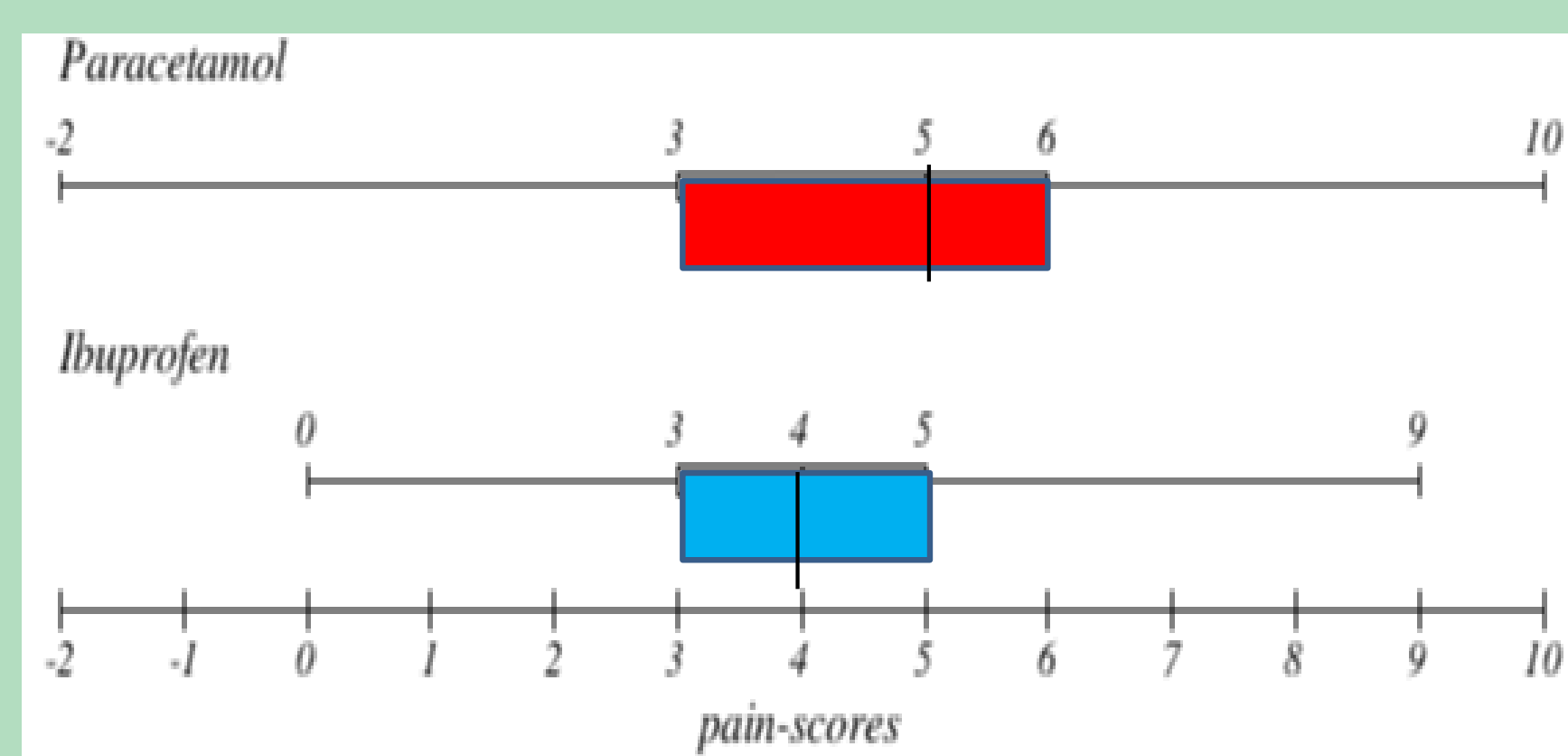


Fig. 2 Box-plot showing median difference in pain scores after the study intervention in the two groups

Table II Outcome after the Study Drug (N=43)

Outcome	Paracetamol group, No. (%), n=22	Ibuprofen group, No. (%), n=21	Total, No. (%), N=43	P-value
Pain-freedom	8 (36.4)	7 (33.3)	15 (34.9)	0.88
Pain-relief <sup>#</sup>	20 (90.9)	20 (95.2)	40 (93)	0.80
No relief	2 (9.1)	1 (4.8)	3 (7)	
Photophobia n=20, n=20, n=40				
Some relief	5 (25)	6 (30)	11 (27.5)	0.61
Moderate relief	5 (25)	8 (40)	13 (32.5)	
Complete relief	8 (40)	5 (25)	13 (32.5)	
Phonophobia n=20, n=20, n=40				
Some relief	4 (20)	4 (20)	8 (20)	0.94
Moderate relief	6 (30)	7 (35)	13 (32.5)	
Complete relief	8 (40)	8 (40)	16 (40)	
Nausea n=13, n=15, n=28				
Some relief	4 (30.8)	4 (26.7)	8 (28.7)	0.35
Moderate relief	3 (23.1)	5 (33.3)	8 (28.2)	
Complete relief	4 (30.8)	6 (40)	10 (35.4)	
Vomiting n=6, n=11, n=17				
Some relief	2 (33.3)	1 (9.2)	3 (21.2)	0.21
Moderate relief	0	5 (45.4)	5 (22.7)	
Complete relief	3 (50)	5 (45.4)	8 (47.7)	
Drug side-effects n=3, n=7, n=10				
Epigastric pain	2 (9.1)	3 (14.3)	5 (11.7)	0.11
Vomiting	1 (4.5)	1 (4.8)	2 (4.6)	
Bloating	0	2 (9.5)	2 (4.7)	
Loose stools	0	1 (4.8)	1 (2.4)	

<sup>#</sup> Including children who had achieved pain-freedom

## CONCLUSION

BOTH PARACETAMOL AND IBUPROFEN MAY BE CONSIDERED EQUI-EFFICACIOUS AS FIRST-LINE DRUGS IN THE TREATMENT OF AN ACUTE MIGRAINE ATTACK IN CHILDREN