

# The majority of sick children receive paracetamol during the winter

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## ABSTRACT

**INTRODUCTION:** Even though fever is a common symptom in childhood, it often worries parents and they may try to reduce discomfort by giving the child paracetamol, which is currently the most commonly sold over-the-counter medicine. The objective of this study was to investigate parent-administered paracetamol in toddlers during a winter period in relation to symptoms, doctor contacts and severity-rated illness.

**MATERIAL AND METHODS:** The study was conducted as a prospective diary study covering a three-month winter period. It comprised a cohort of 183 infants born in February 2001 in a district of the capital area in Denmark.

**RESULTS:** According to the parents, a total of 119 toddlers (65%) received paracetamol at least once during the study period; 9.3% of the toddlers received paracetamol for more than ten days. The administration of paracetamol rose as the number of symptoms increased. Paracetamol was given in 37% of days with fever. The most frequent combinations of symptoms to trigger paracetamol administration were fever and earache with a probability of 64%. For the symptoms of vomiting and earache, the probability was 60%. In the rare cases with monosymptomatic fever, some 23% used paracetamol.

**CONCLUSION:** The majority of ill toddlers received paracetamol if they had several symptoms. However, paracetamol was administered in 37% of days with fever. This use of paracetamol seems reasonable as the parents differentiate between degrees of illness and withhold paracetamol until the second day of the illness episode

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Fever in childhood is a common symptom which may worry parents [1, 2]. Fever is often accompanied by other symptoms, such as impaired fluid and food consumption, reduced activity, drowsiness and restless sleep [3]. Studies exploring parents' reasons for using paracetamol found that the most prominent reason for the use given by parents is that they were hoping to relieve the child from the symptoms of fever [1, 4]. This is in agreement with a Danish survey among parents showing that in two thirds of cases, paracetamol was given to

reduce fever, and in half of the cases to relieve pain [5].

The indications of paracetamol are to relieve pain and reduce fever [6], but health professionals disagree about the need to administer antipyretic drugs to children with fever episodes [3].

In Denmark, parents often contact their GP for advice when their child has a fever [5]. The GP sometimes recommends paracetamol as a fever-reducing drug, as it also seems to reduce the discomfort caused by the high fever, and this can help the family to gain control over the situation [1, 2, 7]. The Federal Drug Institute recognized paracetamol as safe against fever and pain when taken in prescribed doses [6]. Thus, health care professionals may support a high consumption of paracetamol, which can reinforce fever phobia. Fever phobia is a phenomenon in which the causes and consequences of fever are misunderstood, e.g. the belief that fever is an illness itself, that fever causes brain damage or that febrile seizures could cause death [8].

During recent decades, the sale of paracetamol has increased, and it is now the most commonly sold over-the-counter medicine for children in Denmark [6]. A study reported that children aged 1-2 years have the highest consumption of paracetamol [9], even though the pharmaceutical companies producing paracetamol do not recommend its administration to this age group unless it has been advised by a health care professional [6].

The majority of studies on paracetamol administration to children are retrospective with the risk of recall bias. In this study, we collected information prospectively. The aim was to investigate parents' administration of paracetamol to their toddlers in relation to symptoms, doctor contacts, and parent-rated severity of illness during a three-month winter period.

## MATERIAL AND METHODS

### Study population

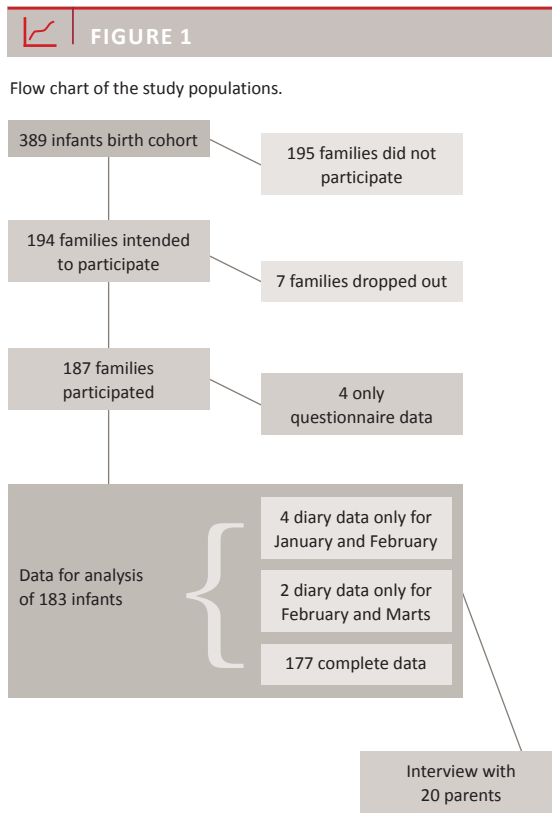
The records of a cohort of 389 infants born in February 2001, Frederiksborg County, Denmark, were retrieved from the National Health Service. The parents received a letter of invitation to participate in the study, and 194 parents gave their informed consent. Retrospective data from birth to the age of 11 months were collected by a questionnaire. The prospective data were collected from

## ORIGINAL ARTICLE

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the age of 11 to 14 months using a structured diary (January, February and March). The questionnaire and the diary were filled in by the parents (Figure 1). A total of 187 completed both the questionnaire and the diary.

## Clinical data

### 1. Questionnaire

Based on the questionnaire, baseline data were collected covering the infants' state of health and family data. The parents answered the questionnaire when the infants were ten months old. The questionnaire was pilot-tested and adjusted [10].

### 2. Diary

The diary consisted of three one-month calendars. Each day, the parents were to tick whether they considered that their infant had experienced any of the following:

- selected symptoms*: crying more than usual, cold/runny nose, not eating normally, not sleeping well, affected breathing, fever, cough, vomiting, diarrhoea, earache;
- doctor-contacts*: telephoned their doctor, visited their doctor, had a home visit by a doctor from the out-of-hours service, visited a specialist doctor or went to the hospital;
- parent-rated illness severity*: how they rated the severity of their infant's illness: 0 = not ill, (X) = not really ill, but not really well either, X = ill, XX = very ill, XXX = severely ill. A rating of X or higher was defined as

parent-rated illness [11]. The diary was pilot-tested and adjusted according to the comments [10].

## Statistical methods

For each participating family, the prevalence of the various events was calculated as the number of occurrences in the 90-day diary period; for families with incomplete data, the number of occurrences was multiplied by the inverse of the fraction of the diary period that had not been completed. The prevalence of paracetamol use in relation to a certain criterion, e.g. the presence of a particular symptom, was calculated as the proportion of days with paracetamol use corresponding to the days the criterion applied. Data is displayed as medians with the inter-quartile range and full range of the data or numbers in each category with percentages.

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## RESULTS

### Study population

The entire cohort of children born in the study period were invited ( $n = 389$ ). In all, 194 agreed to participate, seven families withdrew their initial agreement, and four families did not complete the questionnaire and diary, which left 183 children for analysis (Figure 1). A total of 70% of the families had two or more children.

The characteristics of the study population are given in Table 1. Most of the toddlers were ill at some time and had been in contact with a doctor during the study period. The toddlers who received the most paracetamol were those who had an anamnestic episode of illness, high frequency of doctor consultations, earache and restless sleep in the diary period [10].

### General symptoms and use of paracetamol

During the three-month period, a total of 16,284 days were surveyed. The symptoms and illness periods are presented in Table 2. On average, the toddlers experienced symptoms one out of two days; 38% of the toddlers had more than five symptoms for more than six days, and the vast majority (92.9%) had more than ten days with at least one symptom. Half of the 183 toddlers had six days of fever, and 86.9% of the families contacted a doctor. The doctor contact was primarily to the GP (77.6%) and out-of-hours service (55%).

A total of 65% of the toddlers received paracetamol during the three-month period, and 9.3% of the toddlers received paracetamol for more than ten days (Table 2).

The occurrence of paracetamol administration in relation to specific symptoms is given in Table 3. When earache, fever, and vomiting were among the symp-



TABLE 1

Baseline characteristics of the cohort of 183 children assessed at nine months of age at the start of the data collection period. Listed are (for interval-scale data) medians with inter-quartile range and full range of the data, or (for categorical data) numbers in each category with percentages. The data summaries are presented separately for those children who did and did not use Panodil in the diary period. A p-value (Fisher's exact test for categorical variables, Kruskal-Wallis test for continuous variables) denotes whether there is a difference between these two groups.

Characteristic	Total (n = 183)	No Panodil use (n = 64)	Some Panodil use (n = 119)	p-value	Missing
<i>Sex, n (%)</i>				0.4376	0
Boys	102 (55.7)	33 (51.6)	69 (58.0)		
Girls	81 (44.3)	31 (48.4)	50 (42.0)		
<i>Mother's age, years</i>				0.9042	0
Median (IQR)	32 (29-34)	32 (28-35)	31 (29-34)		
Range	21-41	21-41	22-39		
<i>Father's age, years</i>				0.3026	0
Median (IQR)	34 (30-37)	35 (31-37)	34 (29-37)		
Range	23-51	25-37	23-51		
<i>Episodes of illness since birth, n</i>				0.003	2
Median (IQR)	2 (1-4)	2 (1-3)	3 (2-4)		
Range	0-15	0-15	0-14		
<i>Medication regularly, n (%)</i>				0.6293	2
No	160 (88.4)	58 (90.6)	102 (87.2)		
Yes	21 (11.6)	6 (9.4)	15 (12.8)		
<i>Visits to the GP since birth, n</i>				0.0031	0
Median (IQR)	1 (0-2)	1 (0-2)	1 (1-2)		
Range	0-9	0-9	0-8		
<i>No. of siblings, n (%)</i>				0.1031	11
0	52 (30.2)	26 (41.9)	26 (23.6)		
1	85 (49.4)	25 (40.3)	60 (54.6)		
2	28 (16.3)	10 (16.2)	18 (16.4)		
3	5 (2.9)	1 (1.6)	4 (3.6)		
≥ 4	2 (1.2)	0 (0.0)	2 (1.8)		
<i>Siblings who are often ill, n (%)</i>				0.0484	2
No	146 (80.7)	56 (88.9)	90 (76.3)		
Yes	35 (19.3)	7 (11.1)	28 (23.7)		
<i>Parent-rated health of the child, n (%)</i>				0.5493	0
Very good	72 (39.3)	29 (45.3)	43 (36.1)		
Good	95 (51.9)	31 (48.4)	64 (53.8)		
Fairly good	15 (8.2)	4 (6.3)	11 (9.2)		
Poor	1 (0.6)	0 (0.0)	1 (0.8)		
Miserable	0 (0.0)	0 (0.0)	0 (0.0)		
<i>(Selected) symptoms since birth, n (%)</i>					
Fever	150 (82.0)	49 (76.6)	101 (84.9)	0.2258	0
Cough	140 (76.5)	48 (75.0)	92 (77.3)	0.7187	0
Vomiting	61 (33.3)	18 (28.1)	43 (36.1)	0.3249	0
Diarrhoea	88 (48.1)	24 (37.5)	64 (53.8)	0.0438	0
Rash	47 (25.7)	18 (28.1)	29 (24.4)	0.598	0
Wheeze	58 (31.7)	15 (23.4)	43 (36.1)	0.0961	0
Pain in the ear	44 (24.0)	6 (9.4)	38 (31.9)	0.0001	0
Cold, snotty, runny nose	172 (94.0)	59 (92.2)	113 (95.0)	0.5197	0
Eye infection	67 (36.6)	18 (28.1)	49 (41.2)	0.1073	0
Sleep fitfully	123 (67.2)	34 (53.1)	89 (74.8)	0.0047	0
Allergic reaction	11 (6.0)	3 (4.7)	8 (6.7)	0.7496	0
<i>(Selected) illness since birth, n (%)</i>					
Cold	169 (96.6)	58 (98.3)	111 (95.7)	0.6651	8
Pneumonia	19 (10.9)	4 (6.8)	15 (12.9)	0.3053	8
Otitis media	33 (18.9)	5 (8.5)	28 (24.1)	0.0137	8
Bronchitis	14 (8.0)	0 (0.0)	14 (12.1)	0.0028	8
Fevercramps	1 (0.6)	1 (1.7)	0 (0.0)	0.3371	8
Eczema	26 (14.9)	10 (17.0)	16 (13.8)	0.5789	8
Diarrhoea and/or vomiting	57 (32.6)	15 (25.4)	42 (36.2)	0.1502	8

IQR = inter-quartile range.

 TABLE 2

Prevalence of selected events – symptoms, parent-rated illness and doctor contacts – over the 90 days of observation<sup>a</sup>. The distribution of the occurrences is represented by 1) the number (percentage) of children within each of four classes of prevalence, and 2) the median prevalence with inter-quartile range and full range (min.-max.).

Event	Prevalence of the event (out of 90 days), n (%)				Median	IQR	Range
	0 days	1-5 days	6-10 days	> 10 days			
At least one symptom <sup>b</sup>	1 (0.5)	2 (1.1)	10 (5.5)	170 (92.9)	40	28-56	0-90
2 or more symptoms <sup>b</sup>	1 (0.5)	15 (8.2)	27 (14.8)	140 (76.5)	21	11-34	0-78
3 or more symptoms <sup>b</sup>	10 (5.5)	44 (24.0)	31 (16.9)	98 (53.6)	11	5-18	0-70
4 or more symptoms <sup>b</sup>	23 (12.6)	57 (31.1)	51 (27.9)	52 (28.4)	7	2-11	0-55
5 or more symptoms <sup>b</sup>	41 (22.4)	72 (39.3)	50 (27.3)	20 (10.9)	4	1-7	0-41
Crying more than usual	34 (18.6)	56 (30.6)	38 (20.8)	55 (30.1)	6	2-12	0-56
Cold/runny nose	4 (2.2)	7 (3.8)	22 (12.0)	150 (82.0)	28	15-41	0-90
Not eating normally	26 (14.2)	63 (34.4)	42 (23.0)	52 (28.4)	6	2-12	0-50
Not sleeping well	16 (8.7)	47 (25.7)	39 (21.3)	81 (44.3)	9	4-17	0-80
Breathing affected	77 (42.1)	54 (29.5)	23 (12.6)	29 (15.8)	2	0-7	0-67
Fever	16 (8.7)	75 (41.0)	66 (36.1)	26 (14.2)	6	3-9	0-22
Cough	21 (11.5)	28 (15.3)	25 (13.7)	109 (59.6)	15	5-25	0-75
Vomiting	89 (48.6)	77 (42.1)	14 (7.7)	3 (1.6)	1	0-2	0-23
Diarrhoea	70 (38.3)	77 (42.1)	26 (14.2)	10 (5.5)	2	0-5	0-32
Earache	118 (64.5)	42 (23.0)	11 (6.0)	12 (6.6)	0	0-3	0-42
Parent-rated illness (X), X, XX or XXX	13 (7.1)	13 (7.1)	34 (18.6)	123 (67.2)	15	9-23	0-78
Parent-rated illness X, XX or XXX	28 (15.3)	45 (24.6)	60 (32.8)	50 (27.3)	7	3-11	0-41
Parent-rated illness XX or XXX	118 (64.5)	52 (28.4)	7 (3.8)	6 (3.3)	0	0-2	0-21
Parent-rated illness XXX	175 (95.6)	7 (3.8)	1 (0.5)	0 (0.0)	0	0-0	0-6
Doctor contact	24 (13.1)	122 (66.7)	30 (16.4)	7 (3.8)	3	1-5	0-18
Contact to own GP	41 (22.4)	132 (72.1)	9 (4.9)	1 (0.5)	2	1-3	0-12
Contact to out-of-hours service	81 (44.3)	101 (55.2)	1 (0.5)	0 (0.0)	1	0-2	0-6
Contact to specialized care <sup>c</sup>	134 (73.2)	43 (23.5)	6 (3.3)	0 (0.0)	0	0-1	0-10
Panodil use	64 (35.0)	76 (41.5)	26 (14.2)	17 (9.3)	2	0-5	0-36
Penicilin use	111 (60.7)	23 (12.6)	30 (16.4)	19 (10.4)	0	0-6	0-40

GP = general practitioner; IQR = inter-quartile range.

a) The seven children with an observation period shorter than 90 days had their nominal observed number of occurrences multiplied with the inverse of the fraction of the 90 days they were observed; this was done to make these observations comparable to the remaining data.

b) Of the ten named symptoms in the diary data.

c) Visit to a hospital or to a specialist physician.

tooms, it often led to parents administering paracetamol. Paracetamol was given in 37% of the days with fever. "Mono-symptomatic" fever occurred rarely with 43 out of 16,284 days of observance, and ten (23%) of those cases were treated with paracetamol. The presence of several symptoms, a condition rated by the parents as severe illness, also resulted in paracetamol being administered.

The occurrence of paracetamol use was related to doctor contact. There was a tendency to withhold paracetamol on the first day of illness compared with the second and third.

Symptoms often co-occurred, and specific combinations of symptoms had different effects on paracetamol use. Most effects were in concordance with Table 3 in so far as crying more than usual, cold/runny nose, not eating normally and coughing were very common symptoms that did not cause the parents to give paracetamol. Also, if fever or earache were present, the prevalence of

paracetamol use increased. An interesting association was that vomiting in combination with cold/runny nose, not eating normally, not sleeping well and affected breathing appeared to increase the prevalence of paracetamol use, while vomiting in combination with crying more than usually appeared to lead to a decrease. The combination of vomiting and earache led to the highest probability of administering paracetamol.

## DISCUSSION

### Main findings

During the three-month winter period, the majority of toddlers (65%) had received paracetamol at least once, and 9.3% had received paracetamol for more than ten days. The administration of paracetamol increased with the frequency of symptoms. The two most frequent combinations of symptoms to trigger paracetamol administration were fever with earache and vomiting with earache.



TABLE 3

Prevalence of Panodil use concurrent with the presence of specific symptoms, parent-rated illness, doctor contact and days with illness.

Symptom	Probability of Panodil use
Crying more than usual	0.27
Cold/runny nose	0.09
Not eating normally	0.24
Not sleeping well	0.20
Breathing affected	0.20
Fever	0.37
Cough	0.12
Vomiting	0.30
Diarrhoea	0.18
Earache	0.46
≥ 1 symptom	0.09
≥ 2 symptoms	0.14
≥ 3 symptoms	0.22
≥ 4 symptoms	0.31
≥ 5 symptoms	0.38
Doctor contact	0.33
Parent-rated illness (X), X, XX or XXX	0.17
Parent-rated illness X, XX or XXX	0.31
Parent-rated illness XX, XXX	0.62
Parent-rated illness XXX	0.65
Worry	0.27
1st day of illness	0.28
2nd day of illness	0.36
3rd day of illness	0.36
> 3rd day of illness	0.27

### The use of paracetamol

Our finding of a high frequency paracetamol usage is in accordance with other studies [5, 9]. However, the studies are not absolutely comparative, as our study is prospective, and the data collection period was in the winter, where infection rate was at a peak [9]. The high level of administration of paracetamol reported may raise a concern about its overall usage. We report that 9.3% received paracetamol for more than ten days, but these were not necessarily consecutive days. This figure may represent toddlers with earache, as it is well-known that earache is a symptom leading to consultations and advice regarding paracetamol administration [9, 11]. However, parents may misjudge the symptoms and administer paracetamol for reasons other than pain, e.g. fever phobia or parents' anxiety [4]. This point of view is controversial, as studies of parents' perceptions and health care use are reflected and relevant as they seek medical consultation for specific reasons related to the principal complaint and the severity of the symptoms [12]. Vomiting is a common co-symptom when a child perceives pain, and this could explain the high probability of paracetamol administration associated with vomit-

ing [13]. When the parents have administered paracetamol for their sick children, they may perceive an improvement in the child's wellbeing [1, 5]. The parents' perception of the paracetamol-induced improvement can give a sense of increased control of the situation [5]. The psychological impact from the act of giving paracetamol should therefore not be neglected [14]. In contrast, the concepts of control, educational level, and number of children have shown to have only a slight influence when it comes to dosing paracetamol [1].

In our diary study, we did not ask the parents why they used paracetamol for their children, but 20 of the participating families also took part in an interview study in which they related that they used paracetamol to calm the toddlers, to enable them to drink and sleep, and to relieve them of pain [10]. In our study, 70% of the parents had two or more children, and experienced parents may have a lower threshold for administration of paracetamol, as they may have experienced that it is useful and safe. This is presumably supported by a study showing that experienced parents are more likely to administer paracetamol "to promote sleep", whereas single-child parents use it "to prevent the disease from worsening" [15].

It is controversial whether or not the use of paracetamol for fever reduction has a negative influence on the body's ability to fight an infection [16]. Even though fever is associated with increased immune function, any benefits of fever and clinical outcome have never been demonstrated [17]. In contrast, no studies have shown that antipyretics have a negative effect on the body's immune response [16]. Studies show that the use of antipyretic medicine does not prolong the febrile period [16] and does not improve clinical outcome [18].

In our study, the parents used paracetamol in 37% of days where fever was one of the symptoms of infection and in 23% of days with fever as a single symptom. We do not know if parents had the idea that fever is a normal immune system reaction against an infection. The trend today seems to be that the patients' use of over-the-counter medicine is increasing, and the promotion of paracetamol from the medicine industry is heavy. Also, paracetamol is being recommended by healthcare personnel every now and then. Despite such pressure, it seems as if the parents are still cautious about using paracetamol, at least for monosymptomatic fever. Nevertheless, 65% of children were given paracetamol, and one might fear the increase of this number with the potential for overmedication as a result. The GP could promote fever as a normal reaction to start the immune response.

### Strengths and limitations

To our knowledge, this study is the first prospective lon-

A crying toddler with his caring and comforting father. Photographer: Christie Munc



gitudinal diary study investigating toddlers' use of paracetamol. A winter period was chosen, because we wanted to study multiple symptoms [19]. The diary card design enabled us to investigate minor symptoms, illness development, and parental reactions – which are often forgotten [20]. Of the invited parents, 50% accepted to participate, and 20% answered the invitation letter and the questionnaire about why they did not want to participate [11]. The drop-out analysis shows that the reasons most frequently given were lack of time or already participating in investigation. The diary method may have led to the selection of particularly resourceful parents, since it took a certain amount of effort to fill in a diary card. Furthermore, an overrepresentation of resourceful parents may have had an influence on the low quantity of paracetamol given [1]. The high response rate avoided bias attributable to missing data. However, the clinical evaluation of the symptoms by a physician was not compared with the parental assessments [12]. Unfortunately, the parents were not asked to record the precise level of fever or the amount of paracetamol given. On the whole, however, we do not think that these aspects jeopardize the overall conclusions.

## CONCLUSION

In conclusion, this prospective study demonstrated that the majority of ill toddlers received paracetamol if they had several symptoms. However, paracetamol was administered in 37% of days with fever. Fewer toddlers got paracetamol against mono-symptomatic fever. In most

incidences, the parents' use of paracetamol seemed reasonable, because they differentiated between severe and mild symptoms and did not give paracetamol until the second day of the illness episode. Further research could explore the connections between families' stress factors, such as problems with staying home to care for the sick toddler, and the question of when the paracetamol dosage is administered.

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