

# Effect of Certain Indigenous Drugs on Diarrhea – A Clinical Trial

**Sudipta Poddar**

*Professor & Head, Department of Kaumarbhritya  
Rajib Gandhi Memorial Ayurvedic College and Hospital, India*

*\*Corresponding Author Email: drsudiptapoddar@gmail.com*

## ABSTRACT

Diarrheal diseases constitute one of the leading causes of morbidity and mortality in children world wide, causing for 9 per cent of all deaths among children under age 5 in 2015. This translates to over 1,400 young children dying each day, or about 526,000 children a year, (UNICEF 2016). Most of the diarrheal episodes are self limited. All patients with diarrhea require fluid and electrolyte therapy a few need other non specific support and some may benefit from antimicrobial therapy. But the antimicrobials and antibiotics are not safe. Treatment of Diarrhea or 'Balatisara' has been described in different ayurvedic classics and various indigenous drugs have been recommended for the said disease. Research works have been undertaken on various compositions with satisfactory results. The present study has been carried out to evaluate the efficacy of 'Bilvadyavaleha' (the indigenous drug compound stated by Bangasen) through assessment of clinical potentiality and laboratory findings on scientific parameters in diarrhea or 'atisara' of children.

**Keywords:** *Diarrhea, Balatisara, Indigenous drugs, Clinical Trial*

## INTRODUCTION

Diarrheal diseases constitute one of the leading causes of morbidity and mortality in children world wide, causing for 9 per cent of all deaths among children under age 5 in 2015. This translates to over 1,400 young children dying each day, or about 526,000 children a year, (UNICEF 2016). Most of the diarrheal episodes are self limited. All patients with diarrhea require fluid and electrolyte therapy a few need other non specific support and some may benefit from antimicrobial therapy. But the antimicrobials and antibiotics are not safe. The injudicious use of antimicrobial agents cause emergence of resistant strains of organisms, resistant flora of the gut which are protective are destroyed and toxic complications of some antibiotics are a real and significant danger. There is little scientific evidence that the binding agents (e.g. pectin, kaolin or bismuth salts) are useful in diarrhea (Galbraith *et al* 2013).

The antimotility agents (synthetic analogues of opiates and loperamide)( Rutter P 2013) also have undesirable side effects and the antisecretory agents (Aspirin, chlorpromazine, beta- adrenergic blockers etc.) have been evaluated but are not recommended (Pitcher S Y B 2015). So, we are always in search of a better alternative which can safely given to the children.

Treatment of Balatisara has been described in different ayurvedic classics and various indigenous drugs have been recommended for the said disease. Research works

have been undertaken on various compositions with satisfactory results. In the present a composition has been taken, described by Bangasen. Till now no works have been done on particularly this composition.

## Aim & Objects

The study was carried out to evaluate the efficacy of Bilvadyavaleha (the indigenous drug compound stated by Bangasen) through assessment of clinical potentiality and laboratory findings on scientific parameters in Atisara of children.

## Material & Methods

The research work was done as per the following procedure.

- A) Selection of Patient.
- B) Selection of Drug.
- C) Procedure of Drug Administration.
- D) Parameter of Laboratory Investigations.
- E) Parameter of Assessment of response.

### *A) Selection of Patient*

The patients attending O.P.D. and I.P.D. of our institution, Gopabandhu Ayurveda Mahavidyalaya and Hospital, Puri with complaints of loose motion for 10 days or more were included in the study. The research study has been carried out on 44 individuals during the

period of April 2001 to March 2002. The patients were selected for treatment on the basis of the following criteria.

1. Age – 2 to 10 years
2. Sex – Both sex
3. Frequency of loose motion – 4 to 10 times/day
4. Duration of illness – 10 days or more
5. Dehydration – Up to mild dehydration
6. Fever – Up to moderate fever (1020 F)
7. Vomiting – Up to moderate vomiting

#### *B) Selection of Drug*

The trial drug for the present study was selected from Bangasen Samhita Balarogadhikara. It contains Bilva (*Aegle marmelos* Corr), Dhataki (*Woodfordia fruticosa* Kurz), Nagakeshara (*Mesua ferrea* Linn), Lodhra (*Symplocos racemosa* Roxb) and Gajapippali (*Scindapsus officinalis* Schott Melet) in equal proportion. It is administered in the form of Avaleha with honey. It was prepared in the Rasashala of our institution, Gopabandhu Ayurveda Mahavidyalaya and Hospital, Puri.

In the present research project a comparative study was carried out with the control drug Gramogyl®, a combination of Nalidixic acid and Metronidazole in the dose of 50mg of Nalidixic acid and 35mg of Metronidazole/kg body weight/day (Malik S 1995).

#### *C) Procedure of Drug Administration*

In the present investigation 44 individual patients of atisara were selected, and randomly classified into two groups. 24 individual were taken under Group A (Table 1) and 20 individual patients under Group B (Table 2). Group A was put under the trial drug (Bivadyavaleha) with honey in a dose of 400mg/kg body weight/day in 2 to 3 divided doses for a period of 10 days.

Group B Patients were treated with the control drug Gramogyl® suspension a combination of Nalidixic acid and Metronidazole (150mg and 100mg respectively per 5ml suspension) in a dose of 50mg of Nalidixic acid/kg body weight/day in 3 divided doses for 5 to 10 days.

In both the groups duration of treatment was maintained up to a maximum limit of 10 days according to the recovery from the clinical sign and symptoms of the disease.

During the treatment the patients of both groups were given easily digestible and nutritive diet. A well cooked gruel of rice and lentil, mashed bananas, khichri with oil, rice with milk or curd, mashed potato with oil etc. were advised to take rest during the treatment.

#### *D) Parameter of Laboratory investigations*

The patients included in the study have undergone following laboratory investigations before treatment, after 5 days of treatment and after treatment (i.e. after 10 days)

1. Examination of stool –
  - a) Physical Examination – for colour, consistency, mucus, visible blood and reaction.
  - b) Microscopic Examination – for Bacterial flora, fecal leucocytes, R.B.Cs, mucus flakes, undigested particles, vegetative cells, fat droplets, muscle fibers, starch granules, and also for parasites- Protozoa (cyst / vegetative form), Helminths (ova / larva).
  - c) Chemical Examination – for reaction, occult blood, pH and reducing substances.
2. Examination of Urine – Physical, Chemical and microscopic examination of urine is done routinely for all the patients.
3. Examination of Blood – Hb%, TLC, DLC, of blood is examined routinely for all the patients.

#### *E) Parameter of Assessment of Response –*

The cases were assessed by subjective and objective sign and symptoms, before treatment, after 5 days of treatment and after treatment.

The parameters are as follows –

- 1) consistency of stool, 2) Frequency of defecation per day, 3) Loss of appetite, 4) Abdominal colic, 5) Fever, and the parameters from laboratory findings, 6) Mucus in stool, 7) Undigested particles in stool, 8) Pus cells in stool.

#### *Assessment Scale of Sign and Symptoms*

In order to estimate the percentage of relief the following pattern of assessment scale is made since measurement of certain symptoms like pain, appetite are difficult, certain gradation of scale was adopted to facilitate the assessment.

1. Frequency of defecation /day

G III - >8/day

G II- 6-8/day

G I- 4-5/day

G 0- 1-3/day

2. Consistency of stool

G III - Watery

G II - Liquid

G I - Semiliquid/Curdy

G 0 - Normal (Formed stool)

3. Mucus with stool

G III - Mucus in large quantity

G II - Mucus in less quantity

G I - Occasionally mucus in stool

G 0 - No mucus - Normal stool

4. Loss of Appetite

G III - After 12-15 hrs of taking food appetite appeared

G II - After 10 hrs of taking food appetite appeared

G I - After 8 hrs of taking food appetite appeared

G 0 - After 4 - 6 hrs of taking food appetite appeared

5. Abdominal Colic

G III - Pain hampering the sleep

G II - More frequent pain but not hampering the sleep

G I - Occasional pain

G 0 - No pain

6. Fever

G III - Severe Fever (>1020 F)

G II - Moderate Fever (100 -1020 F)

G I - Mild Fever (98.6 -1000 F)

G 0 - No Fever (upto 98.60 F)

7. Vomiting

G III - > 4 times/day

G II - 2-3 times/day

G I - Occasional

G 0 - Normal

8. Undigested food particles

G III - If found many in numbers

G II - If found few in numbers

G I - If found very few in numbers

G 0 - Not found or if found occasionally

9. Pus cells

G III - 7 and above

G II - 3-7

G I - 1-3

G 0 - No pus cell

10. Cyst and vegetative form of parasites in stool are assessed by simple present /absent basis.

**Description of grades and its relation with severity**

Grade	Grade point	Sign (Degree)	Remark
G III	3	+++	Severe
G II	2	++	Moderate
G I	1	+	Mild
G 0	0	0	Normal

**Results & Discussion**

*Assessment of Result*

The assessment of progress was first noted at the end of 5 days and then 10 days. An assessment scale was framed to assess the rate of improvement.

At the end of treatment the result in view of percentage of relief was classified under the following heading,

i) Cured-100% free from cardinal and associated sign and symptoms.

ii) Maximum improvement -More than 75% improvement of the cardinal sign and symptoms.

iii) Mild improvement-More than 50% but less than

75% improvement of the above mentioned cardinal sign and symptoms.

iv) No improvement-Less than 25% or no improvement of cardinal sign and symptoms.

**Table 1. Degree of severity and percentage of improvement of different Sign/symptoms before and after treatment of Trial Drug to Group A patients**

Sl. No.	Sign & Symptoms & Laboratory Findings	Before Treatment degree of severity				After Treatment (5days)					After Treatment (10 days)				
		G0	G1	G2	G3	G0	G1	G2	G3	P*	G0	G1	G2	G3	P*
1	Frequency of defecation/day	0	5	13	6	2	18	4	0	46.94	15	6	3	0	75.51
2	Consistency of stool	0	7	14	3	1	22	1	0	45.5	15	9	0	0	79.55
3	Mucus with stool	8	3	9	4	8	11	5	0	36.36	17	5	2	0	72.72
4	Loss of appetite	3	2	18	1	6	13	5	0	43.9	16	8	0	0	80.48
5	Abdominal colic	6	6	10	2	11	8	5	0	43.75	17	7	0	0	78.13
6	Fever	10	7	7	0	13	11	0	0	47.62	20	4	0	0	80.95
7	Vomiting	17	5	2	0	20	4	0	0	55.56	21	3	0	0	66.67
8	Undigested food particles	2	1	13	8	2	11	11	0	35.29	12	7	5	0	66.67
9	Pus cells in stool	3	7	11	3	9	8	7	0	41.11	14	4	6	0	57.89

Number of patients = 24

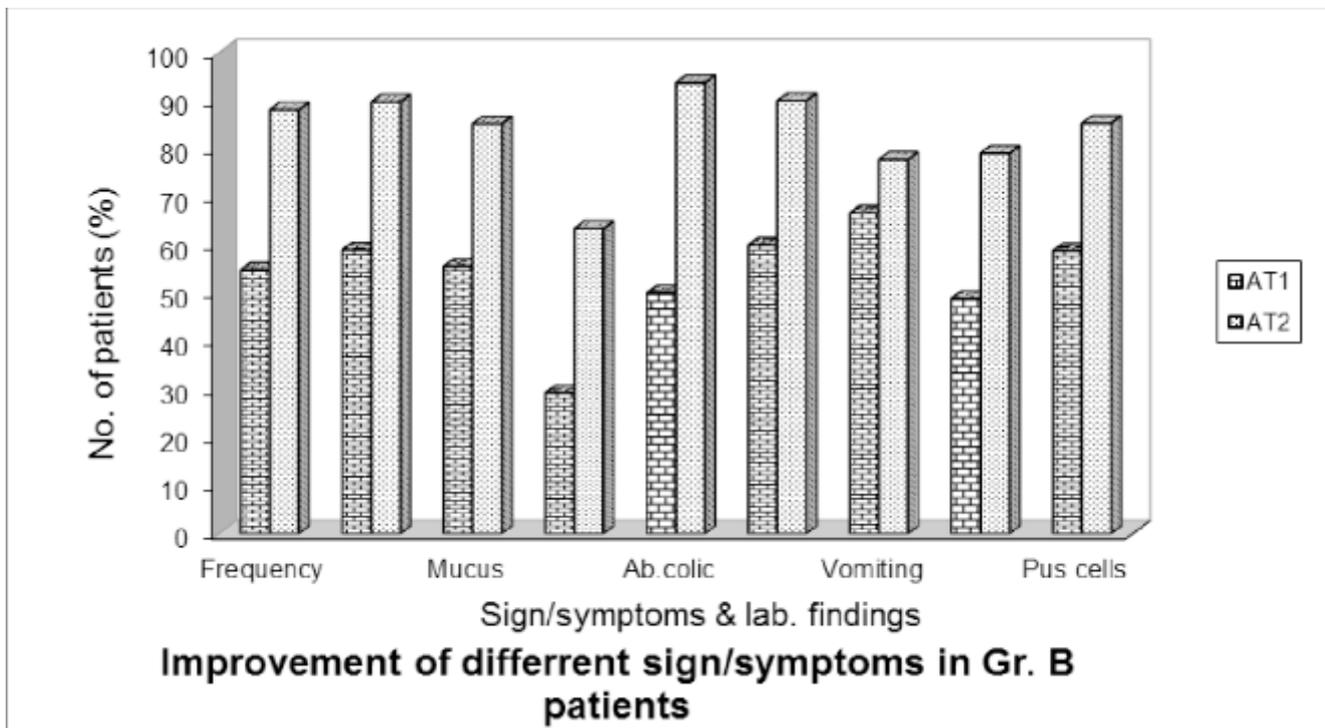
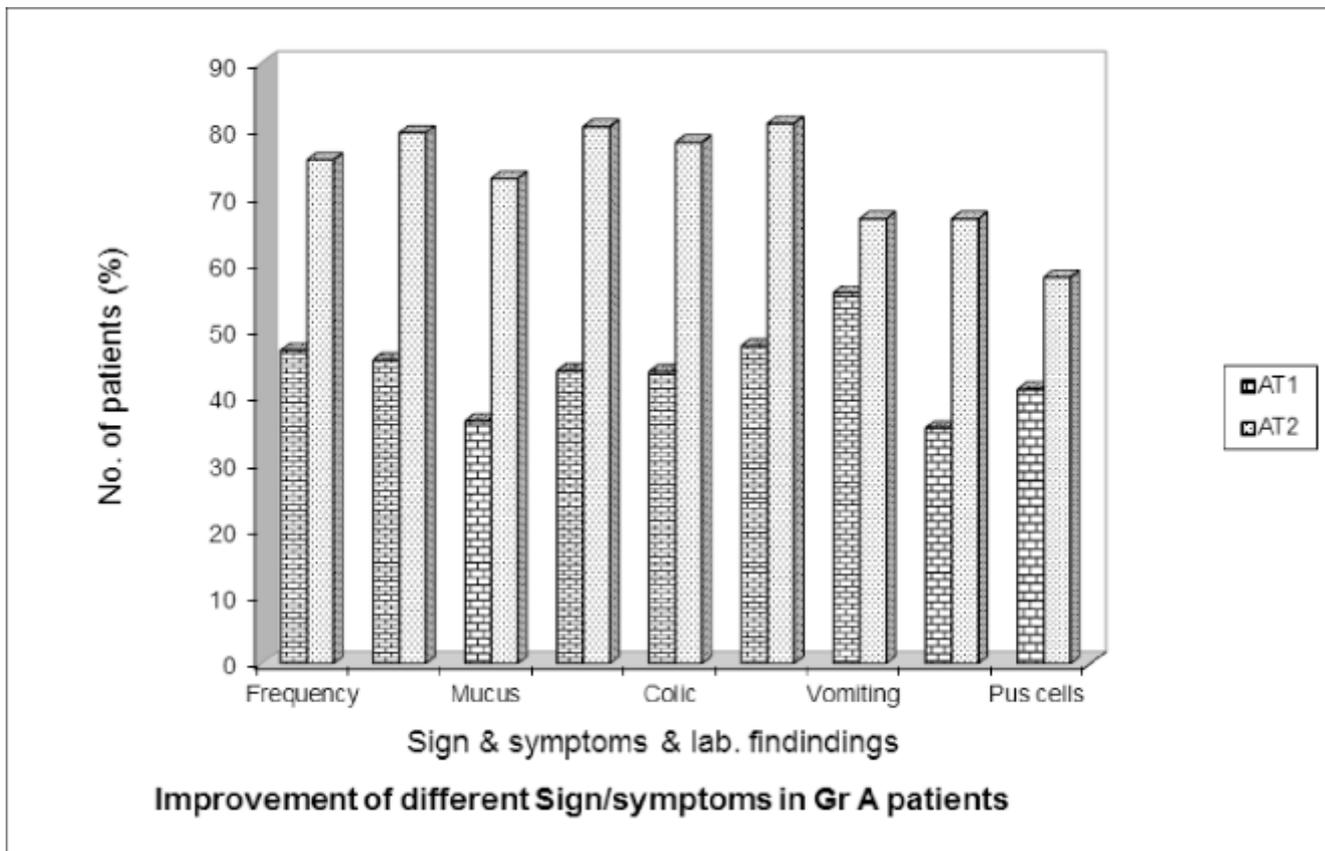
P\* = Percentage of improvement

**Table 2. Degree of severity and percentage of improvement of different Sign/symptoms before and after treatment of Control Drug to Group B patients**

Sl. No.	Sign & Symptoms & Laboratory Findings	Before Treatment degree of severity				After Treatment (5days)					After Treatment (10 days)				
		G0	G1	G2	G3	G0	G1	G2	G3	P*	G0	G1	G2	G3	P*
1	Frequency of defecation/day	0	4	10	6	8	5	7	0	54.76	15	5	0	0	88.09
2	Consistency of stool	0	5	11	4	6	12	2	0	58.97	16	4	0	0	89.74
3	Mucus with stool	8	1	7	4	12	5	2	1	55.56	18	0	0	0	85.19
4	Loss of appetite	0	1	17	2	0	11	9	0	29.27	8	9	3	0	63.41
5	Abdominal colic	4	3	10	3	6	12	2	0	50	18	2	0	0	93.75
6	Fever	8	4	8	0	12	8	0	0	60	18	2	0	0	90
7	Vomiting	12	7	1	0	17	3	0	0	66.66	18	2	0	0	77.77
8	Undigested food particles	0	4	9	7	7	5	7	1	48.84	14	3	3	0	79.07
9	Pus cells in stool	2	5	10	3	9	8	3	0	58.82	17	1	2	0	85.29

Number of Patients = 20

P\* = Percentage of improvement



The mean value S.D. before treatment for each sign and symptom was compared with that of the 5 days after treatment and 10 days after treatment. Student's t-test (paired) was used for the purpose to test the level of significance of the investigation results (Sokal and Rohlf 1987). The effectiveness of the trial drug and control drug to different signs and symptoms and laboratory findings were assessed through 'p' value.

In the clinical study it was observed that the drug is highly effective in normalising consistency of stool, frequency of defecation and appetite. It was also observed that the patients were remarkably relieved from the sign and symptoms of vomiting fever and abdominal colic. The comparative study regarding laboratory findings before and after treatment have shown a remarkable improvement in undigested particles, pus cells, cysts and vegetative forms of pathogens in stool. pH was also observed to become normal in most of the cases.

In comparison with the control drug it was observed that improvement of appetite was better in trial drug than the control drug. In other aspects both the drug have been effective though control drug have shown some better response than the trial drug in some patients.

It is revealed from the results of the present study that 29.16% were cured, 29.16% was achieved maximum improvement 25% in moderate improvement and 12.5% patients achieved mild improvement and no improvement was observed in only one patient.

Hence, it is established that the trial drug Bilvadyavaleha is proved effective in curing atisara in children.

## CONCLUSION

In the present study the size of the sample was small to draw a generalized conclusion. The period of study was

also limited hence no definite conclusion can be made. But it is suggested that the study can be repeated with larger sample for a longer duration. The study design can be done with double blind placebo control to get an exact therapeutic effect. It is expected the present study will definitely disclose some clues to the future researchers.

## REFERENCE

- Bangasen Samhita (Cikitasasara Samgraha): Balarogadhikara Sloke-32.
- Diarrhoea remains a leading killer of young children, despite the availability of a simple treatment solution, Current Status and Progress, UNICEF Global Databases 2016).
- Galbraith Alan, Bullock Shane, Manias Elizabeth, Hunt Barry, Richards Ann, Bullock Shane, Manias Elizabeth (2013). Fundamentals of Pharmacology: An Applied Approach for Nursing and Health. Pearson Higher Education AU, 7th ed. 1249 pages.
- Indian Drug Review. edited by Malik S., (1995) 1(2):214. M. H. Pvt. Ltd., Delhi.
- Pitcher Simon Young Ben (2015) Medicines Management for Nurses at a Glance. John Wiley & Sons
- Rutter P (2013). Community Pharmacy: Symptoms, Diagnosis and Treatment. Elsevier Health Sciences 352 pages.
- Sokal R. R. and. Rohlf F. J, (1987). Single classification of analysis of variance, in Introduction to Biostatistics, pp. 363. W. H. Freeman, San Francisco.