Original Article

Antipyretic Effects of Nimesulide, Paracetamol and Ibuprofen-Paracetamol

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Abstract. The antipyretic effect of nimesulide has not been adequately compared with paracetamol and ibuprofen-paracetamol combination in children. Hence, a randomized, double blind, and parallel groups' design and multicenter study was conducted on children with respiratory tract infections. Eighty-nine patients with temperatures above 38.5°C were randomly administered nimesulide (1.5 mg/kg/dose), paracetamol (10.0 mg/kg/dose), or ibuprofen-patients combination (10.0 mg/kg/dose), thrice daily for five days. The axillary temperature was recorded at the baseline and at different time intervals post administration of drugs. The hematological and biochemical investigations were performed at the basal level and at the end of the treatment period. The adverse drug reactions were monitored during the trial. All the drugs produced a significant fall in temperature as compared to their respective basal values ($p<0.001$). However, on looking at the change in temperatures at different time intervals from the respective basal levels, no significant difference was found among all the drugs. Surprisingly, nimesulide had a tendency to raise serum glutamate pyruvate transaminase and serum glutamate oxaloacetate transaminase levels as compared to its baseline values. There was no marked adverse effect of the drugs on other hematological and biochemical parameters investigated. No other serious adverse reaction occurred in the study. Ibuprofen-paracetamol combination, nimesulide, and paracetamol had almost similar antipyretic effects in children. **[Indian Journal of Pediatr 2000; 67(12) : 865-870]**

Key words: *Pyrexia; Nimesulide; Paracetamol; Ibuprofen.*

Fever, a complex physiologic response to a number of diseases, is a condition in which the body temperature is raised above the normal range bacause of the action of pyrogenic cytokines on the hypothalamic thermoregulatory center[1]. It is also a complex manifestation of inflammatory responses, though it is not clear whether this defensive response is always beneficial[2]. As such, the incidence of fever as a sign or symptom of infection is high in young children[3].

Acute respiratory tract infections invariably produced fever are frequently occur in the pediatric population. Therefore, the antipyretics thatlower the body temperature are often required for them. After the suspected association of antipyretic aspirin with Reye's syndrome[4], metabolic acidosis and gastric toxicity happened[5]–the control of fever mainly rests on paracetamol, ibuprofen-paracetamol combination and nimesulide. Out of these, nimesulide (4-nitro-2-phenoxymethane sulfonanilide) is relatively a new nonsteroidal anti-inflammatory agent (NSAID). Although it has also been shown to possess antipyretic, analgesic and anti-inflammatory effects[6-8], no comparative evaluation (efficacy and safety) of this drug with other antipyretic agents has been reported.

The present study was, therefore, undertaken to compare the antipyretic effect of nimesulide with paracetamol, and ibuprofen-paracetamol combination in children with acute respiratory tract infections.

MATERIALS AND METHODS

Eighty-nine children with respiratory tract infections–upper as well–lower and having temperature above 38.5°C were enrolled. The patients suffering from any circulatory collapse, blood dyscrasia hematological disorder, cardiac disease, hepatic disease, peptic ulcer disease, glucose-6-phosphate dehydrogenase deficiency, meningitis, tuberculosis, septicemia, or other severe illnesses were excluded from the trial. In addition patients with a history of hypersensitivity to any NSAIDs or those already receiving antibiotics or steroids were also excluded.

The study design was randomized, double blind, parallel groups, and multicenter. The trials were carried out simultaneously at the inpatient pediatrics wards of the University College of Medical Sciences & Guru Teg

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Bahadur Hospital, Delhi, and the Maulana Azad Medical College & Associated Lok Nayak Hospital, New Delhi. The institutional ethical committee approved the study and an informed written consent was obtained from the parent/guardian of the child enoled in the study.

The drugs selected for the assessment of comparative antipyretic effects were nimesulide (1.5 mg/kg/dose), paracetamol (10.0 mg/kg/dose), and ibuprofen-paracetamol combination (10.0 mg/kg/dose). These were administered thrice a day for five days. To maintain the double-blind design of the study, the drugs were prepared in the form of suspensions and put in identical coded bottles. Even the concentrations of the drugs were adjusted so that a similar volume of the suspension provided the equivalent amount of the drug under consideration.

The exillary temperature (°C) of each patient was measured at the basal level (0.0 hour), every 0.5 hours till 1.0 hour, every 1 hour till 3 hours and at 6.0 hours, 10.0 hours, 12.0 hours and 24.0 hours on Day 1 and thrice a day (9.00 am, 2.00 pm. and 9.00 pm) from Day 2 through 5. The maximum fever and the number of temperature peaks were also recorded. If the temperature remained above 39.5°C for 2 hours, cold sponging was applied. However, if the fever did not decrease even with the cold sponging, syrup ibuprofen 10mg/kg body weight per dose was administered to the patient. The blood pressure, heart rate, and respiratory rate were monitored, whenever required, both before and after the administration of the drug.

A few hematological parameters such as hemoglobin (Hb), total leukocytes count (TLC), differential leukocyte count (DLC), platelet count, erythrocyte sedimentation rate (ESR) and C-reactive proteins were measured at the basal level and at the end of the treatment period. Some biochemical investigations namely blood sugar (B. Sugar), blood urea (B. Urea), serum creatinine (S. Creatinine), serum glutamate pyruvate transaminase (SGPT), serum glutamate oxaloacetate transaminase (SGOT) were estimated at the similar time periods.

The patients were withdrawn from the study if the body temperature increased above 40°C or decreased below 35°C, the disease worsened, or the consent of the patient had been withdrawn by the parent/guardian of the child.

The adverse drug reactions (ADR) voluteered by the parents/guardians of the patients or detected by the investigators were also recorded. The results from both the centers were pooled together and the data were expressed as Mean (Confidence interval 95%). The data were analyzed by Analysis of Variance and Student's 't' test wherever appropriate. The results were considered significant at a probability level of <0.05.

RESULTS

Eighty-nine patients were enrolled in the trial. Nine patients dropped out of the study, leaving only eighty patients for the final analysis. There was no significant difference among the three different groups as far as their basal characteristics were concerned. There was also no difference in the basal temperatures among all the groups. These were 38.82 (37.53-40.11)°C, 38.96 (38.70-39.22)°C, and 38.78 (38.63-38.93)°C in nimesulide, paracetamol, and ibuprofen-paracetamol combination groups respectively (Table 1).

The effect of the drugs on the change of body temperature from baseline, at different time intervals on day 1 has been depicted in (Fig 1). The administration of nimesulide, paracetamol, and ibuprofen-paracetamol combination produced a singnificant fall of temperatures as compared to their respective basal values from 0.5 to 24. hours ($p<0.001$). The ibuprofen-paracetamol combination had a better tendency of lowering the temperature from 0.5 to 2 hours as compared to nimesulide and paracetamol. Contrarily, nimesulide had a tendency of loweing little more temperature from 3.0 to 6.0 hours as compared to paracetamol and ibuprofen-paracetamol combination. The paracetamol also had a little better antipyretic effect from 10.0 to 24 hours as compared to nimesulide and ibuprofen-paracetamol combination. Surprisingly, on looking at the change of temperature from the respective basal levels with all drugs, no statistical significance difference was found.

The effect of the drugs on the change of temperature at different time intervals from day 2 to 5 has been illustrated in Fig. 2. It was observed that the significant fall of temperature achieved with the administration of all the drugs on day 1, as compared to the respective basal level was well maintained from 9.00 AM on Day 2 to 9.00 PM on day 5 ($p<0.001$). However, there was no significant difference in the change of temperature from the basal

TABLE 1. Basal Characteristics of the patients expressed as mean (Confidance Intervals 95%)

Basal Characteristics	Treatment groups		
	Nimesulide (N = 29)	Paracetamol (N = 33)	Ibuprofen paracetamol (N = 18)
Age (years)	2.27 (1.20-3.34)	2.85 (1.75-3.95)	3.02 (2.34-3.70)
Gender			
Male (%)	55	42	61
Female (%)	45	58	39
Baseline temperature (°C)	38.82 (37.53-40.11)	38.96 (38.70-39.22)	38.78 (38.63-38.93)

N = is the number of patients in each group

Table 2. Effects of Nimesulide, Paracetamol, and Ibuprofen-paracetamol Combination on a Few Hematological and Biochemical Parameters.

Parameters	Nimesulide group (N=29)		Paracetamol group (N=33)		Ibuprofen-paracetamol group (N=18)	
	Before drug	After drug	Before drug	After drug	Before drug	After drug
Hemoglobin (g%)	10.50 (9.73-11.29)	10.22 (9.56-10.88)	10.76 (10.11-11.41)	10.86 (10.19-11.53)	11.49 (10.67-12.31)	11.16 (10.27-12.05)
TlC (X 10^3/cu mm)	11.74 (8.07-15.41)	9.82 (7.77-11.87)	11.91 (9.32-14.50)	9.84 (8.56-11.12)	7.99 (6.28-9.70)	7.02 (5.92-8.12)
DLC (%)						
* Polymorphs	61.42 (55.89-66.95)	52.26 (48.29-56.23)	5.95 (44.78-61.12)	52.00 (47.21-56.79)	56.44 (48.28-64.61)	47.72 (44.58.50.86)
* Lymphocytes	37.37 (31.90-42.84)	44.68 (40.21-49.15)	47.70 (40.63-54.77)	47.40 (42.61-52.19)	43.06 (39.94-51.18)	51.11 (47.78-54.44)
Platelets (X 10^{10}/L)	37.73 (27.08-48.38)	39.08 (31.89-46.27)	24.21 (16.44-31.98)	27.76 (21.53-33.99)	24.02 (16.61-31.43)	26.12 (18.08-34.17)
ESR (mm/hour)	19.33 (12.00-26.66)	15.56 (10.32-20.60)	19.50 (11.78-27.22)	15.68 (9.91-21.44)	13.28 (7.94-18.62)	14.67 (9.97-19.37)
C-Reactive Protein	0.41 (0.16-0.66)	0.41 (0.16-0.66)	0.41 (0.17-0.65)	0.35 (0.11-0.59)	0.33 (0.10-0.56)	0.22 (0.01-0.43)
S.G.P.T. (I.U.)	30.29 (23.18-37.40)	64.38 (18.95-109.81)	49.29 (9.59-88.99)	30.11 (24.06-36.16)	33.50 (27.70-39.30)	38.31 (29.83-46.79)
S.G.O.T. (I.U.)	38.23 (28.48-47.98)	57.27 (34.02-80.52)	63.42 (21.99-104.85)	39.50 (26.38-52.62)	35.31 (27.55-43.07)	42.13 (29.22-55.04)
B. Sugar (mg%)	90.85 (84.03-97.67)	80.59 (73.09-88.09)	92.93 (87.63-98.23)	89.20 (82.95-95.45)	90.59 (84.20-96.98)	85.00 (79.28-90.72)
B. Urea (mg%)	30.81 (24.99-36.63)	26.70 (23.89-29.51)	23.52 (21.03-26.01)	26.66 (23.54-29.78)	26.50 (22.91-30.09)	24.44 (21.80-27.08)
S Creatinine (mg%)	0.50 (0.38-0.62)	0.60 (0.42-0.78)	0.39 (0.27-0.51)	0.49 (0.37-0.61)	0.46 (0.33-0.59)	0.56 (0.43-0.69)

N=Number of patients is each group
Date : Mean
(confidence inerval 95%).

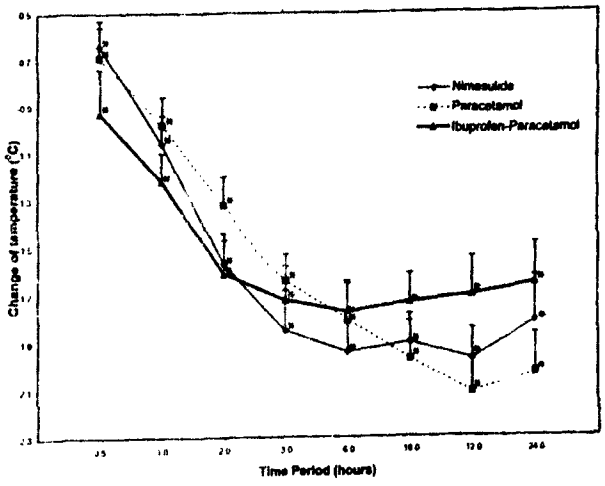

Fig. 1. The change of body temperature (°C) from the baseline, with the administration of nimesulide, paracetamol, and ibuprofen-paracetamol combination at different time intervals on day 1 (Data are X ± SEM). *p < 0.001 vs respective baseline values.

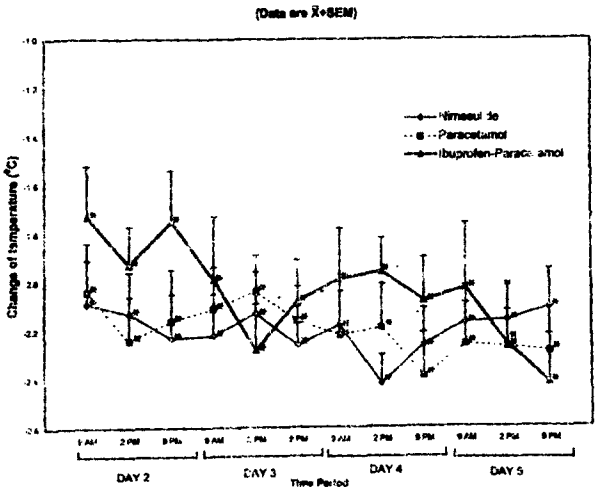

Fig. 2. The change of body temperature (°C) from the baseline, with the administration of nimesulide, paracetamol, and ibuprofen-paracetamol combination at different time intervals from day 2 to day 5 (Data are X ± SEM). *p < 0.001 vs respective baseline values.

level amongst all the treatment groups.

The effects of different drugs on a few hematological and biochemical parameters hve been shown in Table 2. There was no difference in the hemoglobin levels at the basal level and after the drug administration among all the groups. The TLC was on the higher side before the administration of all the drugs, but it decreased effectively after their administration, though the results were non-significant. There was no significant difference in DLC

in all the groups, both at the basal level and after the administration of drugs. There was no significant effect of the drugs on platelet counts and erythrocyte sedimentation rate (ESR). The ESR fell to a little extent in nimesulide and paracetamol groups, but the results were not significant. There was no effect of nimesulide on the level of C-reactive protein. However, the ibuprofen-paracetamol combination and paracetamol had some tendency of lowering the levels, though the results were not significant.

There was no significant difference in the values of SGPT and SGOT at the basal level in all the groups. Surprisingly, SGPT and SGOT values were found to be raised after the administration of nimesulide, even if the results were not significant conversely, the values SGPT and SGOT fell after the administration of paracetamol, despite the results being non-significant. These values did not change after the administration of ibuprofen-paracetamol combination. After the administration of different drugs, the SGPT value was twice the normal in 14.3%, 0.0% and 5.6% of the patients taking nimesulide, paracetamol and ibuprofen-paracetamol combination respectively. Similarly, the value of SGOT was also twice the normal in 10.7%, 3.1% and 11.1% of patients taking nimesulide, paracetamol and ibuprofen-parcetamol combination respectively.

There was no difference in the basal levels of blood sugar in all the groups. However, the nimesulide caused a little fall in B. Sugar as compared to paracetamol and ibuprofen-paracetamol combination groups, in spite of the results being non-significant. There was no significant difference in the B. Urea and s. Creatinine among all the groups at the baseline and after the administration of drugs.

As far as the monitoring of other ADR was concerned, only a few adverse effects namely, epigastric pain, vomiting were encountered and on comparing it in different groups, no marked difference was found. The number of cold sponges that were required for the control of temperature in nimesulide, paracetamol and ibuprofen-paracetamol combination groups were 1.7%, 1.0%, and 2.7% respectively. There was no difference in the blood pressure and heart rate, both at the basal level and after the drug administration in all the groups. The respiratory rate was on the higher side at the basal level in all the groups and it decresed after the administration of drugs to almost similar extent.

DISCUSSION

Fever is a complex, coordinated autonomic, neuroendocrine, and behavioural response. It usually occurs in response to a variety of infectious organisms and noninfectious inflammatory conditions. Its manifestations are stereotyped and largely independent of its causation. The fever arises from an abnormally high hypothalamic thermostasis, triggered by the actions of interleukin or pyrogenic cytokines on the hypothalamic thermoregulatory centre[9]. It impairs the immunological reaction, increases general discomfort, metabolic demands and the risk of convulsions in children. The mediators of febrile response (*i.e.*, pyrogenic cytokines such as tumor necrosis factor and interlukin-1) also contribute to the morbidity and mortality of gram-negative sepsis[1,10,11].

The rational treatment of fever is to restore this abnormal hypothalamic thermostasis. For this, a variety of NSAIDs (*i.e.*, aspirin, paracetamol, mefenamic acid, nimesulide, and ibuprofen-paracetamol combination) have been used in children. However, on looking at their antipyretic effects, conflicting reports have been cited in the literature[12-15]. The present study clearly demonstrated that paracetamol, nimesulide, and ibuprofen-paracetamol combination had almost similar efficacy of lowering the raised temperature. This held true even for their clinical efficacy (significance) as well as for the statistical significance effects

Our findings are contrary to Goyal *et al*[16], who found a better antipyretic effect with nimesulide as compared to paracetamol. However, our study was different from that report[16], since they included a wide variety of patients presenting with acute respiratory infections, enteric fever, post measles bronchopneumonia, tuberculosis, septicemia and others, whereas we enrolled the patients of respiratory tract infections only. Though, their trial was also randomized, due to the unevenly distribution of heterogeneous cases among the study groups, a lot many confounding variables could have affected the study outcome. On the other hand, by including the homogeneous patients' population of respiratory tract infections only in our randomized, double blind trial, the potential of the study was enhanced. Moreover, by distributing evenly these patients among the study groups, the chance of any confounding variable affecting the results could have been very minimal. Furthermore, Goyal *et al*[16] did not comre the effet of ibuprofen-paracetamol combination in their study. On the contrary the present study was more elaborate in including this also as a study group. Even, our multicenter trial helped in the availability of desired cases in short time frame, further decreasing the effect of some other confounding variables on the study results.

To a little extent our study was in line with those of Polidori *et al*[17], who found no clinical relevant difference between the nimesulide and paracetamol, although a borderline statistical significance was recorded in favour of the theraphy with nimesulide. However, they also did not include ibuprofen-paracetamol combination in their study.

The potential of the study was 88% and a difference in the temperatures of 0.5°C could be measured by the study sample size. The study was randomized. Nine dropouts occurred in all the groups investigated. But they were little more in patients taking ibuprofen-paracetamol combination. The fate of the dropouts was not recorded, since the study was not planned to answer this question.

In the present study, the drugs did not effect the vital parameters such as blood pressure, heart rate and respiratory rate. The number of cold sponges used for lowering of the temperature were slinghtly more in the nimesulide and ibuprofen-paracetamol combination roups as compared to those in the paracetamol group. However, it is difficult to comment on this parameter alone. All the drugs were well tolerated.

The hematological and biochemical parameters were performed in this study to determine the adverse effects of the drugs. On comparing the hematological parameters among the study groups, it was found that all the drugs effected these parameters almost to a similar extent. However, paracetamol and the ibuprofen-paracetamol combination groups had a little better tendency of decreasing the C-reactive protein, one of the important parameter for anti-inflammatory effect, though the results were not significant. The study drugs did not diffect most of the biochemical parameters.

Surprisingly, nimesulide caused a rise in SGPT and SGOT, whereas paracetamol produced a fall, despite the results being non-significant. In the light of these findings, one could anticipate some hepatotoxicity with the use of nimesulide. To our knowledge, ours is the first study that has attempted to investigate the comparative effects of antipyretics on SGPT and SGOT values in India. The SGPT and SGOT values were twice the normal in more patients taking nimesulide as compared to that of taking paracetamol and ibuprofen-paracetamol combination respectively. Futhermore, the present study findings have been substantiated by a few recent reports of fulminant hepatic failure with the use of nimesulide[18-20]. It was also felt that the nimesulide be stopped if any abnormal liver functions tests develop[18]. Perhaps, due to these types of reports, the pediatirc preparation of nimesulide was been withdrawn from sale in Portugar[21]. and Israel[22]. Astonishingly, nimesulide, has not been registered in Canada, USA, UK, Scandinavia, Australia, New Zealand and even in Sri Lanka[23]. Liver damage with nimesulide is a serious adverse effect requiring further elucidation and monitoring in larger patient populations.

As far as the monitoring of other ADR was concerned, only a few adverse effects were encoundtered in the present study. These were of mild nature and did not require any drug discontinuation. The less identification of ADR in this study could be due to the limited number of patients evaluated in this trial. However, these do not rule out the possibility of occurrence / risk of other adverse effects, particularly in the presence of hepatic and renal insufficiency or failure. Moreover, to know the extent of complete adverse reactions profile of nimesulide, an efficient post-marketing surveillance study is required, which at present is lacking in less developed countries[20].

CONCLUSION

The results of the present investigation reveal that the antipyretic efficacies of nimesulide, ibuprofen-paracetamol combination and paracetamol are almost similar. But, the safety of nimesulide deserves appraisal in larger patient population.

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How to Start Talking To Your Child About Sex

Don't Panic: Your children will probably do some things that you don't want them to do. Panic won't stop them, but good information can help them to stay safe and make wise decisions.

Start young: The earlier you begin the easier it is. By the time your children are teenagers, they will be prepared and less likely to make unwise choices.

Encourage Talk: Be open to talking with your children about all kind of things. Create an environment of trust and communication. Find ways to gently start talking about difficult things now.

Talk Often: A once-in-a-lifetime sex talk will not give your children all the information they need. Repeat yourself and make sure you have been understood.

Be Sensitive: Respect the age and stage your child is at. Don't give more information than they want or need.

Be Supportive and Positive: If you shout at your children or ignore difficult question, you will make communication very difficult.

Say What You Believe: Don't be shy to tell your children what you believe. They want and need some moral guidance from you.

Listen : When your children come to you with a question, show respect and listen. Make sure you understand their questions.

Be Honest : If you don't know the answer, say so. If you don't feel good talking about sex, say so. But try to say so in a way that dose not stop communication. Suggest someone else that your child could speak to, to get answers. Try to learn with them.

Courtesy : Loveline
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