COMPARISON OF DEXIBUPROFEN VERSUS IBUPROFEN AS AN ANTIPYRETIC IN FEBRILE CHILDREN- A RANDOMIZED CLINICAL TRIAL

Adnan, Khawaja Kamran Wajid, Amir Muhammad✉

Department of Pediatrics, Lady Reading Hospital (Medical Teaching Institute) Peshawar-Pakistan.

Address for correspondence:
Amir Muhammad
Department of Pediatrics, Lady Reading Hospital (Medical Teaching Institute) Peshawar-Pakistan

E-mail:
amirmuhammad786@yahoo.com

Date Received:
June, 08th 2021
Date Revised:
February, 02nd 2022
Date Accepted:
February, 14th 2022

ABSTRACT

Objective: To compare the efficacy of dexibuprofen and ibuprofen for management of fever in febrile children.

Methodology: This randomized clinical trial was conducted at the Pediatric Department, Lady Reading Hospital, Peshawar-Pakistan from October 2019 to April 2020. A total 150 patients were randomly allocated into two arms (Group I; dexibuprofen and Group II; Ibuprofen) and were enrolled through non-probability consecutive sampling technique. Participants between the ages of 6 months and 12 years, with febrile illness were enrolled in this study. Data analysis was done using Stata version 14, independent samples t-test was applied to compare mean change in temperature between the groups at different stages.

Results: The mean age of the participants in the study was 2.84±1.655 years. The number of males were 107(71.33%) and females were 43(28.67%). There was no statistical difference in axillary temperature of participants in both groups before the intake of analgesics (p=0.527). The mean temperature after 4 hour of using dexibuprofen (100.14± 1.27 0F) was lower than ibuprofen (101.29±1.23 0F) with statistically significant difference (p<0.001).

Conclusion: Dexibuprofen and ibuprofen are both effective in control of febrile illness but mean reduction in temperature for dexibuprofen was statistically more significant than ibuprofen.

Keywords: Children; Dexibuprofen; Ibuprofen; Temperature.

INTRODUCTION

Children usually present with fever as the most prominent symptom of viral and bacterial diseases.[1] Fever is usually the main chief complaint of parents bringing their children for consultation.[2] Fever is symptoms occurring due to raise in body temperature which is recorded with thermometer. The most common cause of fever among children is respiratory tract infections.[3] Analgesics or antipyretics are from non-steroidal anti-inflammatory drugs and are commonly used to relieve fever among children.[4] In case of infection along with adequate antibiotics, antipyretics are routinely prescribed for symptomatic relieve of fever.[5] Paracetamol and iburprofen are commonly used analgesics for febrile children due to their overall safety profile, high efficacy and less cost.[6]

Ibuprofen has been improved by producing its racemic enantiomer called dexibuprofen. The less dose of Dexibuprofen can produce effective control of fever and pain as compared to ibuprofen.[7] A study was conducted on comparison of dexibuprofen and ibuprofen in the management of febrile children showed that after 4 hours intake of these drugs the mean body temperature in dexibuprofen (0.99°C ± 0.84) was lower statistically than ibuprofen (1.38°C ± 0.84) (p= 0.007).[8] However, another study reported that the mean difference in decrease of body temperature between these two drugs were not statistically significant.[9]

The rationale of this study is that no such study has been conducted in our local population. The current study will provide us the latest and updated information regarding efficacy of dexibuprofen versus ibuprofen in children with fever. This conclusive data will be helpful and can be used as baseline for further research work in the subject matter.

METHODOLOGY

This randomized clinical trial was conducted at Pediatric Department, Lady Reading Hospital, Peshawar-Pakistan from October 2019 to April 2020. Ethical approval was obtained from hospital ethical committee. After in depth explanation of the study to parents

This article may be cited as
Adnan, Wajid KK, Muhammad A. Comparison of dexibuprofen versus ibuprofen as an antipyretic in febrile children- a randomized clinical trial. J Postgrad Med Inst 2021;35(4):210-3. https://doi.org/10.54079/jpmi.35.4.2917.

of the participants verbal informed consent was achieved. The total sample size was 150 (75 patients in each group) by taking anticipated population mean: 1.384 value of population mean: 0.99[4] Pooled standard deviation: 0.84, Power of study, 80%, Level of significance 5% . The sampling selection was done through non-probability consecutive technique.

The inclusion criteria were participant having age between 6 months and 12 years, either gender, Pakistani nationals (assessed on basis of parent's NIC) and having febrile illness. The operational definition of febrile illness was axillary temperature in range of 100.4°F to 106°F measured by thermometer by a pediatrician. The demographics of participants like age and genders were recorded. The participants were randomly allocated into two equal groups by computer generated random numbers. In group I dexibuprofen was used as an analgesic and in group II Ibuprofen. In group I 5mg kg-1 dexibuprofen (oral syrup four to six times a day) while in group II 10mg kg-1 ibuprofen (oral syrup four to six times a day) was provided. Baseline and after 4 hours, the axillary temperature was recorded from both groups. Bias and confounders were controlled by randomization and strictly following inclusion criteria.

Microsoft excel sheet 2016 was used to record the data and was then imported to Stata 14 for analysis. Qualitative data like gender and age groups was presented as frequencies and percentages. Mean and SD were computed for continuous data like age and axillary temperature. Outcome variable (axillary temperature) was compared among the two groups by using two samples independent t-test under two sided hypothesis at P≤0.05 significant level. The results were stratified among genders to see effect modifiers using post stratification two samples independent t test

RESULTS

The mean age was 2.84±1.655 years with range from 1 to 8 years. The males were 107(71.33%) and females were 43(28.67%). Table No 1 shows that there was no difference in axillary temperature of participants in both groups before the intake of analgesics (p=0.527). The mean temperature after 4 hour using dexibuprofen (100.14± 1.27 0F) was lower than ibuprofen (101.29±1.23 0F). The difference were highly statistically significant (p<0.001). (Table No 1). Similarly in both males (p=0.0081) and females (p<0.001) the mean temperature after 4 hour in dexibuprofen group was lower than ibuprofen statistically. (Table No 2)

DISCUSSION

Myriad of literature are available on comparison of antipyretic efficacy of various analgesics.[10]

This randomized controlled trial was aimed to compare the antipyretic effect of ibuprofen and dexibuprofen in a sample of Peshawar population. Our findings showed that both dexibuprofen and ibuprofen are effective in control of febrile illness but mean reduction in temperature for dexibuprofen was statistically more than ibuprofen among under 12 years children.

The dexibuprofen is modified innovative drug having better efficacy due to better pharmakonetics than ibuprofen theoretically.[11] Theoretical claims are the phrased hypotheses which should be judged by evidence based research. Randomized clinical trials are considered the good source of evidence if performed correctly.[12] We conducted this randomized clinical trial to answer the question whether dexibuprofen is more effective than ibuprofen or not. Our results showed that dexibuprofen is more effective in reducing body temperature than ibuprofen statistically though no clinical difference as observed in their efficacies.

An RCT was conducted on Korean population on comparison of efficacy and safety of dexibuprofen compared with ibuprofen in febrile children due to upper respiratory tract infection. Their results showed that the mean difference in decrease of body temperature between these two drugs were not statistically significant.[9] These results are different from our study. The difference can due to genetic and environmental factors.

Table 1: Comparison of Baseline Temperature Between Ibuprofen and Dexibuprofen

Group		Mean ± SD	95% CI	P-Value*
Baseline	Ibuprofen	103.04±1.21	-0.401, 0.37	0.5270
	Dexibuprofen	103.05±1.19		
After 4 hour	Ibuprofen	101.29±1.23	0.74, 1.55	<0.001
	Dexibuprofen	100.14± 1.27		

*Independent samples t test

Table 2: Comparison of After Temperature Between Ibuprofen and Dexibuprofen Stratified By Gender

Gender	Group	Mean ±SD	95% CI	P-Value*
Male	Ibuprofen	101.21±1.41	0.21, 1.99	0.0081
	Dexibuprofen	100.13± 1.27		
Female	Ibuprofen	101.33±1.15	0.71, 1.62	<0.001
	Dexibuprofen	100.72± 1.31		

*Independent samples t test

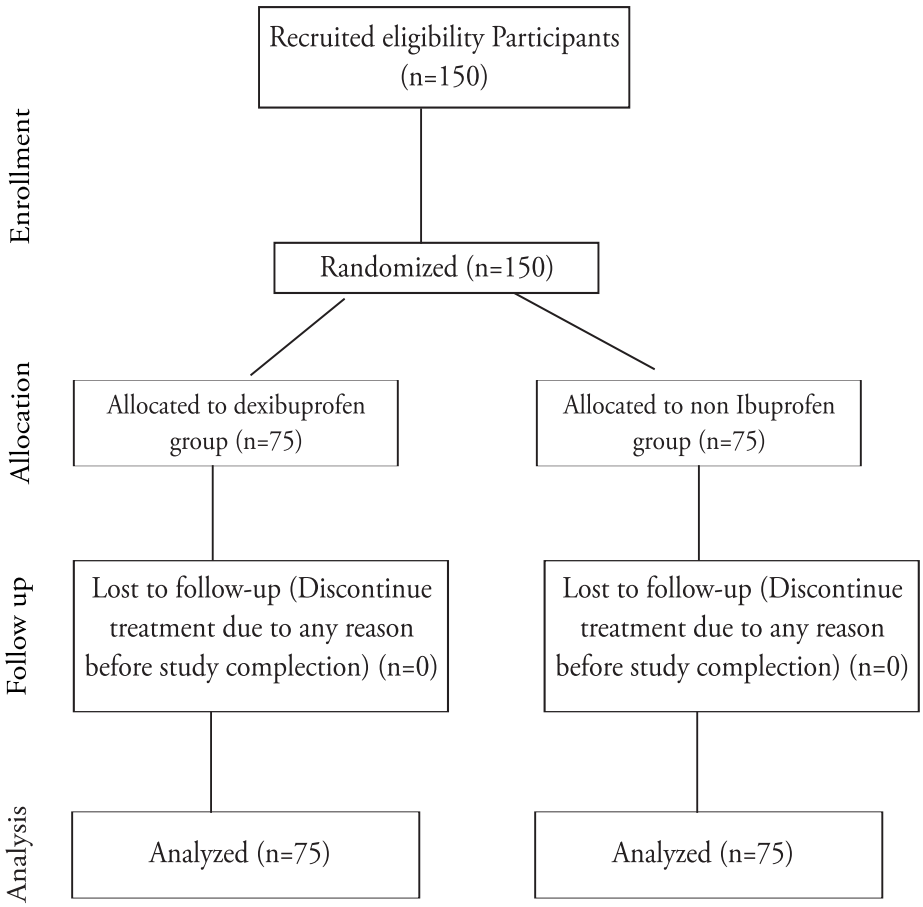

Figure 1: A CONSORT Diagram Showing the Flow of Participants Through Each Stage of the Trial

Another study was conducted on comparison of dexibuprofen and ibuprofen in the management of febrile children. Their results showed that 4 hours after the intake these drugs the mean body temperature in dexibuprofen (0.99°C ± 0.84) was lower than ibuprofen (1.38°C ± 0.84) statistically (p= 0.007).[8] These results are in consistent with our study.

CONCLUSION

Both dexibuprofen and ibuprofen are effective in control of febrile illness but mean reduction in temperature for dexibuprofen was statistically more than ibuprofen among under 12 years children.

REFERENCES

1. Bertille N, Purssell E, Hjelm N, Bilenko N, Chiappini E, De Bont EG, et al. Symptomatic management of febrile illnesses in children: A systematic review and meta-analysis of parents' knowledge and behaviors and their evolution over time. Front Pediatr. 2018; 6:279.
2. Irwin A, Wickenden J, Le Doare K, Ladhani S, Sharland M. Supporting decisions to increase the safe discharge of children with febrile illness from the emergency department: A systematic review and meta-analysis. Archiv Dis childhood. 2016; 101(3):259-66.
3. Sullivan JE, Farrar HC. Fever and antipyretic use in children. Pediatr. 2011; 127(3):580-7.
4. De Martino M, Chiarugi A. Recent advances in pediatric use of oral paracetamol in fever and pain management. Pain Therapy. 2015; 4(2):149-68.
5. Escalante MCK, Abdennour A, Farah A, Rivera-Richardson E, Burgos F, Forero I, et al. Prescription patterns of analgesics, antipyretics, and non-steroidal anti-inflammatory drugs for the management of fever and pain in pediatric patients: A cross-sectional, multicenter study in Latin America, Africa, and the Middle East. Pragmatic Obser Res. 2019; 10:41-9.
6. Meremikwu MM, Oyo-Ita A. Paracetamol versus placebo or physical methods for treating fever in children. Cochrane Databas Systematic Rev. 2002; 2. doi/10.1002/14651858. CD003676.
7. Polat M, Kara S, Tezer H, Tapısız A, Derinöz O, Dolgun A. A current analysis of caregivers' approaches to fever and antipyretic usage. J Infect Develop Countr. 2014; 8(03):365-71.
8. Kim CK, Callaway Z, Choung JT, Yu JH, Shim KS, Kwon EM, et al. Dexibuprofen for fever in children with upper respiratory tract infection. Pediatr Int. 2013; 55(4):443-9.
9. Yoon JS, Jeong DC, Oh JW, Lee KY, Lee HS, Koh YY, et al. The effects and safety of dexibuprofen compared with ibuprofen in febrile children caused by upper respiratory tract infection. Br J Clin Pharmacol. 2008; 66(6):854-60.
10. Choi SJ, Moon S, Choi UY, Chun YH, Lee JH, Rhim JW, et al. The antipyretic efficacy and safety of propacetamol compared with dexibuprofen in febrile children: a multicenter, randomized, double-blind, comparative, phase 3 clinical trial. BMC Pediatrics. 2018; 18(1):1-7.
11. Kaehler S, Phleps W, Hesse E. Dexibuprofen: pharmacology, therapeutic uses and safety. Inflammopharmacol. 2003; 11(4):371-83.
12. Goulooze SC, Zwep LB, Vogt JE, Krekels EH, Hankemeier T, van den Anker JN, et al. Beyond the randomized clinical trial:

innovative data science to close the pediatric evidence gap. Pharmacol Therapeut. 2020; 107(4):786-95.

Author's Contribution

A designed the study, collected the data and drafted the manuscript. WKK collected the data and drafted the manuscript. AM collected & analyzed the data and drafted the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

Grant Support and Financial Disclosure

None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.