Section: Pediatrics

Original Research Article

A RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFICACY AND ACCEPTABILITY OF PARACETAMOL AND MEFENAMIC ACID IN PAEDIATRIC PATIENTS WITH FEVER

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ABSTRACT

Background: Fever is a common symptom of childhood illness, accounting for 19% to 30% of Paediatric emergency visits. Although fever might be a beneficial physiological response to the infectious process, it can lead to irritability among children and anxiety among the parents. Antipyretics drugs are the main form of treatment, to inhibit the synthesis of prostaglandins, thereby causing less stimulation of the temperature set point in the hypothalamus.

Objectives

1. To compare the efficacy of Paracetamol and Mefenamic acid in children aged 1-14years with fever.
2. To compare the ease of acceptance of Paracetamol and Mefenamic acid.

Materials and Methods: The study was a randomized controlled trial carried out on children admitted in BIMS Belagavi in the department of Paediatrics for one year between January 2019 – December 2019. Children aged from 1 yrs to 14 yrs were randomized into two groups by computer generated random number table, as group A comprising of 200 patients and group B comprising of 200 patients. Group A received Paracetamol 15mg/kg and Group B had received Mefenamic acid 6.5mg/kg. In both groups, initial body temperature, heart rate and respiratory rate were recorded. The patient is being onitored at 1st hour, 4th hour, and 6th hour with the parameters like temperature, heart rate, and respiratory rate. The ease of acceptance of drugs is assessed if the child had more than 2 episodes of vomiting within 30 minutes of administration.

Results: The response for treatment was seen in both groups and the response was seen faster in patients treated with mefenamic acid compared to paracetamol and the difference was statistically significant.

Conclusion: Based on our findings, we conclude that Mefenamic Acid is the better antipyretic as in-terms of their efficacy and tolerability in pediatric patients with fever.

Keywords: Antipyretic drug, Fever, Mefenamic acid, Vomiting

INTRODUCTION

Fever is a physiologic mechanism with beneficial effects in fighting infection and it is not associated with long-term neurologic complications.[1] The only purpose for treating fever in children must be to relieve the child's discomfort and not to lower the body temperature.[2]

Infectious fever develops in a characteristic sequence of steps starting with the appearance of the pathogenic agent, the "exogenous pyrogen," that is, from outside the organism, in the afflicted host. This exogenous pyrogen, in turn, causes the release of

fever producing substances by the host's polymorphonuclear leukocytes, the "endogenous pyrogens".[3,4] These were eventually identified as belonging to a family of relatively small polypeptides now denominated "cytokines." Predominant among these originally, are interleukin (IL)-1β, IL-6, tumor necrosis factor-α (TNF-α), and the interferons (IFNs).[5,6] These putative endogenous pyrogens are then transported by the bloodstream to the preoptic-anterior hypothalamic area(POA), the brain region in which fever is generated by an action of locally elaborated prostaglandin E2 (PGE2) on neurons within the central thermoregulatory circuitries.[7,8] Preoptic PGE2 is therefore often also assessed as a central corollary of the temperature rise.

Most paediatricians agree that treatment of a febrile child with antipyretics is mostly for the relief of the symptoms of fever. Antipyretics are the main form of treatment to inhibit the synthesis of prostaglandins, thereby causing less stimulation of temperature set point in the hypothalamus,[9] by also being analgesics, lead to an improvement in the children's level of activity and alertness. This is perhaps the main reason why antipyretics have maintained their popularity among parents and have continued in use for over a century.[10,11]

Antipyretics like Paracetamol, Ibuprofen, Mefenamic acid are the NSAID's used for treatment of fever in children. They inhibit cyclooxygenase (COX) which catalyzes the conversion of arachidonic acid to prostaglandin E2. This reduction of prostaglandin E2 in the brain is believed to lower the hypothalamic set point.

With the decrease in the use of Paracetamol as antipyretic in some of the paediatric patients and increase in the use of Mefenamic acid, the study is being undertaken to recommend better drug among both antipyretics by comparing the efficacy and acceptability of both these drugs.

MATERIALS AND METHODS

This Randomized controlled trial was conducted among children attending in Patient Dept. in Belgaum Institute of Medical Sciences at Belgaum over a period of one year from January 2019 to December 2019. Study place: Paediatrics dept., BIMS, Belgaum, Karnataka. Study period was 12 months.

Sample size: 264 cases, No. Of samples studied: 400 cases

Sample design: Samples selected were randomized into two groups according to computer generated random number chart.

Inclusion Criteria

- Children aged 1 year to 14 years with fever attending IPD.
- Children with documented fever (axillary temperature >98.6˚F) measured by digital thermometer.
- Fever irrespective of any cause.

Exclusion Criteria

- Hypersensitivity to Paracetamol or Mefenamic aci
- All haemodynamically unstable patients
- Patients with renal failure, asthma, inflammatory bowel disease, gastro-intestinal bleeding, liver disease.[58,59]

Materials Required: Digital thermometer

Procedure

The entire procedure will be carried out by a trained personnel (a nursing staff or a house surgeon or on duty doctor). After washing hands and checking the temperature of the child by placing the digital thermometer in the axilla and the temperature is recorded when thermometer beeps.

Parental Consent

Before Randomization, informed written consent was obtained by either parent of the child to be enrolled in the study.

In all the cases, relevant information was collected in a predesigned Proforma.

Randomization

The total study was divided into 2 groups randomly by computer generated random number table.

Group A: Paracetamol 15mg/kg

Group B: Mefenamic acid 6.5mg/kg

The formulations being tablet in children weighing more than 20kgs body weight and suspension in less than 20kg body weight. The dose is repeated if the patient vomits either of the preparation within 30 mins for a maximum of two times.

Monitoring

The patient is being monitored at 1st hour, 4th hour, and 6th hour with the parameters like temperature, heart rate, and respiratory rate and vomiting within 30 minutes of administration.

Statistical Analysis: By student paired t test and unpaired t test, chi square test.

RESULTS

Total 400 children were enrolled in the study and randomised into 2 groups. 200 children in Group A (Paracetamol) and 200 children in Group B (Mefenamic acid).

Overall, males were 223 (55.75%) and females were 117 (44.25%). Out of 223 male patients, 115 (51.56%) were in group A and 108 (48.44%) in group B. Out of total 177 female patients, 85 (48.02%) were in group A and 92 (51.98%) were in group B. Majority of cases were males (55.75%).

Overall male:female sex ratio was 1.26:1, with ratio of 1.35:1 in group A and 1.17:1 in group B.

Table 1: Distribution of Cases as per Age

AGE IN YEARS	GROUP A (PARACETAMOL)		GROUP B (MEFENAMIC ACID)		TOTAL
	N	%	N	%	
1.0 – 3.0	42	42.85	56	57.15	98
3.1-6.0	49	62.02	30	37.98	79
6.1-10.0	55	50	55	50	110
10.1-14.0	54	47.79	59	52.21	113
MEAN (SD)	7.3 (4)		7.2 (4.34)		7.3 (4.16)
TOTAL	200		200		400

The p value using student's unpaired t test was 0.8763 (Not Significant).

The cases of age group 1 to 3 years were 98 (24.5%), 42 (42.85%) in group A and 56 (57.15%) in group B; of age group 3 to 6 years were 79 (19.75%), 49 (62.02%) in group A and 30 (37.98%) in group B; of age group 6 to 10 years were 110 (27.5%), 55 (50%) in group A and 55 (50%) in group B; of age group 10 to 14 years were 113 (28.25%), 54 (47.79%) in group A and 59 (52.21%) in group B.

Majority of the cases were seen in age group of 6 to 14 years (55.75%). Mean age of cases selected for group A was 7.3 (±4) years and for group B was 7.2 (±4.34) years.

Analysis of Outcome

Table 2: Intergroup comparison of mean temperatures at successive time intervals

	MEAN TEMPERATURE (°F)								P VALUE	INFERENCE
	GROUP A (Paracetamol)				GROUP B (Mefenamic acid)					
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
0 hour	101.53	1.27	98.7	103.9	101.7	1.32	98.7	103.8	0.1787	NS
1st hour	100.07	1.34	97.1	103.2	99.74	1.25	97.2	102.6	0.013	S
4th hour	98.81	0.95	97	101.9	98.58	0.81	96.4	102.7	0.0095	VS
6th hour	98.49	0.96	97	104	98.36	0.88	96	103.1	0.1614	NS

The p value calculated using student's unpaired t test.

The mean temperature in group A at 0 hour, 1st hour, 4th hour and 6th hour was 101.53 (±1.27)°F, 100.07(±1.34)°F, 98.81 (±0.95)°F and 98.49 (±0.96)°F respectively. The mean temperature in group B at 0 hour, 1st hour, 4th hour and 6th hour was 101.70 (±1.32)°F, 99.74 (±1.25)°F, 98.58 (±0.81)°F and 98.36 (±0.88)°F respectively.

Faster reduction of temperature was seen in group B at 1st and 4th hour compared to group A. The difference in the mean temperature between the 2 groups at 1st and 4th hour was statistically significant (p=0.0130 and 0.0095 respectively). However, there was no significant difference in mean temperature in both groups at 6th hour.

Table 3: Intergroup comparison of heart rate at successive time intervals

	HEART RATE IN BEATS PER MINUTE								PVALUE	INFERENCE
	GROUP A (Paracetamol)				GROUP B (Mefenamic acid)					
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
BASE	123.25	14.51	86	166	123.69	14.46	84	162	0.7615	NS
1st hour	114.34	13.33	88	165	112.93	13.22	82	150	0.2889	NS
4th hour	105.48	12.70	76	137	104.27	13.36	74	140	0.3498	NS
6th hour	101.18	15.19	70	150	99.01	15.46	70	142	0.1567	NS

The p value calculated using student's unpaired t test.

The mean heart rate in group A at 0 hour, 1st hour, 4th hour and 6th hour was 123.25 (±14.51) bpm, 114.34(±13.33) bpm, 105.48 (±12.70) bpm and 101.18 (±15.19) bpm respectively. The mean heart rate in group B at 0 hour, 1st hour, 4th hour and 6th hour was 123.69 (±14.46) bpm, 112.93 (±13.22) bpm, 104.27 (±13.36) bpm and 99.01 (±15.46) bpm respectively. The difference in the mean heart rate between two groups was not significant.

Table 4: Table 4: Intergroup comparison of respiratory rate at successive time intervals

	RESPIRATORY RATE IN CYCLES PER MINUTE								PVALUE	INFERENCE
	GROUP A (Paracetamol)				GROUP B (Mefenamic acid)					
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
BASE	25.57	6.59	16	48	26.20	7.00	16	46	0.3509	NS
1st hour	23.97	6.33	14	46	24.76	6.98	14	46	0.2395	NS

4th hour	22.49	6.28	12	46	23.36	6.98	12	44	0.1908	NS
6th hour	20.89	6.00	12	40	21.78	6.73	12	43	0.1635	NS

The p value calculated using student's unpaired t test.

The mean respiratory rate in group A at 0 hour, 1st hour, 4th hour and 6th hour was 25.57 (±6.59) cpm, 23.97 (±6.33) cpm, 22.49 (±6.28) cpm and 20.89 (±6) cpm respectively. The mean respiratory rate in group B at 0 hour, 1st hour, 4th hour and 6th hour was 26.20 (±7) cpm, 24.76 (±6.98) cpm, 23.36 (±6.98) cpm and 21.78 (±6.73) cpm respectively. The difference in the mean respiratory rate between two groups was not significant.

Table 5: Distribution of average percentage fall from baseline to 6 hours for all parameters

PARAMETERS	AVERAGE PERCENTAGE FALL		PVALUE	INFERENCE
	GROUP A (Paracetamol)	GROUP B (Mefenamic acid)		
Temperature	2.98	3.27	0.0372	S
Heart rate	17.86	19.93	0.0144	S
Respiratory rate	18.63	17.45	0.1082	NS

The p value calculated using Chi-Square test.

The average percentage fall from baseline to 6 hours for temperature was 2.98% for group A and 3.27% for group B. The average percentage fall from baseline to 6 hours for heart rate was 17.86% for group A and 19.93% for group B. The average percentage fall from baseline to 6 hours for respiratory rate was 18.63% for group A and 17.45% for group B.

The average percentage of fall from baseline to 6 hours for temperature and heart rate between the 2 groups was statistically significant (p= 0.0372 and 0.0144 respectively).

ANALYSIS OF ACCEPTABILITY FOR DRUGS

Table 6: Number of cases had vomiting after drug intake

	GROUP A (Paracetamol)		GROUP B (Mefenamic acid)	
VOMITING	**N**	**%**	**N**	**%**
PRESENT	10	5	11	5.5
ABSENT	190	95	189	94.50
TOTAL	200	100	200	100

The value of p using Chi-Square test is 0.8226 (Not Significant).

The acceptability for both the drugs was assessed based on presence of vomiting within 30 minutes of drug intake and found that majority of the cases (94.75%) accepted both the drugs well. Vomiting was seen in 10 (5%) cases in group A and 11 (5.5%) cases in group B. The difference between the 2 groups was statistically not significant (p=0.8226). Hence, the acceptability for both paracetamol and mefenamic acid is same.

DISCUSSION

Fever is an increase in body temperature due to an elevated thermoregulatory set point temperature. It is generally accepted that antipyresis does not seem to prolong the illness or adversely affect the outcome. While appropriate management of the illness must be the central part of looking after febrile children, concern for the comfort of children has made antipyretic use common place. Antipyretic medication must therefore be both safe and effective. Antipyretic medication should be used to make the child more comfortable, rather than used routinely with the sole aim of reducing temperature. The use of antipyretic medication and attention to the fever must not detract from ensuring that the child's activity and level of consciousness (as an indicator of worsening illness) are both monitored, and that attention is given to adequate hydration. Confidence in paracetamol, the most commonly used antipyretic in children, results from its long standing use. Ibuprofen is also safe and effective for short-term use in children. Mefenamic acid may be an alternative nonsteroidal anti- inflammatory drug (NSAID) to ibuprofen in children with fever.

Both paracetamol and mefenamic acid are NSAIDs and act by inhibiting COX enzyme responsible for generating Prostaglandins (PGE2). Paracetamol has only central action with weak anti-inflammatory effect and so has been reported to be the best antipyretic drug. Mefenamic acid has central and peripheral action with anti- inflammatory effect.

In our study we compared the efficacy and acceptability of paracetamol with mefenamic acid in pediatric patients presented with fever in pediatric ward, BIMS, Belagavi.

In our study the Mean age of cases selected for group A was 7.3 (±4) years and for group B was 7.2 (±4.34) years. Majority of the cases were seen in age group of 6 to 14 years (55.75%).

In our study, majority of the cases were males (55.75%) with male:female ratio of 55.75%:44.25%.

In our study both Paracetamol and Mefenamic acid proved to be effective antipyretic drugs. Antipyresis was achieved within 6 hours of administration of the dose in both the groups.

The mean temperature in group A at 0 hour, 1st hour, 4th hour and 6th hour was 101.53

(±1.27)°F, 100.07 (±1.34)°F, 98.81 (±0.95)°F and 98.49 (±0.96)°F respectively. The mean temperature in group B at 0 hour, 1st hour, 4th hour and 6th hour was 101.70 (±1.32)°F, 99.74 (±1.25)°F, 98.58 (±0.81)°F and 98.36 (±0.88)°F respectively.

Faster reduction of temperature was seen in group B at 1st and 4th hour compared to group A. The difference in the mean temperature between the 2 groups at 1st and 4th hour was statistically significant (p=0.0130 and 0.0095 respectively). Similar results were seen in study conducted by R P Khubchandani et al,[12] where they found mefenamic acid showing significantly better antipyretic activity compared to paracetamol and ibuprofen ($P < 0.05$) in the 2 to 4 hour range.

The average percentage fall from baseline to 6 hours for temperature was 2.98% for group A and 3.27% for group B. The average percentage fall from baseline to 6 hours for heart rate was 17.86% for group A and 19.93% for group B. The average percentage fall from baseline to 6 hours for respiratory rate was 18.63% for group A and 17.45% for group B. The average percentage of fall from baseline to 6 hours for temperature and heart rate between the 2 groups was statistically significant (p= 0.0372 and 0.0144 respectively). Similar results were found in the study conducted by Kunkulol Rahul et al.13 where significant fall of body temperature, pulse rate, respiratory rate, systolic blood pressure, diastolic blood pressure were noted.

Our results are also in accord with S. Keininen et al,[15] S Simila et al,[14] which states Mefenamic acid to be more potent and powerful antipyretic drug.

The acceptability for both the drugs was assessed based on presence of vomiting within 30 minutes of drug intake and found that majority of the cases (94.75%) accepted both the drugs well. Vomiting was seen in 10 (5%) cases in group A and 11 (5.5%) cases in group B. The difference between the 2 groups was statistically not significant (p=0.8226). Hence, the acceptability for both paracetamol and mefenamic acid is same. Similar results were found in Kunkulol Rahul et al,[13] where they found same acceptability for both the drugs.

CONCLUSION

The response for treatment was seen in both groups and the response was seen faster in patients treated with mefenamic acid compared to paracetamol and the difference was statistically significant.

Our study showed that Mefenamic Acid is the better antipyretic as in-terms of their efficacy and tolerability in pediatric patients with fever.

Based on our findings, we conclude that Mefenamic acid helps in faster reduction of temperature, and can be used as alternative antipyretic agent in treating febrile illness in pediatric age group more effectively.

However, more clinical experience and information about side-effects are needed before they can be recommended for wider routine use.

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