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Antifebrile effects of dexibuprofen suppository on children with high fever

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Abstract: **Background**: Acute fever is a frequently-seen disease in the department of paediatrics. **Objective**: This study aims to evaluate the antipyretic efficacy of dexibuprofen suppositories in pediatric patients with high fever. **Methods**: 100 children with high fever who received antipyretic treatment in our hospital from March 2022 to March 2023 were retrospectively analysed. Among them, 57 children treated with dexibuprofen suppositories were taken as the study group and 43 children treated with ibuprofen suspension were taken as the control group. The body temperatures of the two groups were analyzed and compared before medication and at 0.5, 1, 2, 4 and 6 hrs after medication. The two groups were compared in the therapeutic effects and adverse reactions. Independent sample t-tests and repeated measures analysis of variance were used for comparisons between groups and chi-square tests or Fisher's exact tests were used for categorical variables. **Results**: The study group had significantly lower temperatures at 0.5, 2, 4 and 6 hrs ($P < 0.0001$), with similar overall efficacy ($P > 0.05$) and fewer adverse reactions ($P = 0.0272$). Multivariate logistic regression analysis determined that the disease course and admission body temperature were independent risk factors. **Conclusion**: Dexibuprofen suppository provides rapid and effective antipyresis with better safety in pediatric emergency settings.

Keywords: Antipyretic effect; Acute fever; Dexibuprofen suppository, Prognosis; Therapeutic effect

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INTRODUCTION

Acute fever is a frequently-seen disease in the department of pediatrics (Green *et al.*, 2021). It refers to the elevated body temperature due to the dysfunction of the thermoregulation center in children infected with viruses, bacteria, fungi or other pathogens (Pulcini *et al.*, 2021). Without timely treatment, it can trigger serious, life-threatening conditions such as febrile convulsions (Penda *et al.*, 2023). Too long a time of high fever may even cause long-term cognitive, learning and behavioural disorders in some children (Marseglia *et al*., 2025). Thus, looking for a rapid and effective treatment of acute fever in children has become the focus of research on children.

Currently, acute fever in children is mostly treated with Western medicine, which can quickly and effectively lower the body temperature of children. Ibuprofen is a frequently adopted analgesic and antipyretic drug in the department of pediatrics, which can quickly exert antipyretic, analgesic, and anti-inflammatory effects and has good safety, so it is extensively adopted for children with high fever (Birbeck *et al.*, 2024, Paul and Walson, 2021). Dexibuprofen suppository is a pure spatial enantiomer of ibuprofen, with higher safety than ibuprofen. There are two dosage forms: dexibuprofen suppository and dexibuprofen suspension (Gliszczynska and Sanchez-Lopez, 2021). Dexibuprofen suppository takes effect quickly through oral mucosal absorption and usually takes effect within minutes (Hanif *et al.*, 2024). Compared with L-Ibuprofen, dexibuprofen can be better absorbed by the human body, thus providing more efficient therapeutic effect (Lapi *et al.*, 2025). However, there are limited studies on dexibuprofen suppositories in children with acute fever and the differences in the speed of antipyretic onset, duration of action and safety compared to commonly used ibuprofen suspensions remain unclear, lacking direct clinical comparative evidence.

Accordingly, this study compared the antipyretic effect of dexibuprofen suppository and ibuprofen suspension on children with acute high fever to explore the antipyretic effect of dexibuprofen suppository on children with acute high fever, thereby providing a rationale for optimizing treatment strategies in pediatric cases with acute high fever.

MATERIALS AND METHODS

Sample information

This study employed a consecutive sampling method to retrospectively select pediatric patients with high fever who presented to the emergency department of our hospital between March 2022 and March 2023 and met the inclusion criteria.

Sample size calculation: Using the G*Power software and based on the two-sample t-test, with α set at 0.05 and the test efficacy (1-β) at 0.8, referring to previous studies (Ahn *et al.*, 2019), the average difference in expected body temperature changes was 0.5ºC and the standard deviation

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was 1.0℃. The effect size d was calculated to be 0.5. Based on this estimation, at least 42 patients were needed for each group (with a total sample size of 84 cases). Considering the possible case dropout and exclusion, the sample size was appropriately expanded. A total of 140 pediatric patients with high fever were ultimately included in this study.

Inclusion and exclusion criteria

Inclusion criteria: Patients aged 1-6 years old, children who meet the diagnostic criteria for acute hyperthermia in the "Diagnostic Criteria for Pediatric Diseases" (Penda *et al*., 2023), with a body temperature of ≥39ºC and patients with detailed clinical data.

Exclusion criteria: Special children with severe underlying diseases, such as congenital heart disease, blood disease, tumor, dysfunction of the heart, liver or kidney, asthma, etc., patients who had received antipyretic agents within 4 hours; patients with a history of febrile convulsion, patient who were receiving treatment with corticosteroids; patients who were allergic to drugs adopted in this study.

Sample screening

According to the criteria, 140 children were screened and 100 children met the requirements of this study. Among them, 57 children treated with dexibuprofen suppository were assigned to the study group and the other 43 children treated with ibuprofen suspension were assigned to the control group.

All clinical data of the study subjects were obtained from our hospital's electronic medical record system, including demographic information, medical history, body temperature records, medication use and adverse event reports. All data were analyzed after de-identification, with access restricted to authorized researchers only, strictly ensuring the protection of pediatric privacy and data security.

Pain assessment

Face, legs, activity, cry, consolability (FLACC) scale (Matsuishi *et al.*, 2018) is a behavioral pain assessment tool used to evaluate pain in children and infants, particularly in those unable to self-report their pain verbally. This scale assesses pain intensity based on five behavioral categories: facial expression, leg movement, activity, cry and consolability. Scores are interpreted as follows: 0 = relaxed and comfortable; 1–3 = mild discomfort; 4–6 = moderate discomfort;7–10 = severe discomfort or pain. The total score ranges from 0 to 10, with higher scores indicating more severe pain.

Therapeutic regimen

The conventional treatment for pediatric patients with high fever in the emergency department of our hospital includes physical cooling and pharmacological antipyresis. The choice of medication is determined based on clinical assessment and family preference. Ibuprofen suspension is commonly used as a first-line medication, while dexibuprofen suppositories are also an alternative option. The grouping treatment protocols are as follows:

Control was treated with ibuprofen suspension: The children were treated with ibuprofen suspension (Beijing Hanmi Pharmaceutical Co., Ltd.) and different doses were given according to age and body mass of children. For children at 1-3 years old, 10mg/kg ibuprofen suspension was given each time, three times a day. For children aged 4-6 years old, 7.5-10 mg/kg ibuprofen suspension was given each time, three times a day.

The study group was treated with dexibuprofen suppository (Shanxi Medic Pharmaceutical Co., Ltd., specification: 50 mg). For children aged 1-3 years old, 50 mg dexibuprofen suppository was given; for children over 3 years old, 100 mg dexibuprofen suppository was given. The dexibuprofen suppository was given at a dose no more than 200 mg within 24 hrs. The dexibuprofen suppository was instructed to be inserted into the site 2 cm in the rectum of the children as much as possible after defecation and defecation should be avoided within 2 hrs as much as possible.

Outcome assessment

Primary outcomes: (1) Body temperature was compared between the two groups before and after treatment. The body temperature of the two groups was measured before medication and at 0.5, 1, 2, 4 and 6 h after medication. The body temperature was measured using the axillary temperature measuring method. Specifically, nurse assisted the child to dry the armpit, swung the thermometer mercury below 35ºC and placed it in the middle of the armpit. After 5mins, the nurse read the indicated temperature in the thermometer. Therapeutic effects were analyzed and compared: Markedly effective: The body temperature decreased by ≥ 1.5ºC within 4 hrs after treatment; effective: body temperature decreased by 0.7ºC within 4 h after treatment; ineffective: body temperature did not decrease or decreased less than 0.7ºC within 4 hrs after treatment. It should be noted that repeated medication should be conducted at an interval of more than 4 hrs. After administration, the environmental humidity and temperature were kept basically the same. (2) The FLACC scale was used to objectively evaluate the treatment effect before medication administration, as well as at 0.5, 1, 2, 4 and 6 hrs after administration. Assessments were conducted after body temperature measurement, with each observation lasting no less than 2 minutes.

Secondary outcome measures: Adverse reactions were compared between the two groups: The adverse reactions within 6 hrs after drug intake were monitored, including profuse sweating, nausea and vomiting, rash and so on. The

body temperature of the children was measured at 2 days after treatment and logistic regression was used to analyze prognostic risk factors.

Statistical analysis

Statistical analysis was performed using SPSS version 27.0. Measurement data that conformed to a normal distribution, as confirmed by the Shapiro–Wilk test, were expressed as mean ± standard deviation ($\bar{x}\pm$ s) and comparisons between groups were conducted using independent samples t-test. For repeatedly measured body temperature data, a mixed design analysis of variance was used (with the treatment group as the intergroup factor and the time point as the intra-group factor). If there was an interaction or the main effect was significant, the Bonferroni method was used for post hoc comparison. Repeated measures analysis of variance (ANOVA) was applied to analyze body temperature data collected over time. Count data were presented as frequencies and percentages, with group comparisons performed using chi-square test, rank-sum test, or Fisher's exact test as appropriate. Univariate and multivariate logistic regression analyses were employed to identify factors influencing prognosis. Continuous variables, such as body temperature, were converted into categorical variables based on clinical cut-off points before being entered into the model. Regression results were expressed as odds ratios (OR) with their corresponding 95% confidence intervals (CI). An OR > 1 indicated a risk factor, while an OR < 1 suggested a protective factor. A p-value < 0.05 was considered statistically significant.

RESULTS

Data

The χ^2 test and rank sum test were used to compare the two groups. No significant differences were found in age, body mass index (BMI), or gender distribution, disease duration, admission body temperature and diagnosed disease type (P > 0.05, Table 1) and the baseline characteristics were similar.

Changes in body temperature in the two groups before and after medication

The body temperatures of the two groups before medication and at 0.5, 1, 2, 4 and 6 hours after medication were compared through analysis of variance. According to the results, before medication and at 1 h after medication, no significant difference in body temperature was observed between the two groups (P > 0.05), while at 0.5, 2, 4 and 6 hrs after medication, the study group showed notably lower body temperature (P < 0.0001, Fig. 1).

Changes in FLACC scale scores after medication administration in both groups

The FLACC scale scores were compared between the two groups before medication administration and at 0.5, 1, 2, 4 and 6 hrs after administration using analysis of variance. The results showed that there were no statistically significant differences in FLACC scores between the two groups before medication and at 1 and 2 hrs after administration (P > 0.05). However, at 0.5, 4 and 6 hrs after administration, the study group exhibited significantly lower FLACC scores (P < 0.0001, Fig. 2).

Therapeutic effect in the two groups

The Fisher test was used for comparative analysis and the results showed that there was no difference in the therapeutic effect between the two groups (98.25% vs. 95.35%, P = 0.572, Table 2).

Adverse reactions

The Fisher's exact test was used to compare the total incidence of adverse reactions between the two groups. The results showed that the incidence in the study group was significantly lower than that in the control group (3.50% vs. 16.28%, P = 0.027). In addition, 2×2 Fisher's exact tests were conducted for the three types of adverse reactions (profuse sweating, nausea and vomiting and rash) respectively. The results showed that there were no statistically significant differences among the groups for profuse sweating (P = 0.307), nausea and vomiting (P = 0.307) and rash (P = 0.421) (Table 3).

Analysis of related factors affecting prognosis

High fever or recurrence of high fever within 2 days after medication was judged as unfavorable prognosis. Patients with unfavorable prognosis were included in unfavorable prognosis group (n = 25) and those with favorable prognosis were assigned to the favorable prognosis group (n = 75). Univariate analysis was conducted on the clinical data of the two groups. The univariate analysis identified age, disease duration, body temperature, diagnosis and treatment regimen as risk factors (Table 4). Multivariate logistic regression analysis further revealed that disease duration and admission body temperature were independent risk factors affecting prognosis (Table 5). Multivariate Logistic regression analysis showed that the disease duration (OR = 3.060, 95% CI: 1.020-9.180) was a risk factor for poor prognosis, suggesting that for every one-unit increase in the disease duration, the risk of poor prognosis increased by approximately 2.06 times. Admission body temperature (OR = 0.384, 95% CI: 0.148-0.995) is a protective factor. For every one-unit decrease in body temperature, the risk of poor prognosis is reduced by approximately 61.6%.

DISCUSSION

Children are in the process of growth and development, with immature and underdeveloped function of the immune system, so they are easily affected by various adverse internal and external environments and face a high incidence of disease and high risk of acute and critical illness (GBD 2021 Lower Respiratory Infections and Antimicrobial Resistance Collaborators, 2024).

Table 1: Baseline data

Factors		Control group (n=43)	Study group (n=57)	X^2/Z	P value
Age					
	≥3 years old	15	25	0.823	0.364
	<3 years old	28	32		
Gender					
	Male	25	30	0.300	0.584
	Female	18	27		
BMI					
	≥16.4 kg/m^2	20	29	0.187	0.666
	<16.4 kg/m^2	23	28		
Course of disease					
	≥8h	30	31	2.438	0.119
	<8h	13	26		
Admission body temperature (°C)					
	≥39°C	25	34	0.023	0.879
	<39°C	18	23		
Diagnosed disease					
	Bacterial infection	15	20	0.001	0.983
	Viral infection	28	37		
FLACC	0	0	0		
	0-3	1	3	0.480	0.631
	4-6	38	45		
	7-10	4	9		

BMI: Body mass index

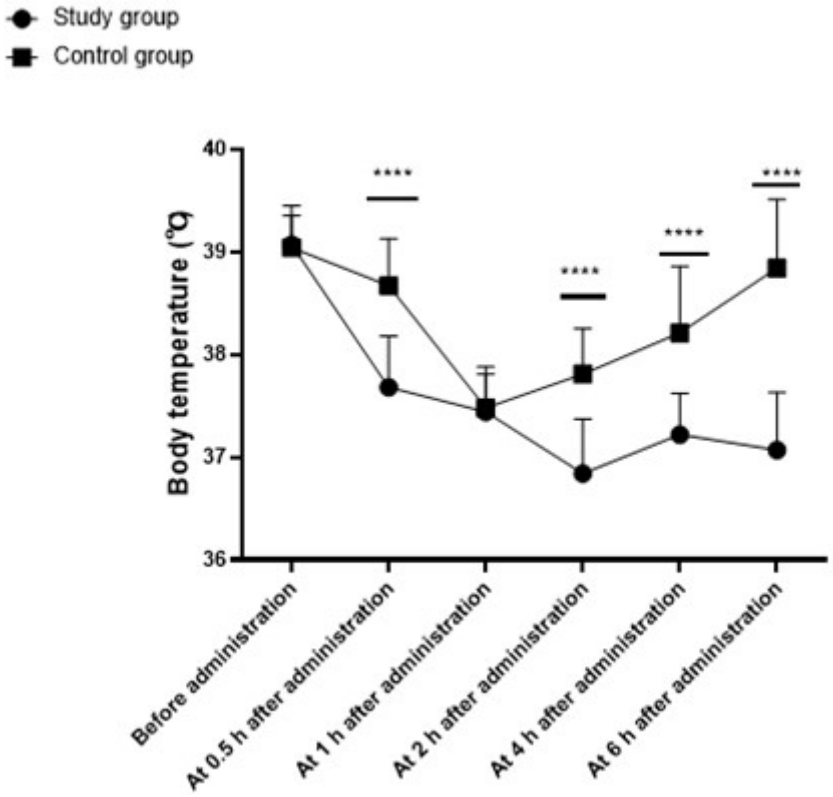

Fig. 1: Changes of body temperature in the two groups before and after medication
Note: ****P < 0.0001 *vs.* the control group.

Table 2: Comparison of therapeutic effect between the two groups (within 6 h)

Group	Markedly effective	Effective	Ineffective	Overall response
Study group (n=57)	50 (87.72)	6 (10.53)	1 (1.75)	56 (98.25)
Control group (n=43)	36 (83.72)	5 (11.63)	2 (4.65)	41 (95.35)
P value				0.572

Table 3: Adverse reactions in the two groups

Group	Profuse sweating	Nausea and vomiting	Rash	Overall response
Study group (n=57)	1 (1.75)	1 (1.75)	0 (0.00)	2 (3.50)
Control group (n=43)	3 (6.98)	3 (6.98)	1 (2.32)	7 (16.28)
P				0.027

Table 4: Univariate analysis

Factors		Favorable prognosis group (n=75)	Unfavorable prognosis group (n=25)	X^2	P
Age					
	≥3 years old	36	4	8.000	0.005
	< 3 years old	39	21		
Gender					
	Male	41	14	0.0135	0.908
	Female	34	11		
BMI					
	≥16.4 kg/m^2	36	13	0.120	0.729
	<16.4 kg/m^2	39	12		
Course of disease	≥8h	40	21	7.412	0.007
	<8h	35	4		
Admission body temperature(°C)	≥39°C	38	21	8.612	0.003
	<39°C	37	4		
Diagnosed disease	Bacterial infection	32	3		
	Viral infection	43	22	7.751	0.005
Medication regimen	Dexibuprofen suppository	50	7	11.441	0.001
	Ibuprofen suspension	25	18		

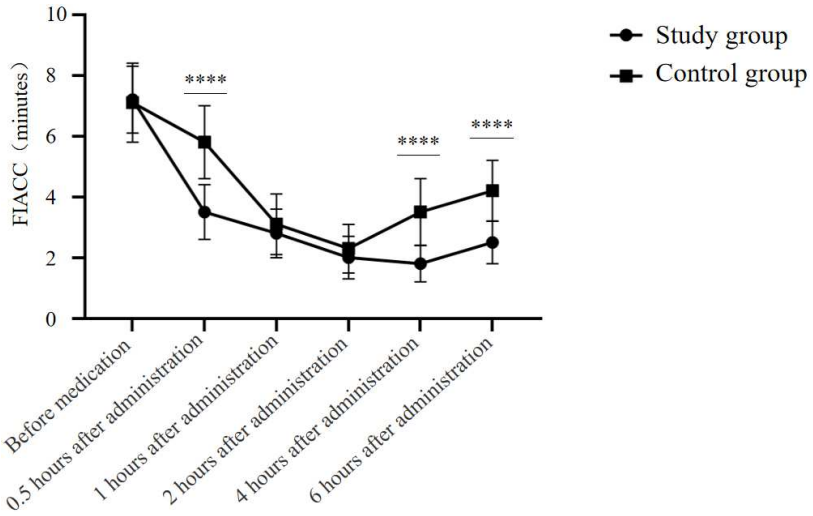

Fig. 2: Flacc scale at 0.5, 1, 2, 4 and 6 hrs after medication
Note: ****P < 0.0001 *vs.* the control group.

Table 5: Multivariate logistic regression analysis

Factors	B	S.E，	Wals	df	Sig.	Exp (B)	95% C.I. of EXP(B)	
							Lower limit	Upper limit
Age	-0.468	0.500	0.878	1	0.349	.626	.235	1.667
Course of disease	1.118	0.561	3.981	1	0.046	3.060	1.020	9.180
Admission body temperature (°C)	-0.958	0.486	3.885	1	0.049	0.384	0.148	0.995
Diagnosed disease	-0.159	0.516	0.095	1	0.758	0.853	.310	2.344
Medication regimen	0.137	0.531	0.067	1	0.796	1.147	0.405	3.246

High fever is a common manifestation of critical illness in children (Lee *et al.*, 2022). Without timely treatment, high fever can easily aggravate and even induce febrile convulsions and organ function damage, threatening the health and life of children (Castellano *et al.*, 2020). Therefore, it is of crucial importance to choose an antipyretic drug with few adverse reactions, quick, strong and long-lasting antipyretic effect and good compliance. Ibuprofen is used to relieve pain and fever (Munir *et al.*, 2025)). Unlike L-ibuprofen, dexibuprofen suppository contains only L-isomers, which is similar to ordinary ibuprofen, but it has higher bioavailability, faster action and rapid metabolism in the body (Pan *et al.*, 2023), (Lamers *et al.*, 2023). This study explored the antipyretic effect of dexibuprofen suppository on children with high fever in the pediatric emergency department.

In this study, before medication and at 1 h after medication, two groups were not different in body temperature, while at 0.5, 2, 4 and 6 hrs after treatment, control group showed notably higher body temperature than experimental group. The results imply a faster and more lasting antipyretic effect of dexibuprofen suppository. In addition, no significant difference in the overall response rate was observed between the two groups, indicating that dexibuprofen suppository can also effectively exert the antipyretic effect. Pan *et al*. 2023 have confirmed that dexibuprofen suppository is as effective as oral ibuprofen (Pan et al., 2023)； It was also suggested that dexibuprofen demonstrates comparable antipyretic efficacy and safety to ibuprofen in the treatment of febrile children in China (Zhao *et al.*, 2025), which is consistent with our results. However, some studies have presented divergent perspectives. For instance, in a comparative pharmacokinetic and safety study conducted in healthy Chinese volunteers by Hua W *et al*. (2023) (Hua *et al.*, 2023), it was observed that differences in formulation, route of administration and study population between dexibuprofen and ibuprofen might lead to inconsistent outcomes.

Ibuprofen can reduce the synthesis of prostaglandins and lower the temperature setting point to achieve the purpose of cooling (Ziesenitz *et al.*, 2022), but it is also easy to trigger adverse reactions such as sweating, nausea and epigastric discomfort (Rosenberg, 2021). In this study, the study group showed a notably lower incidence of adverse reactions, implying that dexibuprofen suppository is safer than ibuprofen suspension. Finally, this study found that age, course of disease, admission body temperature, diagnosed disease, and the treatment protocol were prognostic risk factors in the pediatric population. Logistic regression analysis identified disease duration and admission body temperature as independent risk factors for prognosis in children with high fever. This finding is consistent with the study by Wang *et al*., (2023) (Wang *et al.*, 2023). Furthermore, Zhao *et al*., (2025) also emphasized that the duration of fever is one of the key clinical variables for assessing the severity and prognosis of pediatric patients (Zhao et al., 2025). Persistent high fever often indicates more severe underlying infections or poor response to treatment (Wang et al., 2023, Zhao et al., 2025).

This study, through retrospective analysis, found the antipyretic effect of dexvoibuprofen suppositories on children with high fever in pediatric emergency departments, but limitations to this study. First, the sample size of this study is limited. In addition, the dose of dexibuprofen suppository was not studied.

CONCLUSION

Dexibuprofen suppositories have antipyretic effects in pediatric emergency patients with high fever and have few adverse reactions. In addition, course of disease and admission body temperature are independent risk factors impacting prognosis.

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Authors' contribution
We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. Zhiyang Wu and Junfeng Fu conceived and designed the study and drafted the manuscript. Zhiyang Wu, Pengxiang Lin, Jiawei Li and Zhenjie Zhang collected, analyzed and interpreted the experimental data. All authors revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

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Data availability statement
Data are available from the corresponding author.

Ethical approval
This study was approved by the Ethics Committee of Quanzhou Women's and Children's Hospital (Approval No.: GXD20240912). All patient information was anonymized and the data were used solely for the purposes of this research. Confidentiality was maintained in accordance with the Declaration of Helsinki and relevant data protection regulations.

Conflict of interest
The authors declare that this study was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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