CLINICAL RESEARCH

A prospective multicentre observational study to evaluate the role of homeopathic therapy with a group of predefined homoeopathic medicines in the management of gastroenteritis**

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This observational study aimed to see the usefulness of homeopathic therapy in the management of gastroenteritis. A prospective, non-comparative, multi-centre observational study was conducted by Central Council for Research in Homeopathy at its various institutes and units in India during October, 2005- September, 2008. A total of 498 patients of all age groups suffering from gastroenteritis were enrolled in the study. A total of 22 predefined trial medicines were short listed after repertorizing nosological symptoms of gastroenteritis. Selected medicine was prescribed in 6C potency and was repeated from few minutes to few hours, as per the need of the case. A gastroenteritis symptom score (GSS) was designed to assess the severity of illness and the result was analyzed using SPSS version 16. Three hundred and seventy followed up patients were analyzed. The total mean gastroenteritis symptom score (GSS) evaluated at baseline and at end were 8.56 ±4.26 and 0.45 ±0.85, respectively. The difference in the mean score was found to be statistically significant (p= 0.0001). The results were found to be significant with 18 predetermined trial medicines (p=<0.05). Eighty seven percent (n=323) of the patients needed the following nine trial medicines: *Nux vomica (n=81), Pulsatilla (n=51), Arsenicum album (n=44), Cinchona officinalis (n=44), Sulphur (n=30), Antimonium crudum(n=25), Argentum nitricum(n=23), Bryonia alba (n=15) and Carbo vegetabilis (n=10)*. This multicentre observational study hints the usefulness of homeopathic medicines in case of gastroenteritis. Controlled studies should investigate the efficacy and effectiveness.

Keywords: Gastroenteritis; Homeopathy; Nux vomica; Pulsatilla nigricans; Arsenicum album

Introduction

Acute diarrhea is an important cause of morbidity and mortality in pediatric and geriatric patients. In underdeveloped countries, the incidence and mortality of acute diarrhea is greatest in children (Michel *et al.,* 1999). Estimates suggest that during the 1990s, nearly 1.4 billion diarrhea episodes occurred every year among children younger than 5 years of age in socio-economically developing countries, of which 123.6 million episodes required outpatient medical care and 9 million episodes required hospitalization. Approximately 2 to 2.5 million diarrhea-associated deaths were estimated annually in this age group, concentrated in the most impoverished areas of the world (Ryan *et al.,* 2005). The percentage of children under 3 years of age who suffered from diarrhea in the two-week period before the survey was 10% as per the National Family Health Survey (NFHS)-1 and 19% as per NFHS-2 (International Institute for Population Sciences, 2000; 1995). Estimations of the burden of diarrheal diseases in India by the National Institute of Cholera and Enteric Diseases (NICED)

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indicate that diarrheal diseases contribute to about 9.1% of deaths in the age group of 0– 6 years. (Government of India, 2005).

Floods in tropical climate of India also increase the incidence of these diseases. In a survey of flood-affected area in Orissa (India) (Cariappa, 2003), it was found that among all cases, 54.02% were suffered from diarrhea/gastroenteritis. Diarrheal disease is always associated with poor socio-economic status (Gupta, 1998) also.

Antibiotic resistance (Edgeworth, 2005) is becoming an increasing worldwide problem caused by overuse of antibiotics in both clinical practice and animal farming. Many of the most common and life-threatening bacteria causing diarrheal disease (including Shigella, Salmonella typhi and V. cholerae) are becoming increasingly resistant to the commonly available antibiotics, particularly in the developing world. India is a developing country, with 2nd highest population in world, with more than 27.5% of population lives below poverty line. Homoeopathy is one of the AYUSH (Ayurveda, Unani, Siddha, and Homoeopathy) therapies adopted by the Govt. of India as health care facility for the common man (Singh *et al.,* 2005). About one third population of India prefers AYUSH systems of medicine. Among them, the lower the income group preferred homoeopathy more for their health problems. In 19th century, homoeopathy treatment was employed for controlling cholera epidemic (Gaucher, 1993) with success. Jacobs *et al.,* (1993; 1994 and 2000) had shown effectiveness of homoeopathic medicines in three studies in two different settings.

The causes of diarrhea vary with the location, time of year/season, and population studied (Dennehy, 2005). Complete repertory (Witko, 1999) mentioned 447 medicines against the rubric 'diarrhea', 439 medicines against the rubric 'vomiting' and 461 medicines under the rubric 'abdomen pain cramping'. But, it is a fact that only few medicines among this group are frequently indicated and known as first grade remedies. So, this study was undertaken with 22 predetermined medicines to ascertain the role of homoeopathic therapy in the management of gastroenteritis and to further ascertain whether homoeopathic medicines used during the study have any specific relationship with any particular season or thermal changes.

Materials and methods

Study design and setting

The study was a prospective, non-comparative, multi-centre observational study conducted at various institutes/units under Central Council for Research in Homeopathy (henceforth Council): Regional Research Institutes (RRI) at Puri (Orissa), Jaipur (Rajasthan), Guwahati (Assam) and Clinical Research Units (CRU), Aizwal (Mizoram), Bharuch (Gujarat) during the period October, 2005-September, 2008. The study protocol was in accordance with the Helsinki declaration (World Medical Association Declaration of Helsinki) on human experimentation. Necessary ethical clearance was obtained from Council's Ethical Committee.

Patient population

Four hundred and ninety eight patients of all age groups reporting with diarrhea and/or vomiting and colicky abdominal pain were considered essential for inclusion with other associated symptoms like nausea, loss of appetite, malaise, mucus in stools, bloody stools, if present, were included in the study. Diarrhea cases with severe dehydration as per guidelines of World Health Organization were excluded. Informed consent was obtained from all the patients and in minors the same was obtained from parents/guardians. Each patient was followed up to 7th day of the illness.

Selection of predefined trial medicine

The selection of predefined trial medicines was done by repertorising the rubrics diarrhea, vomiting and cramping pain in abdomen (Braunwald, et al., 2001 and Cook, 2003). Tyler & Weir's elimination method (Tyler & Weir, 1989) of repertorization was used for selection of trial medicines, and thus 22 medicines of 3 marks (first grade) and 2 marks (second grade) were short listed using Complete Repertory in Cara professional software (Witko, 1999). These are: *Sulphur, Apis mellifica, Agaricus muscaris, Silicea, Ferrum metallicum, Carbo vegetabilis, Chamomilla, Bryonia alba, Lycopodium, Veratrum album, Antimonium crudum, Nux vomica, Ipecacuanha, Iris versicolor, Pulsatilla nigricans, Arsenic album, Antimonium tartaricum, Cuprum metallicum, Cinchona officinalis, Calcarea carbonica, Argentum nitricum* and *Dulcamara.* These trial medicines were procured from a licenced homeopathic company [Sharada Boiron Laboratories (SBL), Pvt. Ltd. Sahibabad, Uttarpradesh, India]. Each patient received a homeopathic medicine selected by investigator from the repertorization chart provided. From the repertorization chart the investigator highlights the symptoms of the patient to sort out a group of top ranking medicines. Full scope was given for individualization of patient and final selection of medicine was done in consultation with Materia Medica. However, if the choice of medicine was outside the trial medicines, then that patient was not enrolled, but treated in the general out patient department.

Potency, doses & repetition

All the enrolled patients were given indicated medicine in 6C potency of 4 globules, size no. 30 in frequent doses (few minutes to few hours) depending upon frequency, duration and intensity of the symptoms till perceptible change appears (improvement of signs and symptoms, appearance of new symptoms, worsening of signs and symptoms). Appearance of any change was immediately followed by placebo/change in potency or change in medicine, according to response. Investigators were allowed to change the prescription up to three times (including first prescription) for the second best indicated medicine from amongst the trial medicines. As a part of non-medical management, all the patients were advised to take oral rehydration solution (ORS).

Outcome assessment

A gastroenteritis symptom score (GSS) was designed by the council as an indicator of severity of illness. The GSS was measured by considering 10 signs & symptoms (Table 1). The total GSS score was considered as S1. Dehydration was scored as absent (0), Mild (1) & moderate (2) as per the WHO criteria (World Health Organization, 1992). As the disease is self limiting, a second scale (S2) from 1-7 was designed whereby a patient reporting for treatment on the first day of infection was assigned the highest value of 7 and one reporting on the seventh day, the value, 1. Assessment was done by calculating the percentage using the formula [(S1 at baseline–S1 at completion of the study) /S1 at baseline]. Thus, 100% was defined as cure, >75% -<100% as marked, 50% - <75% as moderate, 25% - < 50% as mild, < 25% as insignificant improvement, 0% as not improved or status quo and any increase in symptom score from the baseline score was counted as worse.

Statistical analysis

Descriptive statistical characteristics and comparative analysis like t-test and one-way ANOVA was done using SPSS (Statistical package for social science), version 16. Pearson correlation coefficient and linear model was also used for analysis.

Results and discussion

Over a period of 3 years, 498 patients were enrolled out of which 370 patients (209 males; 161 females) suffering from gastroenteritis were followed up and studied; 128 patients were excluded for non-compliance according to the protocol. Age distribution and other baseline details of the patients are given in Table 2. The presenting signs and symptoms at baseline and at end are mentioned in Table 3. Diarrhea was present in 99.5% of the patient population followed by diarrhea and abdominal pain in (91.9%), loss of appetite (82.4%), nausea (70%), muscle cramps (57.5%), vomiting (46.7%) and fever (42.4%).

The total mean gastroenteritis symptom score (GSS) evaluated at baseline and at end were 8.56 ±4.26 and .45 ±0.85, respectively. The difference in the mean score was found to be statistically significant (P= 0.001, <0.05; CI: 7.66-8.56). The mean days of suffering and the reduction of symptoms during treatment for gastroenteritis were 1.73±0.64 and 2.6±1.34, respectively.

Pearson's correlation coefficient was used to see any relation among the various age groups. The

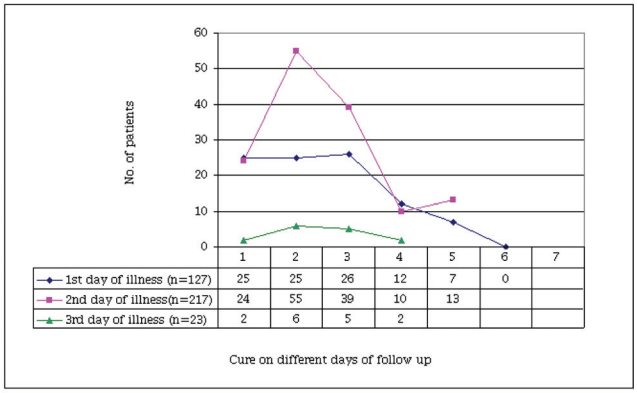
Table 1: Gastroenteritis symptom score (GSS)

Symptom/signs	Score				
	0	1	2	3	4
No. of stool / 24 hrs.	1 to 2	3 to 4	5 to 6	7 to 8	9 or more
No. of vomiting / 24 hrs.	Absent	1 to 3	4 or more		
Abdominal Pain	Absent	Present			
Weakness	Absent	Mild	Profound		
Mucus in Stool	Absent	Present			
Nausea	Absent	Present			
Appetite	Normal	Loss of			
Fever	Absent	Low grade (100.4–102.2°F)	High grade (104.0–106.0°F)		
Muscular cramps	Absent	Present			
Dehydration	Absent	Mild	Moderate		

variables age, no. of stools/24 hrs, no. of vomiting/24 hrs was used. The results of this analysis was statistically significant (P = <0.01) in the age group of under five years and but, not in the other two age groups. Further, a linear model was used for this age group as independent factor with outcome assessment as dependent factor and it was found to be statistically significant (df 3, 234; F=3.76, P =0.01).

Patients were enrolled irrespective of their duration of illness; some of them may be on the way of natural recovery. But, most of the patients (99.2%) were enrolled on 1st, 2nd and 3rd day of illness and only 0.8% were enrolled during 4th–7th day of illness. So, the outcome of the patients who were enrolled on the first three days of suffering from gastroenteritis was assessed. It is observed that 67.8% (n=251) were cured within 5 days of treatment (Figure 1).

Figure 1: Trend of cure on different days of illness and follow up



	1	2	3	4	5	6	7
1st day of illness (n=127)	25	25	26	12	7	0	
2nd day of illness(n=217)	24	55	39	10	13		
3rd day of illness (n=23)	2	6	5	2			

Findings of Strina et al., (2005) shows that acute diarrhea may persist till 8-13th day. So bias due to natural regression of disease might be negligible. Similar to previous studies (Jacobs et al., 1993; 1994), males were more affected than female patients.

An analysis of the useful trial medicines (Table 4) showed that 87% (n=323) of the patients required one of the nine trial medicines: Nux vomica (n=81, 21.8%), Pulsatilla (n=51, 13.7%), Arsenicum album (n=44, 11.8%),Cinchona officinalis (n=44, 11.8%) , Sulphur (n=30,8.1%), Antimonium crudum (n=25,6.7%), Argentum nitricum (n=23, 6.2%), Bryonia alba (n=15, 4.1%) and Carbo vegetabilis (n=10, 2.7%) in their first prescription.The prescribing indications of these medicines are presented in Table 4. Only 12% of the study population required other trial medicines like, *Chamomilla, Ipecacuanha, Lycopodium, Veratrum album, Calcarea carbonica, Dulcamara,* and *Cuprum metallicum.*

In the second prescription, 10 patients required Agaricus muscarius (n=5), Antimonium tartaricum(n=3) and Antimonium crudum (n=2). All other patients were prescribed either placebo when the first prescription acted or potency higher than 6C when the medicine acted for some time and remained unchanged thereafter.

The outcome assessment showed that 260 (70.3%) patients were cured on different days of their follow up (Table 5), while 110 (29.7%) patients improved variedly. Among these, 110 patients, 87 improved markedly, 17 moderately, 5 mildly and in 1 patient the improvement was not significant (Table 5).

This prospective observational study aimed to evaluate the usefulness of homoeopathic therapy with predefined 22 medicines in the treatment of gastroenteritis with encouraging results supplements the claim that homoeopathic medicines when prescribed on the basis of totality of symptoms are useful in treating patients of diarrheal diseases (Jacobs *et al.,* 1993; 1994 and 2000). In this study, all age groups are considered and again commensurate with the positive results of a parallel study on acute diarrhea in children (Nayak, 2009) conducted by the council.

The results of these two parallel studies (Gastroenteritis & acute diarrheal diseases in children) reflect that homoeopathy can play a constructive role in National Health Programme. India is a developing country, where poorer section (Gupta, 1998) prefers homoeopathy and is the vulnerable group for these conditions. Thus, homoeopathy can be better choice for this group of population as the result of this study shows. Besides, homoeopathic therapy is cost effectiveness (Manchanda, 2005) and easy to administer. At the time of disasters and health emergency situations, when there is increased incidence of gastroenteritis (Government of India, 2005), homeopathic system of therapeutics can be thought of.

Gastroenteritis presents with symptoms like diarrhea, vomiting, fever, abdominal pain or cramps. These symptoms and signs again depend on the pathological agents (Edgeworth, 2005; Clark, 2004 and Desselberger, 2005) (viruses, bacteria & protozoa). These studies on gastroenteritis showed that diarrhea was the most common presenting feature of gastroenteritis. In our study, it was also observed that 99.5% of the patients presented with diarrhea. But, as the stool samples were not examined, specific pathogens could not be detected.

Viral gastroenteritis occurs in winter worldwide, with transmission being mainly through the fecal-oral route (Desselberger, 2005), the pathogen causing most endemicity are Rota and Enteric adenoviruses in children while calciviruses and astroviruses causes

Table 2: Baseline details of patients suffering from gastroenteritis

	Study group (n)	Mean ±SD	%
Institutes/Units			
• RRI, Jaipur	114		30.8
• RRI, Puri	107		28.9
• RRI, Guwahati	7		1.9
• CRU, Bharuch	123		33.2
• CRU, Aizwal	19		5.1
Sex			
• Male	209		56.5
• Female	161		43.5
Age			
• Under 5	235	1.83±0.91	67.5
• 6-18	23	11.13±3.79	6.21
• 19 and above	112	43.95±14.41	30.2
Day of illness			
• 1st	127		34.3
• 2nd	217		58.6
• 3rd	23	1.74±.64	6.2
• 4th	01		0.3
• 5th	01		0.3
• 7th	01		0.3
Condition			
• Diarrhea	368		99.5
• Diarrhea + vomiting	174		47.02
• Diarrhea+ fever	157		42.4
• Diarrhea+ vomiting+ fever	91		24.5
• Diarrhea + abdominal pain	338		91.35
• Diarrhea+ vomiting+ abdominal pain	162		43.7
Seasonal variation			
• Hotter months (March-August)	255		68.9
• Cooler months (September – February)	115		31.1

Table 3: Presenting symptoms / signs of gastroenteritis

Symptoms/signs (n)	At baseline			At end		
	No. of patients	Percentage (%)	Total %	No. of patients	Percentage (%)	Total %
No. of stool/24 hrs 1-2/3-4/5-6/7-8/9 or more	2/92/184/57/35	0.5/24.9/49.7/15.4/9.5	100	336/32/2/0/0	90.8/8.6/0.5	100
No. of vomiting 1 to 3/4 or more	133/43	35.9/11.6	47.6	0/0	0	0
Abdominal pain Absent /present	30/340	8.1/91.9	91.9	350/20/0	94.6/5.4/0	5.4
Weakness Mild/ profound	256/65	69.2/17.6	86.8	75/0	20.3/0	20.3
Mucus in stool Nausea Loss of appetite	264 259 305	71.4 70 82.4	71.4 70 82.4	4 4 26	1.1 1.1 7	1.1 1.1 7
Fever Low grade/ high grade	132/25	35.7/6.8	41.5	4	1.1	1.1
Muscle cramps Dehydration	213 61	57.6 16.5	57.6 16.5	7 0	1.9 0	1.9 0

Table 4: Characteristic indications of useful trial medicines

Name of the Medicine	Characteristic indications
Nux vomica	Ailments after taking spicy diet. Ineffectual desire for stool but passes small quantity at each attempt >after stool; mucous in stool. Fever, muscular pain, dehydration, cramps.
Pulsatilla	Ailments after taking fatty fried food; pain in abdomen after one and half hours of eating; no two stools are alike; thirstlessness.
Arsenicum album	Ailments after taking vegetable diet, watery fruits, decayed rice and pulses; offensive diarrhea < at night; unquenchable thirst, thirst for much water but little at a time, at short intervals.
Cinchona officinalis	Ailments after taking fruits, milk and decayed food; flatulency, belching of bitter fluid; eructations give no relief; stool watery, yellowish, frothy with undigested food particles, < at night, after eating; offensive flatus, great debility.
Sulphur	Stool loose, watery; driving out of bed early in morning, itching and burning of anus < after passing stool.
Antimonium crudum	Ailments after taking pickles, bread and over-eating, overheated, in hot weather. Stool watery; contains undigested food particles; desire for acids and pickles. Tongue thickly white coated.
Argentum nitricum	Ailments after taking sweets, ice cream. Stool, watery noisy, greenish like chopped spinach with shreds of mucus; flatulence, as if abdomen would burst; belching is a most prominent symptoms with gastric disorder.
Bryonia alba	Ailments after taking cold food, overheated in hot weather. Stool watery containing undigested food particles, very much acrid; morning diarrhea as soon as the patient gets up from the bed, Great thirst for large quantity of water at long intervals.
Carbo vegetabilis	Watery, frequent, involuntary offensive smelling stools, followed by burning; very weak digestion; eructation after eating and drinking; temporary relief from belching

epidemic in children and both adults and children, respectively. Whereas, no such data is available for bacterial cause of gastroenteritis. Irrespective of this seasonal variation, gastroenteritis was observed throughout the year in our study. Homeopathic medication given on the basis of individualization could improve the health of the suffering patients irrespective of the seasons and can be thought of in epidemic situations where there is lack of time to detect the causative organism for appropriate conventional treatment.

The mean days of suffering from gastroenteritis at the baseline and to become zero was observed to be 1.74±0.64 and 2.6±1.34, respectively which is less than the findings of Jacobs *et al.,* (1993) and parallel study of acute diarrhea in children (Manchanda, 2005) *i.e.* 3.2±0.4 & 3.2±1.5. Thus, it is found that most of the patients improved on 2nd and 3rd day of the follow up.

The trial medicines useful in this observational study were Nux vomica, Pulsatilla, Arsenicum album, Cinchona officinalis, Sulphur, Antimonium crudum, Argentum nitricum, Bryonia alba and Carbo vegetabilis.

The strength of this study lies in the fact that is it represents a pragmatic setting of homeopathic practice, which reflects the day-to-day clinical practice. This ensures a high degree of external validity of the study. To note additional/clinical symptoms was one of the objectives. But, such things were not observed which reconfirms the completeness of these medicines, which are in use since hundreds of years. This study also verifies the elimination method (World Health Organization, 1992) of repertorization, which can be used to choose useful group of medicines from a large number of medicines. As the study did not have any control group, randomization and blinding, observer's bias cannot be ignored. To validate the effect of homoeopathic care in gastroenteritis, controlled study is suggested. Effect of homoeopathic medicine on gastroenteritis of specific etiology should also be considered in future studies.

Conclusion

This multicentre observational study hints the usefulness of homeopathic medicines in *gastroenteritis.* Controlled studies should investigate the efficacy and effectiveness.

Table 5 : Data of predefined trial medicines

Medicine	No. of patients	%	p-value	95% confid. interval diff.	Outcome assessment*				
					Cured	Marked >	Moderate >	Mild >	=
Nux vomica	81	21.8	0.000	5.51-6.45	57	19	4	1	0
Pulsatilla nigricans	51	13.7	0.000	6.34-7.61	29	18	4	0	0
Arsenicum album	44	11.8	0.000	6.86-9.50	33	8	3	0	0
Cinchona officinalis	44	11.8	0.000	10.35-13.55	36	6	1	0	1
Sulphur	30	8.1	0.000	7.88-12.17	30	0	0	0	0
Antimonium crudum	25	6.7	0.000	6.09-7.93	10	13	1	1	0
Argentum nitricum	23	6.2	0.000	8.41-9.84	15	8	0	0	0
Bryonia alba	15	4.1	0.000	4.68-8.51	13	1	1	0	0
Carbo vegetabilis	10	2.7	0.000	6.98-8.61	2	8	0	0	0
Chamomilla	8	2.1	0.001	3.88-8.86	6	0	2	0	0
Ipecacuanha	7	1.8	0.000	5.45-11.09	6	1	0	0	0
Lycopodium	7	1.8	0.001	5.27-11.58	7	0	0	0	0
Agaricus muscarius	5	1.3	0.009	1.82-6.97	0	4	1	0	0
Antimonium tartaricum	5	1.3	0.049	0.23-7.17	1	1	0	3	0
Calcarea carbonica	5	1.3	0.001	4.82-9.97	5	0	0	0	0
Veratrum album	5	1.3	0.026	2.99-27.41	5	0	0	0	0
Dulcamara	4	1.1	0.027	4.24-35.75	4	0	0	0	0
Cuprum metallicum	1	0.2	0	0	1	0	0	0	0
Total	**370**				**260**	**87**	**17**	**5**	**1**

*> Improvement; = Not significant

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