Archives of Disease in Childhood, 1979, **54**, 469–479

Short reports

Rectal paracetamol in small children with fever

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SUMMARY 37 febrile children aged between 3 months and 6 years were treated with paracetamol in a dose of 15–20 mg/kg by either oral elixir or rectal suppository. The rectal route was found to have an equal antipyretic effect and offers a practical alternative in those children for whom the oral route is not possible.

A high fever in a small child brings the risk of a convulsion as well as causing discomfort and increasing fluid loss. It has been shown that antipyretic drugs cool better than mechanical methods (Hunter, 1973), and that paracetamol and acetylsalicylate are equally effective (Colgan and Mintz, 1957; Eden and Kaufman, 1967). Paracetamol is often preferred because it has fewer adverse effects in therapeutic dosage and because accidental poisoning is less likely. The oral route is sometimes impractical—for example in a child who is convulsing, comatose, or vomiting—and absorption after oral ingestion may be impaired by the delay in gastric emptying that accompanies a severe illness (Heading *et al.*, 1973). At present no parenteral form of paracetamol is available. Previous work shows that paracetamol in rectal suppositories is well absorbed, but at a dosage of 10 mg/kg reduces fever in children less effectively than an oral elixir (Keinänen *et al.*, 1977). We therefore compared the antipyretic effect and practicability of the oral and rectal routes in small children using paracetamol in higher dosage.

Patients and method

40 children with rectal temperatures of at least 38·5°C were divided into two age groups (between 3 months and 2 years, and between 2 and 6 years) and randomly allocated within each group to either oral or rectal paracetamol. The oral preparation was the standard BPC elixir containing paracetamol 120 mg/5 ml, and the suppositories, which were made up in the hospital pharmacy, contained paracetamol 120 mg or 240 mg in 1 g of triglyceride base (Witepsol H15). Each child was given a single dose of 15 mg/kg paracetamol rounded to an appropriate multiple of 120 mg. Mean dosages ± 1 SD in the younger children were 20·2 ± 3·8 mg/kg (oral) and 19·7 ± 3·0 mg/kg (rectal), and in the older group 16·3 ± 3·3 mg/kg (oral) and 17·8 ± 2·4 mg/kg (rectal) (differences between dosages within each group were not statistically significant). Difficulties in drug administration were noted. Conditions were standardised as much as possible: the only clothing was nappies or pants, oral fluids were encouraged if appropriate, but no other means of cooling were used. The ambient temperature, which was monitored throughout the study period, was similar for each group of children. Rectal temperatures were recorded every 15 minutes for 3 hours by the same observer using an electric thermometer (IVAC 821).

Among the younger children, in the oral group 6 had upper respiratory tract infection (URTI), 3 bronchiolitis, 1 gastroenteritis, 1 mumps, and 1 encephalitis; in the rectal group 7 had URTI, 2 gastroenteritis, 1 bronchiolitis, 1 pneumonia, 1 urinary tract infection, and 1 encephalitis. Among the older children, in the oral group 5 had URTI, 1 mumps, 1 urinary tract infection, and 1 pyrexia of unknown origin; in the rectal group 4 had URTI, 1 measles, 1 cervical adenitis, and 1 roseola infantum. The groups were comparable in respect of duration of illness, state of hydration, and concurrent therapy, all these factors being recorded. The 2 children with encephalitis exhibited resistant hyperpyrexia and were therefore excluded from analysis, as was a third child in the younger oral group, who was found to have been given an extra dose of paracetamol in error. Paracetamol could not be given orally to 2 of the children initially allocated to this route, one because of vomiting and the other because of a convulsion; their inclusion in the rectal group did not bias the initial mean temperatures. There was no difficulty in giving the suppositories, even in children who had diarrhoea. One child (included in the analysis) extruded a partly-dissolved suppository 2 hours after its insertion.

Results

18 children (10 under 2, and 8 between 2 and 6 years) received oral paracetamol and 19 children (12 under 2, and 7 between 2 and 6 years) received rectal paracetamol. The initial mean temperatures of the younger children were 38·95°C (oral group) and 39·23°C (rectal group), and of the older children 38·89°C (oral group) and 38·99°C (rectal group). Within each age range the relationship between fall in temperature and time up to 3 hours from administration of paracetamol was highly significant ($P<0·001$) for both routes, and there was no significant difference between the routes. Figs 1 and 2 show the mean change from initial temperature at 15-min intervals in both age groups. Generally, the oral group of younger children cooled down more than the rectal group for most of the study period (Fig. 1), and the oral group of older children cooled down better at first but were later overtaken by the rectal group (Fig. 2); however these differences were not statistically significant. The mean fall in temperature of the younger children after 3 hours was 1·83°C (oral) and 1·66°C (rectal), and for the older children 1·63°C (oral) and 1·89°C (rectal) but there was a wider scatter in response among the rectal groups, possibly because of greater variability in absorption.

The younger children had generally reached their maximum fall in temperature by 150 minutes, whereas the temperatures of the older children, despite a smaller mean dosage of paracetamol, were usually still dropping at 180 minutes; this difference did not achieve statistical significance.

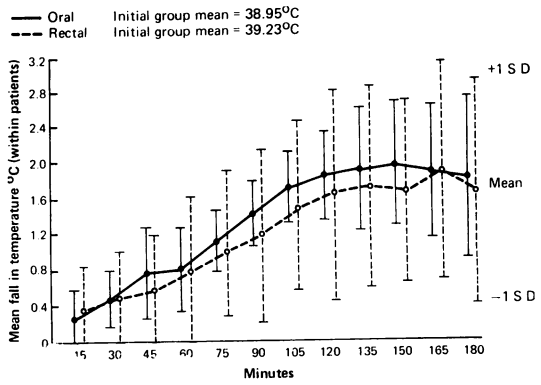

Fig. 1 *Mean change from initial temperature ± 1 SD at 15-min intervals for the children under 2 years on oral or rectal paracetamol.*

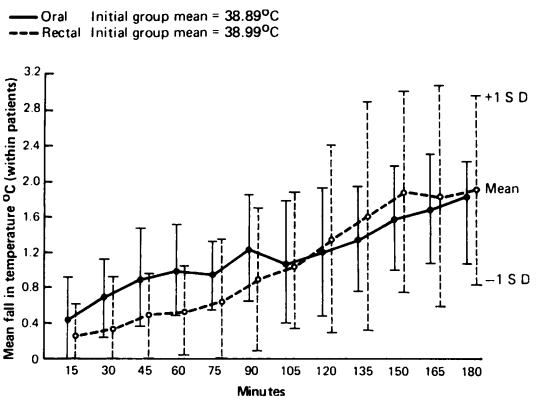

Fig. 2 *Mean change from initial temperature ± 1 SD at 15-min intervals for the children aged between 2 and 6 years on oral or rectal paracetamol.*

Discussion

Our results show that suppositories of paracetamol in small children in a dosage of 15–20 mg/kg offer an effective and practical alternative to an oral elixir. If both routes are available the oral may be preferred because of the greater consistency of response, but if oral administration is impossible the rectal route provides a good substitute. Paracetamol suppositories can be easily manufactured by a hospital pharmacy, but it would be helpful if they were widely available commercially so that they could be used at home. Their absorption characteristics may be improved if polyethylene glycol is used as base rather than triglyceride (Keinänen *et al.*, 1977).

We thank the Boots Drug Company whose grant made this study possible, IVAC (UK) for the electric thermometer, and our hospital pharmacy who made up the suppositories.

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