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ORIGINAL RESEARCH ARTICLE (CLINICAL)

Evaluation of the Effect of *Kutaja* in *Balatisara* (~Infantile Diarrhea) in Relation to *Prakriti*: A Preliminary Clinical Study

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ABSTRACT

Ayurveda, the traditional medicine of India, is based on the concept of human *Prakriti* (~constitutional types), which determines an individual's predisposition to diseases and response to treatment. It is imperative in *Ayurvedic* practice to identify the *Prakriti* of a patient before treatment. *Atisara* (~Diarrhea) is one of the most common illnesses particularly encountered in infants and young children. A number of drugs have been mentioned in *Ayurveda* for its treatment. Hence, the present study was designed to evaluate the effect of a syrup *Kutaja* (*Holarrhena antidysenterica Wall*), in different types of *Balatisara* (infantile diarrhea) occurred in infants of different *Prakriti*.

30 infants suffering from acute diarrhea, irrespective to sex, were registered by considering predefined exclusion and inclusion criteria, after getting written informed consent from the parents. Afterwards, these infants were grouped on the basis of characteristics of stool, and the sign/symptoms portrayed for *Doshika atisara*. The drug *Kutaja* was given to infants in dose of 15 mg/kg/dose, 8 hourly for two days. Infants were evaluated at 24 and 48 hours follow ups. Analysis of the gathered data divulges that *Kutaja* has maximum effect on frequency, color & smell of stool in *Pittaja prakriti* infants, while a maximum improvement in mucus was seen in *Kaphaja Prakriti* infants.

Key words: *Balatisara*, Diarrhea, *Kutaja*, *Prakriti*

INTRODUCTION

Prakriti is an important tool that explains individuality, which is responsible for distinct psychosomatic constitution and genetic inheritance, and up to a large extent also determines predisposition to diseases, prognosis and response to therapy. [1, 2] One or more than one *Dosha* predominates at the time of conception, reflecting one of the seven types of *Doshika Prakriti*, [3] which can be clinically identified by *Dosha* specific characteristics manifested in the growing individual. [2]

It is well-established concept that single *Dosha Prakriti* individuals frequently fall sick i.e. more vulnerable to various diseases, while *Samyavastha* (equilibrium state) of three *Dosha* in an individual results in healthy state. [4] It plays a very important role in deciding diagnosis, therapeutics and prognosis of a disease. [5]

Globally, diarrhoea is the second largest cause of death in children under 5 years of age, causing one in every five deaths. Unfortunately, diarrhoea kills more children than AIDS, malaria and measles combined. [6] In India, 13% of the 1.8 million under 5 years of age death is because of diarrhea, accounting for more than 2, 37, 000 children a year which is almost one fifth of global child mortality. [7]

Both, the incidence and the risk of mortality from diarrheal diseases are greatest among children younger than 1 year of age. [8] The WHO has constituted a diarrheal disease control program, which includes traditional medicinal practices together with the evaluation of health education and prevention approaches.[9] A diversity of recognized microorganisms such as bacteria, viruses and parasites can be associated with severe acute infectious diarrhea in children. However, the frequencies of these pathogens vary with geographic region and also depend upon the socioeconomic/sanitary conditions achieved. Several organisms have been implicated as important causes of diarrhea related deaths.

The enteric pathogens rotavirus and diarrhoeagenic Escherichia coli (DEC) are the most common causes of diarrhoea globally, [12] while DEC has been cited as the most important cause in developing countries. [13]

In *Ayurveda*, diarrhea (~*Atisara*) has been dealt in much detail and categorized into six types, [14,15,16] viz. *Vataja, Pittaja, Kaphaja, Sannipataja, Bhayaja and Shokaja (Aamaja*), [17] based on the vitiation of physical and mental *Doshas* due to numerous factors including contaminated water,[18] and *Krimija*. [18, 19] In infants, *Atisara* is also caused by *Pittajanya Stanya Dushti* (breast milk vitiated by *Pitta Dosha*), [20, 21] and *Mrittika bhakshana* (ingestion of clay). [22]

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Many drugs have been mentioned for the treatment of different types of diarrhea in different *Ayurvedic* texts, but *Kutaja* is one of the drugs which is used as a single or as an important ingredient in most of the antidiarrheal recipes due to its pharmacodynamic properties.[23, 24]

Aims of this study

1. To identify the incidence of infectious etiology in different type of *Atisara* in infants, and
2. To determine the efficacy of *Kutaja*, clinically, in different types of *Atisara* of infants.

MATERIALS AND METHODS

Subjects

Total 30 infants suffering from *Atisara* (acute diarrhea) were registered irrespective of sex, by considering the inclusion/exclusion criteria from the O.P.D of *Kaumarbhritya* /*Balroga*, S.S. Hospital, I.M.S, B.H.U., after getting written informed consent from the parents/guardian.

Inclusion criteria

i. Patients upto age of one year.
ii. Case of acute diarrhea.

Exclusion criteria

i. Signs of severe dehydration or shock.
ii. Not accepting orally/persistent vomiting.
iii. Suffering with any associated severe systemic disease, e.g. septicemia, meningitis associated with diarrhea.
iv. Age more than 1 year.

Ethical clearance

Approval was taken from the ethical committee of the institute [ethical clearance number (E.C. C. No.): 2014-15/EC/1338].

Investigations

Hemogram and stool examination (routine and microscopy as well as culture and sensitivity) of the selected infants were carried out at the time of their registration.

Study design

This was an observational clinical study in which the change in mean score was used for assessment of efficacy of trial drug *Kutaja*.

Assessments and data analysis

The *Prakriti* assessment was done by the PRS-IPA (Prototype research software for Infant *Prakriti* Assessment). [25] A scoring system, [26] based on the signs and symptoms of *Doshika Atisara* (diarrhea due to imbalanced humours) described in *Ayurveda*, [27-30] was used for the purpose of diagnosis and to assess the response of *Kutaja*. The score for each sign and symptom ranged from 0 to 4. The mean of the score of each feature was calculated at registration and on subsequent follow ups.

Intervention

The registered cases were treated by giving syrup *Kutaja* which was made in accordance with the standard procedure of *Kwatha Kalpana* (decoction preparation), [31] and given orally in a dose 15mg/kg/dose, thrice a day (8 hourly). Two follow ups at 24 hours and 48 hours were made, and the effect of the drug was evaluated.

OBSERVATIONS AND RESULTS

Initially, 30 infants of different *Prakriti*, suffering with various types of *Atisara* were registered, but on second follow up, 2 cases of *Vataja Prakriti* were dropped out because of failure to report by the mother.

Out of 30 cases, maximum cases (56.67%) belonged to *Ptittaja Atisara*, followed by *Kaphaja*, *Sannipataja* and then *Vataja Atisara*. Incidence of *Balatisara* (infantile diarrhea) was observed in *KP Prakriti* (n=10), followed by *VK Prakriti* (n=6), *Pittaja and Vata-Pitta Prakriti* (n=4, each), whereas 3 cases were of *Vatika Prakriti* [Table 1].

Table 1: Incidence of type of *Atisara* in different *Prakriti* infants

Prakriti **(n=30)**	**Type of *Atisara***			
	Vataja **(n=3)**	***Pittaja*** **(n=17)**	***Kaphaja*** **(n=6)**	***Sannipataja*** **(n=4)**
V (n=3)	0.00 (0.00%)	3.00 (17.65 %)	0.00 (0.00%)	0.00 (0.00%)
P **(n=4)**	0.00 (0.00%)	4.00 (23.53 %)	0.00 (0.00%)	0.00 (0.00%)
K **(n=3)**	0.00 (0.00%)	0.00 (0.00%)	3.00 (50.00 %)	0.00 (0.00%)
VP **(n=4)**	1.00 (33.33 %)	3.00 (17.65 %)	0.00 (0.00%)	0.00 (0.00%)
VK **(n=6)**	1.00 (33.33 %)	2.00 (11.76 %)	0.00 (0.00%)	3.00 (75.00 %)
KP **(n=10)**	1.00 (33.34 %)	5.00 (29.41 %)	3.00 (50.00 %)	1.00 (25.00 %)

[V=*Vataja*, P=*Pittaja*, K=*Kaphaja*, VP=*Vataja-Pittaja*, VK=*Vataja-Kaphaja*, KP=*Kaphaja-Pittaja Prakriti*]

Out of 30 infants, stool of 18 infants was found sterile; whereas in the rest of stool samples (n=12) growth of pathogens was found positive as follows- *E. coli* was seen in 33.33% cases and there was one case each of *Entamoeba histolytica* and *Ascaris lumbricoides*.

Maximum incidence of *E. coli* was seen in *Pittaja Atisara* in infants of *Vataja* and *Kaphaja-Pittaja Prakriti*, followed by *Kaphaja Atisara* belonging to *Kaphaja-Pittaja Prakriti* infants as shown in [Table 2].

Table 2: Incidence of E. coli in different types of *Atisara* as per infant's *Prakriti*

Prakriti **(n=30)**	**Type of *Atisara***			
	Vataja **(n=3)**	***Pittaja*** **(n=17)**	***Kaphaja*** **(n=6)**	***Sannipataja*** **(n=4)**
V **(n=3)**	0.00 (0.00%)	3.00 (100%)	0.00 (0.00%)	0.00 (0.00%)
P **(n=4)**	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
K **(n=3)**	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
VP **(n=4)**	1.00 (100%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
VK **(n=6)**	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (100%)
KP **(n=10)**	0.00 (0.00%)	2.00 (20%)	2.00 (20%)	1.00 (10%)

Stool characteristics

At the time of registration, mean score of stool frequency was

observed to be maximum in *Vataja prakriti* and minimum in *Kaphaja* and *Kaphaja-Pittaja Prakriti* infants. After administration of *Kutaja* syrup, frequency of stool was reduced in infants of all *Prakriti*, however, maximum reduction was observed in infants of single *Doshaja Prakriti* [Table 3].

Table 3: Effect of *Kutaja* syrup on frequency & consistency of stool in infants of *Atisara*, as per *Prakriti* of infants, at registration and on subsequent follow ups

Prakriti (n=30)	Frequency of Stool (Mean score)				Consistency of Stool (Mean score)			
	R (n=30)	F1 (n=30)	F2 (n=28)	F2- R	R (n=30)	F1 (n=30)	F2 (n=28)	F2- R
V (n=3)	4.00	3.00	2.00	2.50	3.00	3.00	2.00	1.00
P **(n=4)**	3.75	2.75	1.00	2.80	3.00	2.00	1.00	1.60
K **(n=3)**	3.33	2.00	1.00	2.33	2.33	2.00	1.00	1.33
VP **(n=4)**	3.50	2.50	1.50	1.75	3.00	2.25	1.25	1.75
VK **(n=6)**	3.33	2.16	1.50	1.83	2.83	2.16	1.60	1.14
KP**(n=10)**	3.10	2.20	1.20	1.00	2.80	1.80	1.40	1.40

Maximum mean score for the consistency of stool was found in infants of *Vataja*, *Pittaja* and *Vata-Pittaja Prakriti* at registration. After administration of trial drug, it was reduced to minimum (mean score: 1.0) in infants of *Pittaja* and *Kaphaja Prakriti* (F2) [Table 3].

The mean score of mucus was found maximum (3.00) in infants of *Vataja* and *Kaphaja Prakriti* at the time of registration. After administration of *Kutaja* syrup, mean score for the mucus was not found to be reduced in stool of infants of *Vataja Prakriti* at final follow up, while the minimum score was observed in *Vataja-Pittaja Prakriti* infants as evident from the mean score data of F2 as shown in [Table 4].

Table 4: Effect of *Kutaja* syrup on presence of mucus & color of stool in infants of *Atisara*, as per *Prakriti* of infants, at registration and on subsequent follow ups

Prakriti (n=30)	Mucus (Mean score)				Color of stool (Mean score)			
	R (n=30)	F1 (n=30	F2 (n=28)	F2-R	R (n=30)	F1 (n=30)	F2 (n=28)	F2-R
V (n=3)	3.00	3.00	3.00	0.00	3.00	3.00	2.00	1.00
P (n=4)	0.75	0.50	0.25	0.50	3.00	2.00	1.00	2.00
K (n=3)	3.00	2.00	1.00	2.00	2.60	2.00	1.00	1.60
VP(n=4)	1.00	0.50	0.00	1.00	3.00	2.25	1.50	1.50
VK(n=6)	2.00	1.66	1.16	0.84	2.33	2.00	1.16	1.17
KP (n=10)	2.60	1.80	1.00	1.60	2.80	1.90	1.20	1.60

Maximum change in colour of stool of infants of *Pittaja Prakriti* was found after administration of syrup *Kutaja* in dose of 15 mg/kg/ dose every eight hourly, while the minimum change was observed in infants of *Vataja Prakriti*, as evident from the mean score of F2-R of [Table 4].

Mean score for foul smell in stool of infants of *Vataja, Pittaja* and *Kaphaja prakriti* was observed maximum at registration, while the mean score given for the foul smell in stool of infants of *Pittaja, Kaphaja and Vataja-Pittaja Prakriti* was found minimum at final follow up of the study [Table 5].

Table 5: Effect of syrup *Kutaja* on foul smell & frothing in stool in infants of *Atisara*, as per *Prakriti* of infants, at registration and on subsequent follow ups

Prakriti (n=30)	Foul smell of stool (Mean score)				Frothing in stool (Mean score)			
	R (n=30)	F1 (n=30)	F2 (n=28)	F2-R	R (n=30)	F1 (n=30)	F2 (n=28)	F2-R
V (n=3)	3.00	3.00	2.00	1.00	2.00	2.00	2.00	0.00
P (n=4)	3.00	2.00	1.00	2.00	0.00	0.00	0.00	0.00
K (n=3)	3.00	2.00	1.00	2.00	0.00	0.00	0.00	0.00
VP (n=4)	2.00	1.25	1.00	1.00	1.25	1.25	1.2	0.05
VK (n=6)	2.50	2.00	1.60	0.90	1.33	1.16	1.00	0.33
KP (n=10)	2.50	1.90	1.10	1.40	1.20	1.10	1.00	0.20

Frothing was observed in stool of infants of *Vataja, Vataja-Pittaja, Vataja-Kaphaja* and *Kaphaja-Pittaja Prakriti* at registration, i.e. at onset of *Atisara* [Table 5].

Mean score of abdominal distension was observed to be maximum in *Vataja Prakriti* infants at registration, while significant reduction was seen after administration of *Kutaja* syrup in infants of *Kaphaja Prakriti*. The mean score of pain in abdomen of infants of *Vataja Prakriti* was found higher at registration and on subsequent follow ups as well [Table 6].

Table 6: Effect of *Kutaja* syrup on abdominal distension & pain in abdomen in infants of *Atisara*, as per *Prakriti* of infants, at registration and on subsequent follow ups

Prakriti (n=30)	Abdominal distention (Mean score)				Pain in abdomen (Mean score)			
	R (n=30)	F1 (n=30)	F2 (n=28)	F2-R	R (n=30)	F1 (n=30)	F2 (n=28)	F2-R
V (n=3)	3.50	2.50	1.50	2.00	3.50	3.00	2.50	1.00
P (n=4)	0.60	0.40	0.40	0.20	0.40	0.40	0.20	0.20
K (n=3)	0.80	0.80	0.20	0.60	0.80	0.80	0.40	0.40
VP (n=4)	2.00	1.30	0.83	1.17	1.66	1.16	0.66	1.00
VK (n=6)	1.14	0.85	0.80	0.34	1.85	1.57	1.28	0.57
KP (n=10)	1.50	1.23	0.69	0.81	1.92	1.30	0.69	1.23

Out of 30 cases, maximum cases (n=5) of *Pittaja Atisara* (n=17) was seen in *Kaphaja Pittaja Prakriti* (n=10) and minimum in *Vataja* (n=3) as well as in *Vata-Pittaja Prakriti* (n=4), while the maximum cases of *Kaphaja Atisara* were observed in infants of *Kaphaja* and *Kaphaja-Pittaja Prakriti* [Table 7].

Table 7: Mean total score of all signs/symptoms in infants of different *Prakriti* with different types of *Atisara* at registration and on subsequent follow ups

Prakriti **(n=30)**	**Type of *Atisara***							
	***Vataja* (n=3)**		***Pittaja* (n=17)**		***Kaphaja* (n=6)**		***Sannipataja* (n=4)**	
	At Reg.	**At F2**	**At Reg.** (n=17)	**At F2** (n=15)	**At Reg.**	**At F2**	**At Reg.**	**At F2**
V (n=3)	0.00	0.00	1.92 (n=3)	1.07 (n=1)	0.00	0.00	0.00	0.00
P **(n=4)**	0.00	0.00	1.55 (n=4)	0.56 (n=4)	0.00	0.00	0.00	0.00
K **(n=3)**	0.00	0.00	0.00	0.00	1.77 (n=3)	0.52 (n=3)	0.00	0.00
VP **(n=4)**	1.69 (n=1)	0.92 (n=1)	1.48 (n=3)	0.43 (n=3)	0.00	0.00	0.00	0.00
VK **(n=6)**	2.00 (n=1)	1.15 (n=1)	1.07 (n=2)	0.57 (n=2)	0.00	0.00	2.04 (n=3)	1.79 (n=3)
KP **(n=10)**	1.46 (n=1)	1.07 (n=1)	1.95 (n=5)	0.73 (n=5)	1.7 (n=3)	0.5 (n=3)	2.1 (n=1)	1.65 (n=1)

On evaluating the overall effect of drug on various signs and symptoms of *Atisara*, maximum improvement was observed in infants suffering from *Kaphaja Atisara* belonging to *Kaphaja* and *Kaphaja-Pittaja Prakriti* [Table 7].

DISCUSSION

Instead of six types of *Atisara*, in present study, only four types of *Doshika atisara* viz. *Vataja*, *Pittaja*, *Kaphaja* and *Sannipataja Atisara* were observed (n=30) in infants of different *Prakriti*. Most of the cases of *Atisara* have not shown growth of enteropathogens (53.70%) on stool culture, while *E. coli*, *Entamoeba histolytica* and *Ascaris lumbricoides* were isolated from the stool of infective infants (46.30%).

Diarrheagenic Escherichia coli (DEC) were isolated from the stool of infants suffering with *Vataja*, *Pittaja*, *Kaphaja and Sannipataja Atisara*, which together account for a total of 83.33% infectious diarrhea in infants and is much higher than past study according to which DEC is responsible for 30%-40% cases of acute diarrhoea in children below 5 years of age. [32, 33, 34] Astonishingly, *E.coli* was isolated in different types of *Atisara* in *Kaphaja-pittaja Prakriti* infants.

Antidiarrheal activity of *Kutaja* may be because of its specific action as antiparasitic activity against *E. histolytica* and *G. Lambalia*; [35] antibacterial effect on *E.coli* etc, [36, 37] which can be correlated with *Hetu Viprita Upashaya* (allaying disease by diet, drug and regimen) as indicated by *Chakrapani*. [38]

In the present study, maximum cases (n=18) are of *Pitta* affiliated *Atisara* viz. *Pittaja*, *V-P* and *K-P Prakriti*, which supports the concept of *Ayurveda* that a person of specific *Dosha Prakriti* is more prone to develop disorders pertaining to that particular *Dosha* type. [39]

The present study suggests that *Kutaja* has significant positive therapeutic effects, i.e. improvement in stool frequency, consistency, foul smell, color, mucus and pain in abdomen, as well as reduced appetite in infants who were suffering with *Kaphaja Atisara*, followed by *Pittaja Atisara*. *Kutaja* (*H. antidysenterica-Wall*) is well known for its antidiarrheal and antidysenteric activity, attributable to its pharmacodynamic properties viz. *Kapha-Pitta-Rakta Samgrahika* (enhance uniform absorption), *Upashoshana* (astringent property), [40] *Katu-Kashaya Rasa* (pungent-astringent taste), *Ruksha* (dry), *Deepana* (appetizer) and *Amahara* (allays indigestion). [41, 42] The elimination of mucus and subsidence of abdominal pain is due to its anti-inflammatory and analgesic properties. [43, 44]

This effect of *Kutaja* syrup on stool frequency and consistency may be due to its astringent and *Samgrahi* properties respectively. The astringent property of *H. antidysenterica* is attributed due to the presence of alkaloids as connesine, [45] and tannin, [46] which result in antisecretory activity by precipitating superficial proteins and forming a protective layer over the mucous membrane.

Agnimandya (decreased digestive power) and product of improper digestion '*Ama'* has a direct role in the pathogenesis of *Atisara*. The *Deepana* property, *Katu-Kashaya rasa, Amahara, Ruksha* and *Kapha-Pittahara* action of *Kutaja* are responsible for *Amapachana* (digestion of intermediate metabolites), consequentially improving the appetite along with normalising stool colour, foul smell, reducing mucus etc.

The drug has shown minimum effect on frequency of stool in infants of *Kaphaja-Pittaja Prakriti*; consistency, color, and mucus in stool in infants of *Vataja Prakriti*; and even in infants of *Pittaja Prakriti*, least effect of the drug was seen in abdominal distension.

However, significant result was seen in almost all types of *Atisara* except *Sannipattaja Atisara*; but three cases of *Sannipataja Atisara* had not shown significant improvement and were shifted to antibiotics; while a positive case of *E. histolytica* found only in one *Sannipataja Atisara* case, responded to *Kutaja* syrup from the second follow up.

Analysis of the overall mean scores of signs and symptoms in diarrheal infants suggests that a better response of *Kutaja* syrup is seen in *Pittaja* and *Kaphaja Atisara* belonging to *Kaphaja* and *Kaphaja-Pittaja Prakriti*, while poor response is observed in *Sannipataja Atisara* in infants of *Vataja Kaphaja Prakriti*.

CONCLUSIONS

The result of this study, being reported for the first time, provides clear evidence that infantile *Prakriti* has considerable relation with onset of *Doshika Atisara* and also has therapeutic value in management. Therefore it can be concluded that if infants of *Pittaja, Pitta-Kaphaja* and *Kaphaja Prakriti* have onset of *Pittaja, Kaphaja* and *Kaphaja Atisara*, respectively; an improvement will take place.

Trends of data of this study can initiate the research scholars to work in this direction for getting etiopathogenesis based rational therapy. However, a study on larger sample size in infants is required to draw final conclusion.

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