Homœopathic treatment of acute childhood diarrhoea

A randomized clinical trial in Nicaragua

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Abstract

A double-blind, randomized clinical trial to compare homœopathic treatment versus placebo in the treatment of acute childhood diarrhoea was carried out in Leon, Nicaragua, in July 1990. 34 children aged 6 months to 5 years were randomized into active and placebo groups, both of which also received oral rehydration treatment. The mean duration of diarrhoea after treatment in the active group was 2.4 days, compared to 3.0 days in the placebo group, which was not statistically significant. Exploratory analysis revealed a statistically significant decrease ($p = 0.04$) in the subgroup of patients for which an aetiological agent was found. There was also a significant difference in number of stools per day in the treated group ($p = 0.002$) at the end of the treatment period. Since small numbers prevent a definitive conclusion from this study, further study with a larger sample size would seem appropriate.

KEY WORDS: Diarrhoea; Diarrhoea, infantile; Homœopathy; Rotavirus infections; Nicaragua

Introduction

Diarrhoeal illness is the leading cause of mortality among children in the developing world, with an estimated 4.6 million deaths per year from this illness.[1,2] While oral rehydration therapy (ORT) has proved to be effective in preventing death from dehydration caused by acute diarrhoea, it does not generally shorten the duration of individual episodes.[2]

The practice of homœopathic medicine is based on the principle of similars, whereby a substance that can cause symptoms when given in large doses to a healthy person is said to cure those same symptoms in someone who is ill, if given in extremely small doses. It is thought that homœopathic medicines may stimulate the autoimmune system, through the hypersensitivity reaction, in a process similar to anaphylaxis.[4] Double-blind investigations have suggested homœopathy to be effective in seasonal allergic rhinitis,[5] influenza[6] and primary fibromyalgia.[7] Homœopathic treatment is inexpensive, with an

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average cost per dose of medicine of about twenty cents.

Because many of the pathogens associated with acute diarrhoea are viral, the widespread use of antimicrobials is not routinely recommended for its treatment.[8] Historically, homœopathic medicine has been used to treat diarrhoea both in adults and children.[9] Finding an inexpensive treatment that would shorten the course of childhood diarrhoea could have a significant impact on diarrhoea-related morbidity and mortality.

Method

A randomized, double-blind clinical trial comparing homœopathic medicine with placebo in the treatment of acute childhood diarrhoea was carried out in Leon, Nicaragua, in July 1990. 34 children aged 6 months to 5 years with a history of acute diarrhoea were enrolled in the study. Informed consent was obtained in writing from the parent(s) of all children involved. Acute diarrhoea was defined as the passage of three or more liquid stools during the previous 24 hours. Children with a history of diarrhoea for more than 10 days or who had received anti-diarrhoeal medication within the previous 24 hours were excluded from the study.

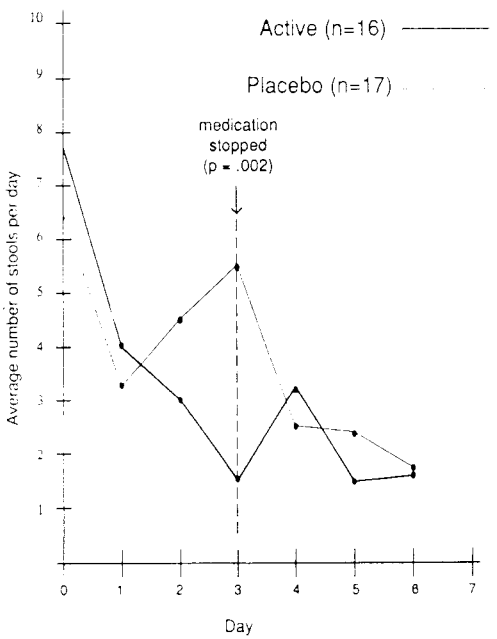

Fig. 1. Average number of stools per day—active versus placebo.

An individualized homœopathic medicine was prescribed for each child, using standard homœopathic methods and the computerized homœopathic program RADAR (Archibel, Brussels, Belgium). The children were randomized into treatment and placebo groups, and medications were dispensed without investigators' knowledge of the code. Active medication was given in the 30c potency on premedicated sucrose/lactose pellets which were identical in appearance and odour to placebo. Medication was given twice daily for 3 days, or until there were less than 3 liquid stools for 1 day, whichever occurred first. Oral rehydration therapy was administered to all children according to WHO protocols.[10]

Age, sex and information about duration of diarrhoea, degree of dehydration, and other symptoms were collected upon enrolment in the study. Height and weight were also measured. Stool specimens were examined for bacteria, rotavirus and ova and parasites.

Daily home visits were carried out by community health workers for 6 days following the initial visit. The parents' recall of the number of loose stools per day was recorded, as well as the degree of dehydration as evaluated by the health worker, use of other medications, and other symptoms. The duration of diarrhoea was defined as the number of days following entry into the study until there were 2 consecutive days with less than 3 liquid bowel movements per day. At the end of 1 week, the child was reweighed.

TABLE 1. *Comparison of outcomes between active group and placebo*

	Active (n = 16)	Placebo (n = 17)	*p*
Mean duration	2.4	3.0	0.28
Days to first diarrhoea-free day	2.0	2.5	0.31
Total days diarrhoea	5.4	6.2	0.53
Mean stools/day	2.8	3.5	0.57
Mean weight gain (kg) (n = 24)	0.36	0.88	0.64
% Days medicine taken	36.3	44.4	0.25
Positive for:			
Any aetiol. agent (n = 17)			
Mean duration	1.7	3.4	0.04
Parasites (n = 13)			
Mean duration	1.2	3.0	0.02
Rotavirus (n = 9)			
Mean duration	2.0	4.0	0.15

The software Epi-Info (USD, Incorporated, Stone Mountain, Georgia) was used to calculate 2-sample, 2-tailed t-test to compare the descriptive characteristics at the initial visit between the 2 groups and the number of stools per day during the course of treatment. The log rank test was used to compare the duration of diarrhoea in each group, since some children did not have follow-up for the entire 6 days and some continued to have diarrhoea at the end of the follow-up period.

Results

A comparison of descriptive characteristics at the initial visit did not reveal any significant differences between the 2 groups. All of the cases in both groups had mild, Type A dehydration.[10] There was no significant difference in the mean duration of diarrhoea following treatment, number of days to first diarrhoea-free day, total number of days of diarrhoea, number of stools per day, and weight gain (or loss) between the two groups (Table 1), although the treatment group did better than placebo in all of these outcomes except weight gain.

In the subgroup of children with a stool that was positive for an aetiological agent, either rotavirus or ova and parasites (or both), there was a statistically significant difference at $p < 0.05$, with the treatment group having a shorter duration of diarrhoea.

The average number of stools per day for each group can be seen in Figure 1. The treatment group showed a linear drop in number of stools per day for the first 3 days, while the control group had an initial decline at day 1, then increased during days 2 and 3. The average number of stools per day at day 3, when the study medication was stopped, was 1.5 for the active group compared to 5.6 for placebo, which is statistically significant at $p = 0.002$.

Discussion

The small sample size of this study limits the significance of any associations found. The fact that the treatment group had slightly better (though not statistically significant) outcomes in all measures, except for weight gain, might be due to a beneficial therapeutic effect of homœopathic medicine. The significant difference between treatment and control among children with identified pathogens might reflect a stimulation of host resistance by homœopathic medicine.

The protocol called for the cessation of treatment after 3 days or until there was one diarrhoea-free day, so all medication was stopped on or before the third day. Since the treatment group improved more rapidly in the first 3 days, as reflected in the average number of stools per day, it is possible that the observed difference between the two groups might have continued if the medicine had been given for a longer period of time. Since studies have shown that over 80% of acute diarrhoeal episodes resolve within 1 week,[3] it is not surprising that the number of stools per day was similar between the 2 groups at the end of the study.

These results suggest that a larger, definitive study of the effect of homœopathic treatment on acute childhood diarrhoea should be done.

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