



Acute Diarrhoeal Diseases in Children treated by Homoeopathy –A Prospective Open Clinical Trial²

Abstract: Diarrhoeal is one condition most amenable to Homoeopathy, in the experience of all practitioners. these are the types of study required to be carried out for all ailments if we want Homoeopathy to be acceptable to the rest of the Medical world

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BACKGROUND AND OBJECTIVE: Acute diarrhoea is the leading cause of all paediatric morbidity and mortality worldwide. Although most cases of diarrhoea in children are caused by viral, bacterial and parasitic pathogens, no specific pathogen can be identified in 50% cases. The objective of the study was to evolve the usefulness of 14 predefined trial Homoeopathic medicines in the treatment of acute diarrhoeal diseases in children.

METHODS: It was a prospective open clinical trial carried out during the period of 2005-2008 at the Extension Centre of Drug Standardization Unit, Hyderabad at Princess Durru Shehvar Children's and General Hosp, Hyderabad. Out of the 281 patients screened, 68 were enrolled as per the inclusion and exclusion criteria of protocol and were followed up regularly. Eleven out of the 14 trial medicines were prescribed basing on the classical Homoeopathic principles. The improvement status of the cases (before and after treatment) has been assessed taking into consideration the diarrhoea index score developed by the Council.

RESULTS: The difference in the mean score was

found to be statistically significant ($t = 17.1$, $df = 67$, $P = 0.000$, <0.05). Out of the 68 children followed, 66 were cured; one child showed marked improvement whereas one child was referred for other treatment as symptoms worsened. Among the trial group of medicines prescribed, *Podo* ($n=31,45.6\%$), *Aethusa-cynapium* ($n=10,14.7\%$), *Chamomilla* ($n=8,11.8\%$), *Sulphur* ($n=6,8.9\%$) and *Ipecac* ($n=4,5.9\%$) were mostly prescribed and found effective.

CONCLUSION: This was an open clinical trial, non-comparative study with positive results. However, further studies including randomized controlled trials need to be conducted to vindicate the efficacy of Homoeopathic therapy and medicines.

KEYWORDS: Acute diarrhoea; children; Homoeopathic treatment; non-comparative study; open clinical trial.

INTRODUCTION: Diarrhoea, one of the most frequent problem encountered by the pediatricians, is defined as an increase in frequency, fluidity and volume of feces. During the first 3 years of life, a child will experience estimated 1-3 acute, severe episodes of diarrhoea. Although most episodes of acute diarrhoea subside within 72 hours with fluid administration and diet change, 1-4% of these episodes, worldwide, will be fatal¹.

Diarrhoea in early childhood is a major public health problem in developing countries.



Dehydration from diarrhoea is an important contributing cause of childhood mortality. Data show a slight decline in the prevalence of diarrhoea over time: from 8% of children under five in 1996-1997, to 6% in 1999-2000, and an increase in the use of oral rehydration solution (ORS) from 49% 1996- 1997, to 61% in 1999-2000². Diarrhoea is an indirect cause of death in much larger numbers, since it precipitates or aggravates malnutrition in children and makes them more vulnerable to infection. No age is exempt, but the diarrhoeal disease is most frequent in children under the age of 2 years, who account for three fourth of the cases. Most cases occur between the ages of 6 and 18 months, with peak incidence of diarrhoea with the onset of summer months, with maximum frequency during the rainy season. Children from poor families are more prone to suffer. The incidence is slightly higher among children living in poor sanitary environment. Incidence is lower in educated families with higher standards of personal hygiene and health consciousness^{3,4}.

In India, Diarrhoeal diseases and acute respiratory infections account for a significant morbidity and mortality among children under five. It is estimated that there are 1.7 episodes of diarrhoea per child per year in the under fives (WHO, 1999). An estimated 400,000 children under-five years of age die each year due to diarrhoea (UNICEF, 2005). India launched the new low-osmolar Oral Rehydration Salts (ORS) in June 2004 and in the process became the first country to adopt the new WHO formulation⁵.

Although most cases of diarrhoea in children are caused by viral, bacterial and parasitic pathogens, no specific pathogen can be identified in more than 50% children with diarrhoeal illnesses⁶.

Homoeopathic remedies have been reported to be highly efficacious in a varied number of diseases in children. The Central Council for Research in Homoeopathy has undertaken clinical trials of Homoeopathic remedies in a number of childhood diseases. An open study in

Pediatric diarrhoea was conducted (Sept. 2003 – March 2004)⁷. The results indicated a positive role of Homoeopathic therapy in the management of diarrhoea in children, but as the number of subjects enrolled was very small, no definitive conclusion could be formed. Keeping in view the importance of diarrhoeal diseases in children, under National Health Programme, the Council undertook a multi-centric clinical trial of Homoeopathic remedies in the management of acute diarrhoeal diseases in children, and the Extension centre of Drug Standardization Unit, Hyderabad located in the premises of Princess Durru Shehvar Children's and General Hospital, Hyderabad is one of the centres.

METHODS

STUDY DESIGN: A prospective open clinical trial of a group of pre-defined Homoeopathic medicines in the management of acute diarrhoeal diseases in children was conducted in the Extension Centre of Drug Standardization Unit, Hyderabad under Central Council for Research in Homoeopathy at Princess Durru Shehvar Children's and General Hospital, Hyderabad from October 2005 – September 2008. Each case was followed up daily, maximum for 7 days or till improvement occurred, whichever was earlier. A diarrhoea index score was designed by the Council to assess the severity of the illness (Table 1). The study protocol was in accordance with the Helsinki⁸ declaration on human experimentation. Ethical clearance was obtained from Council's Ethical Committee.

SELECTION OF MEDICINE: The selection of trial medicines was done by repertorising the nosological symptoms of acute diarrhoea. Tyler M and Weir J's elimination method of repertorization was used for selection of trial medicines⁹. 'Diarrhoea Children in' was taken as the eliminating rubric and thus 14 medicines of first grade were short-listed using Complete Repertory in Cara professional software. These medicines were: *Aethusa-cynapium*, *Calc-sulph*,

Calc-carb, Cham, Mag-mur, Merc-sol, Psor, Ipec, Rheum-palmatum, Sil, Stram, Sulph, Phos and Podo-peltatum. Each child received a homeopathic medicine selected on the basis of presenting totality. However, if the choice of medicine was outside the trial medicines, then that child was not enrolled and treated in general out patient department.

PATIENT POPULATION: Two hundred and eighty one children from Hyderabad of age group between 6 months – 12 years were screened and of these, 68 children (38 males, 30 females) were enrolled as per the Inclusion and Exclusion criteria of the protocol and were followed up. All the patients enrolled were from poor socio-economic status.

INCLUSION CRITERIA

1. Children of 6 months to 12 years of age
2. Acute presentation of diarrhoea (*loose stools without blood*)
3. Minimum 3 unformed stools per day for at least 2 consecutive days

EXCLUSION CRITERIA

1. Diarrhoea of prolonged duration of more than 7 days

2. Diarrhoea with moderate and severe dehydration as per WHO criteria
3. Rice water stools or symptoms suggesting cholera
4. Associated high grade fever
5. Any other condition, gastric or otherwise, requiring emergency invasive procedure
6. Children suffering from life-threatening or chronic diseases, viz: Malignancy, HIV/ AIDS etc.
7. *Pseudo diarrhoea* or frequent passage of small volumes of stool of normal consistency
8. Fecal incontinence (for reasons other than diarrhoea)
9. Parasitic/protozoa infestations
10. Salmonella organisms causing gastroenteritis.
11. Persistent diarrhoea.
12. Children on any other medicine for diarrhoea.

OUTCOME ASSESSMENT: The patients were assessed daily with the help of the diarrhoea index score as shown in Table 1 for a maximum of 7 days. The total score of all the signs and symptoms was designated as S1 on the basis of which the intensity of the case was determined as *mild*

TABLE 1: Diarrhoea index score

Symptom/Sign	Score				
	0	1	2	3	4
No. of Stool per day	0	1	2	3	4
Diarrhoea (stool consistency)	Normal	5hr-6hrly	4hrly	3hrly	2hrly
Fever	0	1	2	3	4
Vomiting / day	Absent	Low grade	High grade		
Gross/Occult blood in stool	0	1	2	3	4
Weakness	Absent	only once	2 to 3	3 to 5	
Muscular cramps	0	1	2	3	4
Weight loss (Dehydration)	Absent	Mild	More	Severe	Profound has to rest
	0	1	2	3	4
	None			Less than 5%	Mild 5-6%



TABLE 2: Parameters adopted for assessment of response of treatment

Response of Treatment	Parameter adopted
• Moderate	50% to less than 75% improvement in symptom score from baseline score
• Mild	25% to less than 50% improvement in symptom score from baseline score
Not significant	Less than 25% improvement in symptom score from baseline score
Not improved	No change in symptom score from baseline score even after sufficient trial of best indicated medicines
Worsened	Increase in number of score
Static	No change of score from baseline
Referred	Referred for other therapy in the eventuality of any adverse event
Withdrawal	Subject withdraws consent or refuses for further treatment
Drop out	Does not fulfill the conditions as per protocol

when the total score was 2- 7, moderate for the score 8-18 and severe for 19-30. Outcome assessment was done by calculating the percentage using the formula [(S1 at baseline- S1 at completion of the study) /S1 at baseline] on the parameters adopted as mentioned in Table 2.

TABLE 3: Data of children suffering from acute diarrhoea at baseline

	Study group (n)	Percentage (%)
Male	38	55.9
Female	30	44.1
Diarrhoea index score (range)		
Mild	49	72.1
Moderate	19	27.9
Referred for treatment on basis of severity	58	85.1

STATISTICAL ANALYSIS: The statistical analysis was done with the help of t test using SPSS (Statistical package for social science) Version 16.

RESULTS: A total of 281 children with diarrhoea were screened during the 3 years of study period, out of whom 212 were excluded as per the protocol. Sixty eight children (38 males; 30 females) were enrolled as per the inclusion and exclusion criteria and were followed up. The incidence of acute diarrhoea was mostly found to be in 1 - below 3 years of age group (n=29) followed by 3 - below 5yrs of age group (n=27), next by 5 - below 10 years age group (n=12). The baseline data of children suffering from acute diarrhoea is given in Table 3. Intensity of the disease in children at baseline and improvement response after treatment as per the



TABLE 4: Improvement Indices

Improvement index No of patients Percentage

Improvement index	No of patients	Percentage
1	61	15.7%
2	1	1.5%
3	01	1.5%

diarrhoea score is given in Table 5.

The mean S1 was evaluated at baseline 6.68 ± 2.1(68) and at end of the study 0.29 ± 2.088(68) using paired t test. The difference in the mean S1 was found to be statistically significant (t = 17.1, df = 67, P = 0.000, <0.05) / CI level 5.64 ± 7.13. The S1 was also evaluated at baseline and at end of the study using paired t test of 5 trial medicines which were frequently prescribed (Table 7). The difference in the mean S1 was found to be statistically significant. The symptoms and signs of the enrolled cases at baseline and their improvement at the completion of the treatment are mentioned in Table 6.

An analysis of the trial medicines (Table 7) showed that 5 trial medicines which were used frequently for treating the patients (n=59, 86.8%) are *Aethusa-cynapium* (n=10, 14.7%), *Chamomilla* (n=8, 11.8%), *Ipecac* (n=4, 5.9%), *Sulphur* (n=6, 8.9%) and *Podophyllum* (n=31, 45.6%). Among the trial medicines, six medicines less frequently used in this study are *Phosphorus* (n=3), *Calcarea-carb* (n=2), *Psorinum* (n=1), *Mercurius* (n=1), *Rheum* (n=1), *Calcarea-sulphurica* (n=1). The characteristic indications of the frequently used 05 medicines are described in Table 8. 97.06% of children (n=66) were cured (Table 4).

Most of the children were cured on 2nd day (n=34) and 3rd day (n=27) of their treatment. Only one child showed marked degree of improvement and one child got worsened and was referred for other treatment.

DISCUSSION: This study is a prospective open clinical trial and non-comparative. Homoeopathic treatment was prescribed for all the patients from the trial group of medicines as per the totality of the symptoms of the patient. The study mainly focused on evolving a group of the useful Homoeopathic medicines in the treatment of acute diarrhoeal diseases in children. Certain medicines were found frequently indicated and their specific role in the management of diarrhoea in children could be defined. Thus the objective of the study was achieved to an appreciable extent. This indicates an encouragingly positive role of Homoeopathy in the management of acute diarrhoeal diseases in children and also affirms a positive participation of Homoeopathy in the *National Health Programme for Diarrhoeal Diseases in Children*.

In this study, it was observed that the incidence of acute diarrhoea is high among children aged less than 2 years than older children, which corroborates with the data of the previous studies^{10,11,12,13}. It is also observed that among the study group, male incidence is higher than the female children, which supports the previous studies which were conducted on Acute Diarrhoea in developing countries^{14, 15, 16}. And most of the cases of this study were enrolled during the hot weather time, thus corroborating with previous study¹² regarding the seasonal

TABLE 5: Intensity of disease and response to treatment

Intensity of disease (S1)	No of Patients before treatment (%)	Response to treatment				
		No of patients (%)				
		Cured	Marked>	Moderate>	Mild>	Worse

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incidence (Hot climate) of diarrhoeal diseases. Children enrolled in this study showed a history of 2-4 days of infection. Fifty eight children (85.3%) enrolled were with 2 days of infection followed by nine children (13.2%) with 3 days of infection and only one child (1.5%) with 4 days of infection. The WHO and UNICEF define acute diarrhoea as a sudden onset of diarrhoea, which usually lasts for 3-7 days but may last for 14 days^{8,17}, only 1.5% of children fall in this category. Thus there is a negligible chance of bias regarding the natural recovery from the disease. In this study also the follow up was done upto seven days of illness or till improvement occurred whichever was earlier. About 97.06% (n=66) of the children showed

complete recovery. The trial medicines *Podophyllum*, *Chamomilla*, *Aethusa*, *Sulphur* and *Ipecac* were found to be frequently indicated and were also effective in treating the disease. Such medicines were also used in the study conducted by *Jacobs et al*¹⁸. This study also supports the findings of the previous studies of *Jacobs et al*^{16,19,20} that Homoeopathic treatment decreases the duration of diarrhoea and number of stools in children suffering from acute diarrhoea .
CONCLUSION: This open clinical trial, non-comparative study with positive results affirms the positive role of homeopathy in treating acute diarrhoeal diseases in children. However, further studies including randomized controlled trials can be conducted for scientific precision.

TABLE 6: Presenting symptoms and signs of acute diarrhoea in children at entry and at end of study

Symptoms and signs	No. of cases At entry	No of cases At end of study Improved (%)	Not improved (%)
No. of stools per day 4/6/8/12	13/26/23/6= 68	67(98.5)	1(1.4)
Diarrhoea (consistency) Loose/watery/slimy/mucoid	30/19/18/1=68	67(98.5)	1(1.4)
Fever Low grade/high grade	41/27=68	67(98.5)	1(1.4)
Vomiting / day Absent/Only once/2-3 times /3-5 times	40/6/18/4=68	68 (100)	Nil
Weakness Absent/Mild	30/38=68	67(98.5)	1(1.4)
Muscular cramps Absent	68	68 (100)	Nil
Weight loss (dehydration) None/Less than 5%	60/8=68	66(97.1)	2(2.9)

TABLE 7: Data of trial medicines frequently used in the study

Medicine Prescribed	No. of cases	%	P-value	95% confidence interval difference	Cured	Marked	Moderate	Mild	Outcome assessment
<i>Podophyllum</i>	31	45.6	0.000	4.09-6.94	30	-	-	-	01
	10	14.7	0.000	5.85-8.95	10	-	-	-	-

TABLE 8: Reliable indications^{1,2,3,4,5} of the useful medicines frequently used in the study

NAME OF MEDICINE	RELIABLE INDICATIONS
Podophyllin	Diarrhoea in early morning, stool offensive, changeable, passes forcibly with sounds; profuse, painless diarrhoea; worse change of weather, hot weather.
Ashtorin eye	Milk intolerance, drowsiness / sleepiness after stool/vomiting, hot weather diarrhoea.
Chorizanin	Stool green and fetid; hot weather diarrhoea; restless impatient child, carrying child on shoulder ameliorates/stops crying.
Sulphur Iodide	Diarrhoea in early morning, painless diarrhoea; anal orifice red. Vomiting with diarrhoea, vomiting of much mucus; nausea constant, clean

Further, the effect of Homoeopathic medicines on acute diarrhoea with specific etiology can also be undertaken.

ACKNOWLEDGEMENTS: Authors thank Dr T Baswaraj, paediatrician of Princess Durru Shehvar Children's and General Hospital, Hyderabad, for his valuable and timely suggestions in the enrollment of cases, Dr Varanasi Roja, Research Officer, CCRH headquarters for verifying the data for statistical evaluation and Mrs Maya Padmanabhan, Statistician, CCRH headquarters for evaluating the report statistically. The authors also acknowledge the hospital authorities of Princess Durru Shehvar Children's and General Hospital, Hyderabad for their co-operation in referring the cases from their OPDs for this study.

Conflict of interest: We declare no conflict of interest. (Endnotes)

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