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EXTRA MURAL RESEARCH

An approach to acute diarrhoeal disorders through sector and constitutional homoeopathic treatment in tribal children attending Balwadis

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Introduction: Diarrhoea is one of the most frequently encountered problems in pediatric age group. The severity of diarrhoeal infections varies from patiens to patient and from few loose motions without much discomfort to severe dehydration. Our literature reviewed has shown usefulness of homoeopathic acute medicines in treating acute diarrhoea. There are a number of clinical studies which have verified this aspect. But at the same time it has also been observed that few cases improve without any treatment. Recurrence of diarrhoea is the major concern as it affects the growth of the child. Hence this study was undertaken to verify the efficacy of acute medicine in the management of diarrhoea and exploring the role of Constitutional medicine in preventing the recurrence.

Materials and Methods: A sample size of 300 children was selected from 10 Anganwadi (Balwadi – day care centre) from the tribal population having a known high prevalence of diarrhoea. Randomized case control, single, blinded method was used to prove the efficacy of the acute medicines. For this purpose, the sample was divided into three groups viz. Acute remedy group, Acute remedy followed by Constitutional and Placebo group as a control. Basic hygienic measures were explained to the parents and they were followed up regularly.

Results: Results of the study clearly demonstrated that, the indicated acute medicines had a definite role in altering the course of acute diarrhoea and when the acute medicine was followed up by the constitutional medicine it had shown a significant impact in bringing down the frequency, shortening the duration and decreasing the intensity of further episodes. This strategy also showed a definite positive response in the general well being of the child in terms of weight gain and general activity of the child.

Conclusion: Result analysis also helped in concluding a definite management strategy using homoeopathic medicines for the management of acute diarrhoeal disorder.

Keywords: acute diarrhoea, tribal children, acute homoeopathic remedy, constitutional remedy

Introduction

Acute diarrhoea is defined as frequent passage of loose to watery stools as compared to the usual stool pattern (usually more than 3 per day) for a period of less than 2 weeks.[1] The mortality rate in 0-5 years due to diarrhoeal disease is 4.9 children per thousand per year in developing countries. The underlying malnutrition has an important role in further increasing the mortality rate. Out of total acute diarrhoeal episodes nearly 80% of the cases belong to infancy age group, particularly between 6 months to 3 years. In children of less than 2 years of age, 99% of the diarrhoeas are due to viral origin.[1] Whereas in children above 2 years, the cause in 20% cases is due to bacterial infection. This problem is commonly seen in the tribal children particularly in the summer and rainy season.[2] This is due to poor hygiene, limited food and unclean water supply. In addition to this, malnutrition is one of the major associated factors in these children. Many of them are unable to break the Diarrhoea –> Malnutrition –> Diarrhoea vicious cycle.

This further predisposes them to other illnesses. Apart form the seasonal changes and age factor, the difference in composition of breast milk, artificial food & cow's milk, the difference between the bacterial flora of the intestine are some of the other contributing factors for the recurrence of the diarrhoeas.[3] The homoeopathic line of treatment has shown that, Acute

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treatment followed by the Constitutional treatment provides the base to develop the child's immunity as well as the nutritional status. This research project was undertaken to study the efficacy of homoeopathic treatment in gently, rapidly and permanently restoring the sick child to health.

Aim

To assess the role of Acute and Constitutional homoeopathic treatment in the treatment of acute diarrhoeal disorders

Objectives

1. To assess the efficacy of homoeopathic treatment in reducing the course & severity of an acute episode of diarrhoea.
2. To assess the efficacy of this line of treatment in the prevention of recurrence of the infection.
3. To evolve a general strategy in managing this common paediatric disease.

Materials and Methods

Randomized, placebo controlled, single blinded study was carried out during the period Nov. 2004 to Dec. 2007, at the Dr. M. L. Dhawale Memorial Trust's Community Health Centre, Bhopoli, Taluka Vikramgarh, Dist. Thane. 300 children between age groups 1 to 7 years having recurrent episodes of diarrhoea were enrolled for the study. Eligible samples were randomly divided into 3 groups by random method as follows:

1. Acute Remedy and ancillary measures
2. Acute Remedy followed by Constitutional Remedy and ancillary measures
3. Placebo and ancillary measures

(Group 1 & Group 2 are treated by acute remedy for acute condition. In group 2 Constitutional remedy is given subsequent to settling of acute episode for studying the change in recurrence)

From the homoeopathic management point of view acute diarrhoea is managed with the help of acute medicines.[4] These medicines are prescribed considering the symptom expressions of the disease and general symptoms expressed by the individual at the time of diarrhoea. Once the acute episode is controlled, then a deep acting constitutional medicine is sometimes indicated. This helps in preventing recurrent attacks. Constitutional medicines are selected by considering the predisposing factors, the disposition and all other expressions which individualizes the patient as a person.[5]

Common Hygienic measures were maintained for all the three groups. Each case was observed for minimum period of one year. Cases were recorded in the Standardized Case Record©. Indicated acute medicine was prescribed after noting the totality of the acute episode. The prescription is finalized after repertorization by using Hompath© software in consultation of Materia Medica. The potency and repetition of the remedy was decided on the basis of susceptibility understanding of the case. The medicine was discontinued once the improvement had taken place. In case of the constitutional group, once the acute episode was over the indicated constitutional medicine was given in a single dose of the indicated potency. In case of the Placebo group, placebo was administered in a similar fashion. In cases where the improvement took place the children were continued on placebo and in cases where the child fulfilled the withdrawal criteria it was excluded from the project and acute management of the episode was done with the help of the indicated homoeopathic medicine. The withdrawal criteria were followed uniformly for all the groups. The ancillary measures like ORS, IV fluids were used only when needed to correct dehydration.

Clinical grading of Diarrhoea episodes

Episodes of diarrhoea were clinically graded depending on symptom intensity/severity and frequency, signs obtained on clinical examination as mentioned in Table 1. This was done with the help of paediatrician working on the project.

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Table 1: Clinical Grading of Diarrhoea

Criteria	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
General Condition	Good	Fair	Unsatisfactory	Poor	Poor
Activity	Active	Active	Dull	Drowsy	Drowsy with altered sensorium
Mood	Playful	Quite	Cranky	Cranky and irritable	Listless
Fever	Afebrile to Mild	Mild to moderate fever	Moderate	Severe	High grade
Intake	Adequate	Adequate	Inadequate	Poor	Very poor
Vomiting	0-1/day	1-3/day	3-5/day	More than 5 /day	5-10/day
Stool Frequency	4 stools/day	5-6/day stools	6-8 stools/day	8-10 stools /day	More than 10 stool/day
Stool Quantity	Scanty	Scanty-moderate	Moderate-profuse	Profuse	Profuse
Urine output	More than 4 times a day or last output less than 4 hrs before	More than 4 times a day or last output less than 4 hrs before	2-4 times a day or last output more than 6 hrs before	1-2 times a day or last output more than 10 hrs before	Scanty to oliguria
Dehydration*	Skin turgor maintained, tongue moist, no change in thirst	Skin turgor maintained, tongue dry, change in thirst	Skin turgor lost, tongue dry, change in thirst	Skin turgor lost, tongue dry, change in thirst, with sunken eyes	Skin turgor lost, tongue dry, change in thirst, with sunken eyes
On Examination					Tachycardia with loss of consciousness

* Standard grading of dehydration has been used.[3,6] Grading of diarrhoea is done for the project by the team working on the project.

Outcome Assessment

General and particular symptoms of the child suffering from diarrhoea were included in the criteria. Signs which were observed by the physician and reported by parents were also included. Clinical examination findings indicating grades of dehydration which were also part of the gradation of diarrhoea episodes.

The data recorded was analysed into 3 categories i.e Aggravation, Amelioration, and Status quo. Each group was analyzed on these categories and the results were compared. Associated complaints in terms of other systems involved were also considered. The recurrence of diarrhoea was analyzed by measuring the grade of the subsequent episode.

Comment

For follow up analysis, the following criteria were used. The intensity of acute diarrhoea was graded as shown in Table 1, but minimum 4 loose stools / day is considered as baseline. The assessment was done after 24 hours of initiation of the treatment.

- Aggravation – it is considered if the grade of diarrhoea was increased by at least one grade e.g Grade 2 diarrhoea becoming to Grade 3.

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- Amelioration – it is consider if grade of diarrhoea was decreased at least by two grades or absence of acute diarrhoea. E.g. Grade 3 diarrhoea becoming Grade 1.
- Status quo – if there was no change in grade of diarrhoea. E.g. Grade 3 remaining Grade 3.

Results

Table 2: Cases included for analysis

Number of total cases identified	385
Number of cases excluded due to severe malnutrition	43* (Cases managed but not included in analysis)
Cases enrolled	342
Cases lost in follow up	42
Cases analyzed	300

Major reason for loss of follow up was due to high rate of migration out of the area.

Table 3: Age wise distribution across the 3 Groups

Age	Male	Female	Total
0- up to 1 yr	38	61	99
1- up to 5 yrs	83	90	173
5- up to 7 yrs	18	10	28
Total	139	161	300

Table 4: Malnutrition status across the 3 groups

	Group 1	Group 2	Group 3
Moderate	12	14	12
Severe	0	0	0

Classification of moderate and severe malnutrition as per WHO criteria.

Table 5: Clinical Grade across the 3 groups

	Group 1	Group 2	Group 3	Total
Grade 1	10	12	14	36
Grade 2	30	28	35	93
Grade 3	38	40	31	109
Grade 4	20	17	19	56
Grade 5	02	03	01	06
Total	100	100	100	300

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Table 6: Outcome of Grade 1 across groups

	Total	Aggravation	Amelioration	Status quo
Group 1	10	02	08	00
Group 2	12	00	12	00
Group 3	14	02	12	00
Statistical Significance: Not present. ***p> 0.05***				

Table 7: Outcome of Grade 2 across groups

	Total	Aggravation	Amelioration	Status quo
Group 1	30	6	20	2
Group 2	28	1	27	0
Group 3	35	6	13	16
Statistical Significance: Present. ***p> 0.01***				

Table 8: Outcome of Grade 3 across groups

	Total	Aggravation	Amelioration	Status quo
Group 1	38	8	23	7
Group 2	40	5	35	0
Group 3	31	17	0	14
Statistical Significance: Present. ***p> 0.01***				

Table 9: Outcome of Grade 4 across groups

	Total	Aggravation	Amelioration	Status quo
Group 1	20	11	4	5
Group 2	17	3	14	0
Group 3	19	19	0	0
Statistical Significance: Present. ***p> 0.001***				

Table 10: Outcome Grade 5 across groups

	Total	Aggravation	Amelioration	Status quo
Group 1	2	2	0	0
Group 2	3	1	2	0
Group 3	1	1	0	0
Statistical Significance: Not present. ***p> 0.05-probably the numbers were too small***				

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Table 11: Result analysis of Combined Acute and Constitutional Treatment group with Placebo

	Total	Aggravation	Amelioration	Status quo
Treatment Group	200	43	132	25
Placebo Group	100	47	18	35
Statistical Significance: Present. ***p> 0.01***				

Table 12: Recurrence of episode across the 3 groups: Number of episode in 6 months

Acute episode / 6 months	Group 1	Group 2	Group 3
Base line	7-8	7-8	7-8
1st 6 Months	4-5	2-3	5-6
From 6 months to 12th month	4-5	0-2	7-8
From 12th months to 24th month	5-6	0-1	8-9

Statistical Analysis

The Chi-Square test with Yates correction was applied to assess whether the differences in the results obtained in all groups in all five grades of diarrhoea were statistically significant.

Table 7 shows that there is statistical difference in cases of Grade 2. Table 8, 9 shows that there is highly significant difference in cases of Grade 3 and 4. In cases having Grade 1 and Grade 5 diarrhoea the difference is not significant. Table 11 shows the combined statistical comparative analysis between treatment group (in both the groups acute remedy has been used to treat acute disease) and placebo group. It shows that the difference is statistically significant.

Table 13: Acute remedies used (In percentage)

Remedy	Male	Female	Total
Arsenic album	4	19	23
Chamomilla	10	6	16
Croton tig.	4	3	7
Mercurius solubilis	7	1	8
Nux vomica	6	1	7
Phosphorus	1	6	7
Podophyllum	7	3	10
Pulsatilla	10	6	16
Sulphur	3	3	6

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Table 14: Potency used for Acute remedies (In percentage)

Potency used	Male	Female	Total
200	48	45	93
1M	3	4	7

Table 15: Constitutional Remedies used (In Percentage)

Remedy	Male	Female	Total
Calcarea carb.	6	11	17
Calcarea iod.	6	11	17
Calcarea phos.	8	25	33
Lycopodium	6	6	12
Phosphorus	2	11	13
Sulphur	7	1	8

Table 16: Potency used for Constitutional remedies (In percentage)

Potency used	Male	Female	Total
200	41	52	93
IM	2	5	7

Table 17: Ancillary measures used (in percentage)

Not Required		ORS		IV Fluid	
Treatment Group	Placebo Group	Treatment Group	Placebo Group	Treatment Group	Placebo Group
03	02	30	45	06	14

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Table 18: Strategy used as per the grade of diarrhoea

Strategy / Grade	Homeopaathic Rx.	Repetition	Ancillary measure	Expected change in time
Strategy 1 Grade1	Placebo	--	ORS - Plenty	4-6 hours
Strategy 2 Grade 2	Acute	8 hourly	ORS	4-6 hours
Strategy 3 Grade 2 - 3	Acute	6 hourly	ORS / SOS IV Fluid	3-4 hours
Strategy 4 Grade 3 - 4	Acute	4 hourly	IV Fluid	2-3 hours
Strategy 5 Grade 5	Acute	2 hourly	NICU+ Pediatrician Consultation	4 hours

Table 19: Indications of remedies found useful
Arsenic album

	Symptoms	Prescribed in	Relieved in
Causation	Dentition during	19	14
Character of Stools	Watery	34	29
	Dark or Black	12	8
	Undigested particles	22	16
	Involuntary and unnoticed	14	8
	Painless	8	4
	Offensive smelling	32	28
Associated with	Burning sensation in anus and rectum	19	12
Modalities	Cold drinks or food agg.	14	6
	Night Agg.	22	18
	Eating or drinking Agg	22	19
	Cold food Agg.	4	3
	Sea shore Agg.	0	0
	Application on abdomen amel.	18	14
General S/O	Weak, extremely tired	34	30
	Anxious	8	4
	Restless	16	12
	Extreme thirst	22	18

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Podophyllum

	Symptoms	Prescribed in	Relieved in
Causation	Dentition	12	8
	Milk after	13	7
Character of Stools	Profuse	24	17
	Gushing	20	17
	Offensive smelling	13	12
	Yellowish or green	14	8
	Watery	22	16
	Involuntary during sleep or while passing flatus	22	18
Associated with	Headache alternate with diarrhoea	10	6
	Prolapse of ani d/b/a Stools	6	4
	Soreness of anus	10	8
Modalities	Morning Agg.	14	12
	Night Agg.	8	4
	Eating or drinking agg.	22	19
	Abdomen pain amel. by pressure	12	10
	Abdomen pain amel. by warmth	8	6
General S/O	Yellow coated tongue with dryness	9	7
	Loss of appetite	14	10
	Thirstlessness	13	9

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Chamomilla

	Symptoms	Prescribed in	Relieved in
Causation	Dentition	10	4
Character of Stools	Frequent excoriating	14	10
	Watery and mucus then bilious and then bloody	6	3
	Slimy with mucus	8	12
	Undigested	12	7
Associated with	Abdominal pain	14	12
	Great urging cutting colic	12	8
Modalities	Sour things Agg.	8	6
	Motion Agg.	8	4
	Eating or drinking agg.	9	8
	Abdomen pain pressure Amel.	12	11
	Abdomen pain Amel. by bending double	8	6
General S/O	Bitter taste	6	5
	Sleeplessness	5	4

Nux vomica

	Symptoms	Prescribed in	Relieved in
Causation	After spoiled food	8	4
Character of Stools	Involuntary	12	10
	Thin brownish mucoid	6	3
	Constant urging	8	8
	Ineffectual desire	12	10
Associated with	Nausea vomiting	12	10
	Alternate with constipation	5	3
	Hiccough	6	4
Modalities	Morning Agg.	8	6
General S/O	Irritability	6	5
	Sour or bitter taste	5	4

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Phosphorus

		Prescribed in	Relieved in
Causation	Dentition	8	4
Character of Stools	Painless while passing flatus	12	10
	Very offensive	6	3
	Undigested	8	6
	Greenish mucus	6	4
Associated with	Weak and empty feeling in the abdomen	12	10
	The rectum has a loose sensation	5	4
	Vomiting with diarrhoea	6	4
	Burning of palms	6	4
Modalities	Morning Agg.	8	4
	Eating Agg.	9	7
	Sleep after Amel.	6	5
General S/O	Exhausted, Weakness, Fainting	6	5
	Tongue dry, Clean	5	4
	Thirst with desire for very cold drinks	9	8

Discussion

The analysis of 300 cases was done out of total 342 cases enrolled. Children having severe malnutrition were not included in the study. However children having moderate malnutrition were included in the study. Table 4 gives the details. Out of 300 cases analyzed 24 cases were withdrawn from the study due to worsening. They were admitted in the hospital & were treated by the pediatrician from the team.

Efficacy of homeopathy in acute diarrhea

It is commonly known that acute diarrhoea at times is a self limiting condition.

The grading of diarrhoea gives much clarity of which types of diarrhoea do not require treatment. Accordingly, Table 1 gives the grading of diarrhoea. Table 5 shows that 36 out of 300 cases i.e. only 12% cases had diarrhoea of Grade 1. Cases having diarrhoea from the Grade 2 onwards had significant complaints that require definite medical intervention. Table 6, 7, 8, 9, 10 shows the changes taken place in respective groups.

Table 12 shows the change in the number of acute episodes of diarrhoea occurring over six months. Since the frequency varies widely, a relatively longer duration of six months was considered. It was observed that in this area majority of children were having 7-8 episodes of diarrhoea in six months. Therefore it is considered as baseline frequency. The frequency of acute episodes in group 2 had significantly reduced as compared to the other two groups. From the baseline frequency of 7-8 episodes per six months, it had reduced to 0-1episodes per six months. In case of Group 1, there was a marginal change in the frequency. That could be attributed to general change made in hygienic condition. But again the increase in the episodes after 2 years indicates that unless the person's susceptibility improves there may not be a

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significant change in the recurrence. Group 3 shows a steady rise in the number of episodes. Thus, we can safely conclude that after the administration of the constitutional medicine, the susceptibility of the person improves and the patient becomes more receptive to the acute medicines.

Table 13 and 15 shows the remedies used as acute and constitutional remedies respectively. Table 14 and 16 shows that majority of times the indicated potency was 200. In the case of diarrhoea, ancillary measures are important since they take care of dehydration. Table 17 indicates that in 95% cases either ORS or IV fluid was required to correct the dehydration. Table 18 demonstrates that as the grade of diarrhoea changes, the requirement of ancillary measures also changes.

Jennifer Jecob[7] also have conducted double blind study on childhood diarrhoea in 242 children aged 6 months to 5 years were analyzed. Children were randomized to receive either an individualized homoeopathic medicine or placebo to be taken as a single dose after each unformed stool for 5 days.

The results from these studies confirm that individualized homeopathic treatment decreases the duration of acute childhood diarrhea and Homoeopathy should be considered for use as an adjunct to oral rehydration for this illness.

Another study was conducted by Dana Ullman[8] on diarrhoea. The study was a randomized, double-blind, placebo-controlled trial on the treatment of Nicaraguan children, conducted by physicians at the University of Washington and University of Guadalajara. The study included 81 children, ages six months to five years. All the children in the study received oral rehydration fluids to prevent dehydration. While these fluids significantly reduce fatalities from dehydration, they do not treat the underlying infection that is causing the diarrhoea. An analysis of homoeopathic remedies used in the studies showed that the most common five remedies used in all studies, *Podophyllum, Arsenicum album,Sulphur, Chamomilla* and *Calcarea carbonica* were used in 85% of cases in Nepal and 78% of Nicaraguan case.

Those children who were given an individually chosen homoeopathic medicine recovered from the diarrhoea approximately 20% faster than those children given a placebo.

Management strategy for Acute diarrhoea

On the basis of the experience of treating a large number of diarrhoeal episodes, a strategy was evolved for the management of the acute episode. As indicated in Table 13 this was based on the grading of the diarrhoea.

In Strategy 1 (seen in 36 patients) as symptoms were of mild intensity the focus is correcting the water loss. This helped the susceptibility to correct itself. Intervention was needed if improvement did not take place within 6 hours. The results obtained in the Placebo group shows that such cases can be safely and successfully managed in this way.

In Strategy 2, (seen in 93 patients) there was a definite need of acute medicine. It was necessary to identify the characteristic symptoms and prescribe. Along with ORS, the similimum brought about changes in the susceptibility. Repetition of the acute medicine was minimal and the improvement was seen taking place from the generals to particulars. If the stools and vomiting was better but the general symptoms like appetite, fever, crankiness did not improve then the remedy was likely to have been a partially indicated remedy and a review of totality was needed. If the child didn't improve after 6-8 hours then the child might need admission.

Strategy 3 (seen in 109 patients) was applicable to Grade 2 to Grade 3. Hence the child needed an admission and IV Fluids along with ORS supplement with homoeopathic medicine. Signs of registration of the remedy action were seen within 3 hours at the general level. If there were no such signs within 3 hours the totality required revision.

Strategy 4 (seen in 56 patients) was applicable to the child who was in Grade 3 - 4 diarrhoea with pre-renal shut down or an impending renal failure. In these cases there was need of an urgent investigation to know the renal status and a close watch was kept on the urine output. Proper correction of fluid loss and its maintenance was of prime importance. Review of the clinical state and a positive change in the status of the patient was expected within 2 -3 hours.

Strategy 5 (seen in 6 patients) was used in case of Grade 5 diarrhoea. Child was in Grade 4 dehydration and in renal failure and metabolic acidosis. This required NICU management. Correction of acidosis was done with the help of a paediatrician. Homoeopathic medicine was given conjointly where characteristic indications were present.

In this study, a general strategy for the management of acute diarrhoea in fields has evolved. This was extremely helpful to the community health workers and doctors in primary health centre as clear cut guidelines for gradation of diarrhoea and its management were available. Identifying the clinical state was very important in order to classify the symptoms as common or characteristic e.g. dullness becomes characteristic in the initial stage of diarrhoea with no dehydration as it was out of proportion to diarrhoea whereas it is common in a child with Grade 3 dehydra-

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tion. Though in most of the cases these strategies were helpful, the final management needed assessment of individual susceptibility. Common clinical indications of various remedies (Table 19) as seen in the field helped the community health workers to identify and prescribe them. In the acute group, the frequently prescribed remedies were *Arsenic album, Pulsatilla, Chamomilla, Podophyllum* and *Sulphur*. Each remedy was studied for its most frequent indications as seen in the balwadis. The indications are mainly observable signs rather than subjective symptoms and hence have concrete value in prescribing. The most frequently used homoeopathic potency is 200 C.

This study clearly suggests that the indicated homoeopathic medicines could alter the course of acute diarrhoeal disorder. Comparison of results of placebo v/s acute showed a statistically significant difference in the response. Following were important observations from the study:

- Observations in the study showed that constitutional medicines used after episodes of acute diarrhoeal disease could make a significant impact by
  - Bringing down the recurrence of diarrhoea
  - Cutting short the duration of further episodes
  - Reducing the intensity of suffering of the child.
  - It also showed a positive response in the terms of weight gain and improvement in the general activity of the child.
- Ancillary measures such as ORS and IV fluid had an important role in the correction and prevention of dehydration. In 75% of cases ORS was used and in 25% of cases IV fluids were used in the management of acute diarrhoea.
- Management strategies evolved for application in the balwadis, OPD and IPD were based on the following criteria:
  - objective data pertaining to the general condition of the child
  - mood and activity
  - intake of solids and liquid
  - vomiting
  - stool frequency and stool quantity
  - urine output and
  - grade of dehydrations.
- Five different strategies were identified with their specific solution guidelines with respect to the following points:
  - Period of observation
  - Use of ancillary measures
  - Follow up frequency
  - Need for admission
  - Need for expert opinion and
  - Use of homoeopathic medicines
- The successful use of these strategies needs the follow up to be recorded on definitive criteria with minimal variation from case to case.

Coclusions

This study clearly suggests that the indicated homoeopathic medicines could alter the course of acute diarrhoeal disorder. Comparison of results of placebo v/s acute showed a statistically significant difference in the response.

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