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A comparative clinical study to evaluate the effect of Pathadi Churna and Balchaturbhadrha Yoga in the management of Atisara w.s.r. to 'Bacterial Diarrhoea.'

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Background: *Balatisara* meaning *atisara* in *bala* or childhood diarrhoea. It is observed that Patients of Bala Atisara mainly took shita jala pana, atiruksha, Atiguru, matra guru, samskar virudha ahara etc, also these Nidhan parivarjan is done & in some patients poorvarupa is observed like udarshul, daurbalya, trishna. **Objective:** To evaluate the efficacy Pathadi Churna and Balchaturbhadrha and evaluate its efficacy in the treatment of Balatisara. **Methodology:** It is Randomized Open label, clinical study conducted among 40 patients diagnosed as *Balatisara* (Diarrhoea) selected randomly from OPD or IPD of the hospital. The drug *Pathadi Churna* given for Group-A and Balchaturbhadrha Yoga given to group B for 7 days. **Results & Conclusion :** In this it was found that both the drugs act against frequency of defecation and *Balchaturbhadrha Yoga* drug is more effective than Pathadi Churna.

Keywords: *Balatisara, Balchaturbhadrha, Pathadi Churna, bala, Dosha*

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Introduction:

Atisara in bala can be considered as Balatisara or childhood diarrhoea. It is the most common disease in children and is preventable as well as treatable disease. A significant proportion of Childhood diarrhoea can be prevented by safe drinking-water, adequate sanitation and proper hygiene. Childhood Diarrhoea is the second common cause of infant death and malnutrition worldwide.[1] In India, nearly 1.5 million children's die due to complications associated acute diarrhoea every year. [2] Infectious types of diarrhoea are considered as second most common cause of morbidity and mortality worldwide. [3] Diarrhoea still continues to be a major cause of hospitalization and death in children and has severe economic consequences. [4] The two most important consequences of childhood diarrhoea are malnutrition and dehydration.

Childhood Diarrhoea is the result of infection acquired through the fecal-oral route or by ingestion of contaminated food or water. Childhood Diarrhoea is associated with poverty, poor environmental hygiene and sanitation. Most common Enteropathogens that causes diarrhoea in children are Shigella, Enterohemorrhagic Escherichia coli, Campylobacter jejuni, Noroviruses, Rotavirus, Giardia lamblia, Cryptosporidium parvum, Entamoeba histolytica. These Enteropathogens can be transmitted by person-to-person contact, whereas others, such

as cholera, are generally a consequence of contamination of food or water supply. Person-to-person direct contact outbreaks of gastroenteritis are usually caused by Norovirus and Shigella species. Some other pathogens including Salmonella typhi, Rotavirus, Giardia lamblia, Cryptosporidium, Clostridium difficile, and C. jejuni. [5,6]

This study was planned for assessment of clinical efficacy of Pathadi choorna[7] and Balchaturbhadrā yoga mentioned by Bhavprakash and Bhaishajya Ratnavali in Balarogadhikara respectively. Pathadichoorna contains the ingredients Pathachaturbhadrā Yoga[8] mentioned in Bhavaprakasha and Baishajya Ratnav and Aamrabija. Balchaturbhadrā Yoga contains Nagarmotha, Ativisha, Pippalikarkat Shringi. Both drugs are having Stambhana property and also having Agnideepan properties which would be beneficial in Samprapti break in Balatisara.

Objective:

To evaluate the efficacy Pathadi Churna and Balchaturbhadrā and evaluate its efficacy in the treatment of Balatisara.

MATERIALS AND METHODS:

Study Design: Randomized Open label, clinical study.

Sample Size: Total 40 patients diagnosed as *Balatisara* (Diarrhoea) were selected randomly from OPD or IPD of the hospital.

Group A: (Experimental) The drug *Pathadi Churna*, Dosage of the drug was fixed according to age adopting by Young's Formula for 7 days.

Group B: (Control) Balchaturbhadra Yoga, Dosage of the drug was fixed according to age adopting by Young's Formula for 7 days.

Young's Formula: Child's Dose = Age of child/
Age of child+12x Adults dose

The Composition of Trial Drug:

Pathadi Churna

Sl. No.	Name of Drug	Latin Name
1	<i>Patha</i>	<i>Cissampelos pareira</i>
2	<i>Amrabeej</i>	<i>Mangifera indica</i>

Balchaturbhadra Churna

Sl. No.	Name of Drug	Latin Name
1	<i>Musta</i>	<i>Cyperus rotundus</i>
2	<i>Ativisha</i>	<i>Aconitum heterophyllum Wall.</i>
3	<i>Pippali</i>	<i>Piper Logum lin</i>
4	<i>Karkat shrungi</i>	<i>Pistacia integerrima</i>

METHOD OF COLLECTION OF DATA:

A special proforma Case Record Form (CRF) was prepared to take clinical history from patients as well as from parents. Subjective and objective parameters were included in case report form and it was documented before treatment and after treatment.

Inclusive Criteria:

- Age group of 5 - 14 years of either sex.
- Patients with complaining of passing loose stool 4-5 episodes per day with mild dehydration features were selected for present study.

Exclusive Criteria:

- Patients suffering from *Balatisara* with vomiting and moderate to severe dehydration, suffering from *Pravahika* and *Visuchika*, Dysentery, Diarrhoea associated with immune-deficiency disorder.

ASSESSMENT CRITERIA:

Subjective parameters:

Trushna, Agnimandya, Jwara, Avasada, Viplutata, Durgandha, Udarshool.

Objective parameters:

Stool Examination

1. Frequency
2. Color
3. Consistency
4. Foul smell

5. Mucous

- Degree of dehydration. (W.H.O. guidelines)

- Stool examination – routine and microscopic

Table.No.1 Gradation of clinical features

Sl. No.	Symptom	Clinical features	Grade
1	Frequency	Normal	0
		1-3/day	1
		4-9/day	2
		≥10/day	3
2	Color of stool	Normal	0
		Normal (Yellowish)	1
		Abnormal (greenish/Blackish)	2
		Abnormal (Red or black stool)	3
3	Consistency of stool	Normal	0
		Soft, Formed	1
		Semi loose	2
		Watery	3
4	Foul smell	Normal	0
		Unpleasant smell	1
		Mild offensive	2
		Highly offensive	3
5	Mucous in stool	Absent	0
		Occasionally present	1
		Frequently present	2
		Every time	3

Results:

Age: It has observed that maximum numbers of children i.e. 35% each were belonged to the age group of 7-8 & 9-10 years age group, 12.5% were belonged to 13-14 years age group, 10% were

belongs to 11-12 years and 7.5% were belongs to 5-6 years age group.

Gender: The study shows that maximum incidence of Diarrhea was reported in male 62.5% while the incidence in female was 37.5%.

Geographical Area: It has been observed that out of 40 children, 39(97.5%) were from rural and 1 (2.5%) were from urban area. This high incidence in rural area may due locality of hospital in rural area.

Socio-economic status: The incidence of Socio-economic status in the sample shows that, 31(77.5%) children belonged to middle class, 8(20%) belonged to lower class and 1(2.5%) was from upper class.

Hygienic environment: The incidence of hygienic environment of surrounding of children showed that maximum 38(95%) have lived in poor hygienic environment and 2(5%) have lived in good hygienic condition.

Ahara sevana prakara: Among 40 children, 22(55%) were on vegetarian diet and 18(45%) were non-vegetarian (Mixed) diet.

Koshta: Out of 40 children, only 5(12.5%) were having Mridu Koshta and 13(32.5%) were having Madhyama Koshta and remaining 5(12.5%) were belonging to Krura Koshta. Mridu and Madhyama Koshta may get easily vitiated with Pitta, Kapha

and Vayu. Usually Pachaka Pitta and Samana Vayu get easily vitiated.

Agnibala: Maximum number of children 23(57.5%) were having Avara Agnibala while 12(30%) were having Madhyama Agnibala and remaining 5(12.5%) were having Pravara Agnibala. After treatment all patient observed with madhyama agnibala.

Nutritional status: The study shows that 95% children of the study group were having normal nutritional status only 5% children were in grade I malnutrition and no children were in Grade II, Grade III and Grade IV malnutrition.

Sign and Symptoms: It is observed that, out of the 40 patients taken for the study Atisara, Udarashula & Trishna was reported in 100%, 45% patients reported complaint of Vivarnata, 40% patients reported complaint of Pus cells/Mucus in stool, and 25% patients suffered from Jwara. In the clinical observations, symptoms like diarrhoea, pain abdomen were observed in all of the children which were the main diagnostic features.

Table No. 2: Sign and Symptoms wise distribution of the patients

Sign and Symptoms	Group A	Group B	Total	% Group A	% Group B	Total %
Atisara	20	20	40	100.0	100.0	100.0
Vivarnata	10	8	18	50.0	40.0	45.0
Jwara	6	4	10	30.0	20.0	25.0
Tenesmus/Udarashula	20	20	40	100.0	100.0	100.0
Trishna	20	20	40	100.0	100.0	100.0
Pus cells/Mucus	9	7	16	45.0	35.0	40.0

It is observed that, out of the 40 patients taken for the study Atisara, Udarashula & Trishna was reported in 100%, 45% patients reported

complaint of Vivarnata, 40% patients reported complaint of Pus cells/Mucus in stool, and 25% patients suffered from Jwara.

Table No 3: Effect Treatment on Frequency

Group	Mean Score		BT-AT	% Relief	Paired 't' Test			
	BT	AT			S.D.	S.E.	't'	P
A	1.75	0.55	1.20	68	0.52	0.11	10	P<0.001
B	2.00	0.50	1.50	75	0.51	0.11	13.0	P<0.001

Group A: On **Frequency** the effect of *Pathadi Churnai*.e. before the treatment the mean score was 1.75 and reduced to 0.55 after the treatment and this change that occurred with the treatment is statistically highly significant (P<0.001).

Group B: On **Frequency** the effect of *Balchaturbhadra Yogai*.e. before the treatment the mean score was 2.00 and reduced to 0.50 after the treatment and this change that occurred with the treatment, is statistically highly significant (P<0.001).

Table No 4: Effect Treatment on Color of stool

Group	Mean Score		BT-AT	% Relief	Paired 't' Test			
	BT	AT			S.D.	S.E.	't'	P
A	1.65	0.55	1.10	67	0.30	0.06	15.9	P<0.001
B	2.20	0.60	1.60	73	0.59	0.13	11.9	P<0.001

Group A: On **Color of stool** the effect of *Pathadi Churnai*.e. before the treatment the mean score was 1.65 and reduced to 0.55 after the treatment and this change that occurred with the treatment is statistically highly significant (P<0.001).

Group B: On **Color of stool** the effect of *Balchaturbhadra Yogai*.e. before the treatment the mean score was 2.20 and reduced to 0.60 after the treatment and this change that occurred with the treatment, is statistically highly significant (P<0.001).

Table No 5: Effect Treatment on Consistency of stool

Group	Mean Score	BT-AT	%	Paired 't' Test
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	BT	AT		Relief	S.D.	S.E.	't'	P
A	1.90	0.60	1.30	68	0.47	0.10	12.3	P<0.001
B	2.15	0.60	1.55	72	0.51	0.11	13.5	P<0.001

Group A: On **Consistency of stool** the effect of **PathadiChurnai**.e. before the treatment the mean score was 1.90 and reduced to 0.60 after the treatment and this change that occurred with the treatment is statistically highly significant (P<0.001).

Group B: On **Consistency of stool** the effect of **Balchaturbhadra Yogai**.e. before the treatment the mean score was 2.15 and reduced to 0.60 after the treatment and this change that occurred with the treatment, is statistically highly significant (P<0.001).

Table No 6:Effect Treatment on Foul smell

Group	Mean Score		BT-AT	% Relief	Paired 't' Test			
	BT	AT			S.D.	S.E.	't'	P
A	1.80	0.60	1.20	66	0.41	0.09	13.0	P<0.001
B	2.05	0.55	1.50	73	0.51	0.11	13.0	P<0.001

Group A: On **Foul smell** the effect of **PathadiChurnai**.e. before the treatment the mean score was 1.80 and reduced to 0.60 after the treatment and this change that occurred with the treatment is statistically highly significant (P<0.001).

Group B: On **Foul smell** the effect of **Balchaturbhadra Yogai**.e. before the treatment the mean score was 2.05 and reduced to 0.55 after the treatment and this change that occurred with the treatment, is statistically highly significant (P<0.001).

Table No 7:Effect Treatment on Mucous in stool

Group	Mean Score		BT-AT	% Relief	Paired 't' Test			
	BT	AT			S.D.	S.E.	't'	P
A	2.00	0.65	1.35	67	0.48	0.10	12.3	P<0.001
B	1.95	0.45	1.50	77	0.51	0.11	13.0	P<0.001

Group A: On **Mucous in stool** the effect of **PathadiChurnai**.e. before the treatment the

mean score was 2.00 and reduced to 0.65 after the treatment and this change that occurred with the

treatment is statistically highly significant ($P < 0.001$).

Group B: On **Mucous in stool** the effect of **Balchaturbhadra Yogai**.e. before the treatment

the mean score was 1.95 and reduced to 0.45 after the treatment and this change that occurred with the treatment, is statistically highly significant ($P < 0.001$).

Table No 8 Comparison between effect of Group A and Group B

Variable	Group	Mean Diff	SD	SE	t-Value	P-Value	Result
Frequency	Group A	1.20	0.52	0.12	-1.831	0.075	NS
	Group B	1.50	0.51	0.11			
Colour	Group A	1.10	0.31	0.07	-3.324	0.002	Sig
	Group B	1.60	0.60	0.13			
Consistency	Group A	1.30	0.47	0.11	-1.611	0.115	NS
	Group B	1.55	0.51	0.11			
Foul smell	Group A	1.20	0.41	0.09	-2.042	0.048	Sig
	Group B	1.50	0.51	0.11			
Mucous in stool	Group A	1.35	0.49	0.11	-0.946	0.350	NS
	Group B	1.50	0.51	0.11			

P-Value is greater than 0.05. Hence, we can conclude that, there is no significant difference observed between Group A and Group B in Frequency. While in Colour, p value is < 0.05 we can conclude that, there is significant difference observed between Group A and Group B. In Consistency there is no significant difference

observed between Group A and Group B. While in Foul smell, p value is < 0.05 we can conclude that, there is significant difference observed between Group A and Group B. For **Mucous in stool** there is no significant difference observed between Group A and Group B.

Table No 9 :Overall improvement of children in the study group

Sl. No.	Criteria's	Improvement in %	
		Group A	Group B
1	Frequency	68	75
2	Color of stool	67	73
3	Consistency of stool	68	72

4	Foul smell	66	73
5	Mucous in stool	67	77

In this study it is observed that overall improvement on the clinical features showed in the above table. From above table we may say that the improvement in all symptoms in group B is better than group A.

DISCUSSION ON DISEASE:

Balatisara meaning *atisara* in *bala* or childhood diarrhoea. Diarrhea has its main impact on infants and young children in the poor section of the developing countries. Existence of malnutrition makes the child much vulnerable to suffer from diarrhea. It is observed that Patients of *Bala Atisara* mainly took *shita jala pana*, *atiruksha*, *Atiguru*, *matra guru*, *samskar virudha ahara* etc, also these *Nidhan parivarjan* is done & in some patients *poorvarupa* is observed like *udarshul*, *daurbalya*, *trishna*. According to *bheda* in *Vataj- Atisar* *sashabda mala pravuruti todvat vedna*. In *Pittaj atisar* *pureesha* with yellow, green, blue colour, with burning sensation & in *kaphaj Atisar* *oily feces & white feces*, cold, heaviness in the body all these *lakshanas* are found but after treatment all these *lakshnas* reduced & patient got marked relief. *Atisara* is the disease of GIT and it has *aaharaj* and *viharaja Nidana* and its *samprapti* involves vitiation of *vata dosha* and *apa dhatu* along with *agnimandya* and *mala dravata*. It occurs mainly due to unhygienic conditions that is why it is found more in children

of low socio-economic status. As its *samprapti* involves *agnimandya* and *mala dravata* and the ayurvedic formulations used in its treatment usually have *deepana*, *pachana* and *grahi* property.

It was seen that the presence of greenish/Blackish color stool is found in almost all cases and after the treatment of both the groups maximum patients were found with Normal (Yellowish) stool, so both the drugs act against the color of the stool. After treatment the relief was 67% in group-A, and in group-B it was 73% this shows that *Balchaturbhadra Yoga* is more effective than *Pathadi Churna*. The study regarding consistency of stool after treatment the relief was 68% in group-A, and in group-B it was 72%. Before the treatment presence of foul smell is found in almost all cases of Group A and B patients, and after the treatment of both the groups maximum patients were free from foul smell. The 66% relief is found in group-A and 73% relief is found in group-B. It shows that the Group-B showed better result than Group-A. Before the treatment of A & B group patients, it was seen that the presence of mucous in stool is found in almost all cases and after treatment of both the groups maximum patients were free from mucous in stool, so it is clear that both the drugs act against the mucus. 67% relief was observed in

Group-A and 77% relief is observed in Group-B. Both the drugs *Pathadi Churna* & *Balchaturbhadra Yoga* showed good results in all the signs and

Discussion on mode of action of drugs:

Mode of action of Pathadi churna:

Pathadi churna works at various levels of samprapti of Atisar and correct Dosha Dushti and improves functioning of Agni. By virtue of its Tikta, Katu-Rasa, Katu-Vipak, Ushna-Virya, Laghu-Guna and Kapha shamak karma, *Pathadi churna* causes shoshna of Apa Dhatus which is Drava, Sara, Adra, Kledak, Sheeta and Guru and there by reduces the Atipravrti lakshana in Atisar. *Pathadi churna* reduces Agnimandya by its Tikta, Katu Rasa, Ushna veerya and Deepan guna, it acts as Amapachan by Katu rasa, Katu vipak and Pachan karma. It causes Vata anuloman and thereby correct Vimarga gaman and Ati Drava pravriti lakshanas in Atisar. In this way *Pathadi churna* corrects Dosha dushti, improves Agni, functioning of Pakwashaya and treat the Atisar.

Mode of action of Balchaturbhadra Yoga:

Balchaturbhadra Yoga is an effective antiviral, antibacterial and anti-cold medicine. In addition to its therapeutic benefits, it also improves appetite, digestion, and hepatic functions. It also helps to treat common cold, fever, and upper respiratory tract infections. It improves appetite and digestion due to its appetizer and digestive stimulant actions. It increases gastric secretion and stimulates bile secretion from the liver, which helps to increase

symptoms of the *Balatisara* but the group-B (*Balchaturbhadra Yoga*) showed higher efficacy than the Group-A (*Pathadi Churna*).

appetite and stimulates digestion. *Balchaturbhadra Yoga* has antispasmodic action. It gives relief from abdominal cramps by relaxing the abdominal muscles and thus, it provides relief in infantile colic. The antibacterial and anti diarrheal actions of this drug is benefit to reduce infection and frequency of loose stools in babies. Its ingredients, especially *Ativisha* reduce liquid content of the stools and help to restore the natural consistency of the stool. In addition, it also kills microbes responsible for diarrhoea.

CONCLUSION:

In the present study, group-A is administered with *Pathadi Churna* and group-B with *Balchaturbhadra Yoga*, for 7 days. Regarding frequency of defecation after treatment the relief was 68% in group-A, and in group-B it was 75%. So, it was found that both the drugs act against frequency of defecation and *Balchaturbhadra Yoga* drug is more effective than *Pathadi Churna*. Because of result of clinical trial, we may conclude that both the drugs are effective in management of *Balatisara* (childhood diarrhea).

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