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EFFECTIVE ANTIPYRETIC IN CHILDREN: PARACETAMOL V/S IBUPROFEN AND COMBINATION THERAPY

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ABSTRACT

Febrile child is always a concern for a clinician but it is distressful situation for parents. High temperature in children not only needs treatment but evaluation as well. Antipyretic medications for children with fevers are mainstay as treatment before one can proceed for evaluation. Other methods of reducing body temperature by advising parents about use of whole body sponging, minimal clothing, use of fans comes after health worker has prescribed antipyretics, this way clinician can alleviate any discomfort associated with high temperatures and can minimize the chance of febrile convulsion. This study was done to evaluate the effectiveness of two of the most available and commonly used over the counter medicines ie paracetamol, ibuprofen and combination. Many previous studies have evaluated the effectiveness of these drugs individually but here we are comparing the effect of individual drug and their fixed dose combination on body temperature between 1 and 6 hours after administration of drug in three different groups. **Objective:-**The objective of this study was to compare the antipyretic activity of Paracetamol, ibuprofen and their fixed dose formulation. **Methodology:-**Children attending outpatient department and causality of Pediatric Hospital with complaints of fever sudden onset and recorded temperature between 101 ^{0}F to 104 ^{0}F were selected and randomly computer generated allocation to three different group. Axillary temperature with mercury thermometer and average of three reading was recorded before administration of drug (0^{th} hr) and then subsequently at 1^{st} hr, 2^{nd} hr, 4^{th} hr and 6^{th} hr, Fahrenheit Fall of temperature over six hours was recorded. In Group 1^{st} Paracetamol in dose of 15mg/kg was given, Group 2^{nd} ibuprofen in dose of 10mg/kg was administered, and Group 3^{rd} combination of Paracetamol (10mg/kg) and ibuprofen (5mg/kg) was used. No other method of temperature reduction was advised to parents, children with high fever were kept under close observation for ist six hours in causality area of hospital. **Results:-**Study was completed with 462 children from the age group of 12 months to 72 completed months, enrolled via computer generate allocation 154 in each group, Out of which 189 were females and 273 were males. Informed consent was obtained from parents. Statistical analysis was done using SSSP software. Quantitative data is analyzed using "student t test" and mean effect of drug at one hour and 6 hours was measured and compared, statistical significance was measured as p value. In the group A 75 were females and 79 were males, Ibuprofen group B 57 Girls and 97 boys. In combined group C group 97 boys and 57 girls. All 462 patients entered into the study took one dose of study medication at the time of presentation and temperature record before investigator. The difference between treatments for the mean change from baseline in body temperature occurred during the first six hours. During the study, the temperature dropped to 99.5 ^{o}F over six hours for 117 /154(76%) patients in the paracetamol group group and 147/154 (95%) patients in the ibuprofen group and 153/154(99%) in group C. And There were no statistically significant differences between the treatment groups in the distribution of the times until the temperature fell below 99^{o}F (median times of 2 hours) over 1-6 hours for paracetamol, ibuprofen and combined group respectively; p=0.25).

KEYWORDS: Pyrexia, Paracetamol (acetaminophen), Ibuprofen, Children.

INTRODUCTION

Antipyretic drugs have been used over decades in adults as well as children in managing pyrexia. As fever is common childhood illnesses, antipyretic drug are first available choice and most widely used.[1] High temperature in children is always distressful to parents, and therefore clinician should choose a safe and efficacious antipyretic drug in children with fever from different causes. In 1986 the Committee on Safety of Medicines advised doctors not to prescribe aspirin routinely for children under 16 years of age because of a possible association with Reye's syndrome.[2,3] This left

paracetamol as the only available antipyretic. Paracetamol has been extensively used, it has a good safety record there have been recent reports indicating the margin of safety of frequent therapeutic doses in infants and young children a lot lower than previously appreciated.[4,5] Ibuprofen is used in treatment of juvenile arthritis and as an effective antipyretic.[6] Ibuprofen is used as an alternative to paracetamol.[7,8]

Table No:-1.

n (n%), Comparison among three treatment regimes									
		Paracetamol 15 mg (A)	**Ibuprofen 10 mg (B)**	**Paracetamol 10 mg + Ibuprofen 5 mg (C)**	**Total**	**A and B**	**A and C**	**B and C**	**Overall**
Sex	Female	75 (48.7)	57 (37.0)	57 (37.0)	189 (40.9)	0.038	0.038	1.000	0.055
	Male	79 (51.3)	97 (63.0)	97 (63.0)	273 (59.1)				
0 - 1 hr dose	No(T>101°F)	46 (29.9)	100 (64.9)	113 (73.4)	259 (56.1)	<0.001	<0.001	0.032	<0.001
	Yes	108 (70.1)	54 (35.1)	41 (26.6)	203 (43.9)				
1 - 2 hr dose	No	120 (77.9)	109 (70.8)	112 (72.7)	341 (73.8)	0.151	0.290	0.704	0.388
	Yes	34 (22.1)	45 (29.2)	42 (27.3)	121 (26.2)				
2 - 4 hr dose	No	84 (54.5)	136 (88.3)	152 (98.7)	372 (80.5)	<0.001	<0.001	<0.001	<0.001
	Yes	70 (45.5)	18 (11.7)	2 (1.3)	90 (19.5)				
4 - 6 hr dose	No	37 (24.0)	7 (4.5)	1 (.6)	45 (9.7)	<0.001	<0.001	0.109	<0.001
	Yes	117 (76.0)	147 (95.5)	153 (99.4)	417 (90.3)				
Age (yr)	Mean ± SD (min, max)	3.5 ± 1.6 (1, 7)	3.5 ± 1.5 (1, 6)	3.5 ± 1.5 (1, 6)	3.5 ± 1.5 (1, 7)	0.711	0.711	1.000	0.912

No = (Body Temperature >101°F) yes= (Body Temperature < 99.5°F).

DISCUSSION

High temperature is always a concern to parents.[9] In pediatric age group fever is an ominous signs of infection and needs evaluation, and use of antipyretics does not affect the duration of illness or its the outcome.[10,5] High temperature in young population needs appropriate evaluation and treatment, concern for the comfort of children and alleviation of parental worries has made antipyretic use as first choice in fever management.[11] Antipyretic medication used therefore must be both safe and effective. . Aspirin was withdrawn as an antipyretic after its association with Reye's syndrome in the USA, paracetamol is widely used as antipyretic in children, many studies backing its safety and efficacy as equivalent to ibuprofen and fixed dose Combined formulation[2] In 1990, ibuprofen became available for use in children as an antipyretic. It is a nonsteroidal anti-inflammatory agent and thus may have adverse effects on gastrointestinal and renal systems and be unhelpful in asthmatic patients.[12,13] Ibuprofen was used in children for treatment of juvenile arthritis and studies showed it to be safe and effective with few reported side effects[10,11] It is NSAID with potent antipyretic properties have also been established,[14,15] In this study our main aim was to evaluate the effect of drug on the body temperature in terms of °F fall from initial record at presentation to baseline body temperature over six hours period after administration of drug . At the study end point there were no statistically significant differences for change in clinical condition, There were no statistically significant differences between the groups in the numbers of patients with adverse events. In conclusion, ibuprofen and paracetamol in the doses used were shown to be equally effective and well tolerated in the treatment of fever in young children as combined fixed dose formulation. The treatments appeared equally safe.

CONCLUSION

This study showed that individual drugs and fixed dose combination of same two drugs (paracetamol and Ibuprofen) where statistically effective in reducing body temperature at one hour and six hours interval after administration without any advantage when compared to one another. Fixed combination of the two drugs had no statistical significance (p>0.005) when compared to individual drugs in group A and Group B. This study concludes that use of paracetamol is as effective as ibuprofen (P<0.005) or their combination and should be first choice for treatment as antipyretic in children.

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