

Study the Effect of Bilwa Amra Yog on Atisara in the Age Group of 1-5 Years

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Abstract: Diarrhoea is the most common pediatric complaint worldwide in tropical and subtropical areas. Incidence of diarrhoea is more in the age group above 6 months. Improper weaning, low socioeconomic status, ignorance, lack of hygiene, improper diet like packet food, more dependency on outside food, untimely food habits. Atisara is characterized by atidravamalapravruthi through guda. Most important factor in the pathogenesis of Atisara (diarrhoea) is mandagni. Mandagni is root cause of amadosha and it is the crucial factor for manifestation of most of the diseases including Atisara (diarrhoea). Bilwa amra yog in syrup form was used for treating Atisara in an informed, consented, open clinical trial on 45 eligible patients and were evaluated at regular intervals on various assessment parameters over a period of 7 days. Syrup was administered orally in appropriate doses every 6 hourly in a day for 7 days. Early improvement in frequency of diarrhoea is found on 3rd day of follow up. Complete relief from loose motion found on 5th -7th day. There is 89.66 % & significant result in improving Swaroop of stool. The mean grade of AAMAVASTHA on 0th day was 0.355 which was decreased to 0.022 at 5th day. The mean increment in score was 93.75% which is significant. The study shows 100% improvement in curing the amavastha of stool. It is 91.11% significant result in reducing vikruta gandha of stool. There are 93.02% significant results in improving.

Keywords: Atisara, Bilwa, Amra, BilwaAmra Syrup

1. Introduction

Diarrhoea is the most common pediatric complaint worldwide in tropical and subtropical areas. Incidence of diarrhoea is more in the age group above 6 months. Improper weaning, low socioeconomic status, ignorance, lack of hygiene, improper diet like packet food, more dependency on outside food, untimely food habits, the incidence of atisara is more in middle class families in developing countries like India. It accounts for approximately 30 % of hospital admissions and approximately 15% of deaths in under 5 children, with an estimated incidence of 1.7 episodes/year/child. If diarrhoea is untreated it may cause dehydration and due to severe dehydration, there may be death of the child. Atisara is characterized by atidravamalapravruthi through guda. Most important factor in the pathogenesis of Atisara (diarrhea) is mandagni. Mandagni is root cause of amadosha and it is the crucial factor for manifestation of most of the diseases including Atisara (diarrhea). Amadosha results due to agnidushti caused by mithyaaharavihara, ultimately manifesting as Atisara (diarrhea). Thus, faulty diet habits play an important role in causation of Atisara (diarrhea) and its treatment comprises suggestion to follow proper aharavidhividhana. Brihatrayees enumerate types of Atisara (diarrhea) as six. The disease atisara is common in age group of 1 to 5 years and the patients visited to balaroga department are also of same age group. Hence the age group of 1 to 5 years is selected. In VangasenaSamhitaAcharya has mentioned BilwaamrastiNiryuha for atisara¹. Bilwa and Amra are grahi and stambhana respectively so they are undertaken for clinical study.

Study the effect of Bilwaamrayoga on Atisara in the age group of 1 to 5 years.

The Bilva Amra kwath mentioned in management of Atisara helps in agnideepana, amapachana and is also purisha

sangrahaneeya, so this digests Ama and also cures diarrhea. As the pulp of unripe bilwa fruit is astringent, digestive and stomachic and useful in atisara. The unripe fruit of bilwa having Kashaya, tiktarasa and laghu, ruksha in guna it is deepanapachana, sangrahihik. The mango seed kernel also acts good in diarrhea, as it is Kashayarasa, having guna like ruksha, laghu causes agnideepan, amapachana, ruksha guna helps in drava mala shoshan and thus causes mala stambhana. Hence an effort is made to assess the action of the above said drugs on Atisara in Balyavastha.

2. Materials and Methods

2.1 Ethical Clearance

The topic of the study, together with case proforma was submitted to the Institutional Ethical committee Bharati Vidyapeeth Deemed To Be University College of Ayurveda, Pune. The significance, aim and objectives, methodology and probable result of the study were clarified to the committee and ethical clearance was obtained for the conduction of the study.

2.2 Type of Study

Informed, consented, randomized, interventional, open clinical trial.

2.3 Place of work

The patients diagnosed as atisara, from daily OPD based patients of Bharati Ayurveda Hospital, Pune will be enrolled for the trial.

2.4 Number of patients

- Prevalence rate is about 3.8%, So 45 patients selected for clinical trial
- 45 patients (Preferably 15 patients of each type of *ekadoshaja Atisara*)

2.5 Clinical study

45 number of patients taken for clinical study, diagnosis done based on *nidanapanchaka*. Mild to moderate dehydration treated by *lajamanda* and *narikelajala*, as an oral supplement along with the trial study.

Form of Drug

Kashaya in the form of syrup

Selection of patient

a) Inclusion criteria

- Age 1 to 5 Year patient will be included.
- Each type of Doshaj atisara as mentioned in Samhita will be included.
- Degree of dehydration none to mild and mild to moderate.
- Patient having atisara only of recent origin i.e., duration of less than 3 days.

b) Exclusion criteria

- Patient below 1 year of age and above 5 years of age
- Patient having atisara due to food poisoning or iatrogenic origin.
- Patient having chronic atisara
- Patient having occult and fresh blood in stool
- Patient with moderate to severe degree of dehydration.

2.6 Dose

Age	Dose
1-2 Years	4ML i.e 1 ml QID of <i>kwatha</i>
2- 3 Years	8ML i.e 2mlQID of <i>kwatha</i>
3-4 Years	12 ML i.e 3 ml QID of <i>kwatha</i>
4- 5 Years	16 ML i.e. 4ML QID of <i>kwatha</i>

2.7 Drug Preparation

Bilwa amra niryuha in syrup form prepared in an educational institute or a GMP certified pharmacy. *Kwatha* being bitter in taste, there will be a chance of non-acceptance of medication by the child. So taking the aspects of palatability and acceptability into consideration the medicine is administered in a sugar based syrup form. Syrup is most suitable for drugs having unpleasant taste and odour. Drug in syrup form exhibits a higher rate of bioavailability compared to other forms of drugs like tablets. This is due to larger surface area and high dissolution.

Material

Aegle marmelos, *Mangifera indica*, Sugar, Honey, Sodium benzoate, Double distilled water

2.8 Procedure

Part A

- 1) Weighed quantity of *Aegle marmelos* powder was added to 16 parts of water.
- 2) Resultant dispersion was stirred under continuous heating till water evaporates to form semisolid mass (decoction method).
- 3) This semisolid mass was then filtered using muslin cloth (# 200) and will be used as extract in syrup preparation.
- 4) The above same steps were followed to get extract of *Mangifera indica*.

Part B

- 1) Weighed quantity of sugar was taken and dissolved in double distilled water to form sugar syrup base under continuous heating and stirring.
- 2) Above solution was then allowed to cool at room temperature.
- 3) To the above syrup base honey and weighed quantity of extracts of *Aegle marmelos* and *Mangifera indica* were added under continuous stirring.
- 4) Weighed quantity of preservative (Sodium benzoate) was added to above solution and stirred for 30 min using overhead stirrer.
- 5) This prepared solution was then filtered again through muslin cloth (# 200) and filled in bottle.

Standard operative procedure

- Raw drugs were procured and collected personally.
- All related required reports like authentication/standardization were done
- The syrup of *bilwa majja* and *amraasthi niryuha* was prepared as mentioned in Indian Pharmacopeia.
- The syrup was prepared at a registered GMP manufacturing unit.
- Patients were screened and registered from Balarog OPD of Bharati Ayurveda Hospital and Research center
- Proper post counseling, consent was taken in the local language or in a language that parents understand.
- The vital data like name, age, sex, religion, occupation, habitat, diet, socioeconomic status, were recorded first.
- Every child was enquired for various etiological factors and various symptoms described for *atisara like vataja, pittaj, kaphaj* during the period of taking history of present illness. All the children were enquired for the presence of specific type of *atisara* sign and symptoms were ascertained and recorded in the proforma.
- *Pramana* of children like height and weight were recorded by using necessary instruments. All the *srotasas* were examined using available Ayurvedic and modern parameters before and after treatment. Special emphasis was given to *Annavaahasrotaspariksha*. The diagnosis of *each type of atisara based on specific lakshanas of each type of atisara*.
- Parents preferably mother was taught to administer the syrup in appropriate quantity and at appropriate time (four time a day i.e. every 6 hourly) also diet for the children.
- Examining parameters were evaluated regular intervals that is on day 0 (registration day), day 3, day 5, day 7.
- If any adverse reaction arise or there is aggravation of any sign, then the trial drug will be stopped and appropriate &

established pharmacological, therapeutic treatment according to modern science will be given.

Assessment Criteria

- Frequency of stool in 24 hours. Assessment of quantity is difficult.
- Urine output – Frequency, assessment of quantity is difficult.
- Thirst & water intake - volume.
- Weight
- Blood Pressure

2.9 Subjective Criteria

1) Frequency of diarrhea in 24 hrs (Atisar vega)

GRADE 0	Normal	Absent
GRADE 1	Mild	Upto 4 vegasin 24 hrs
GRADE 2	Moderate	5-8 vegas in 24hrs
GRADE 3	Severe	More than 8 vegas in 24 hrs

2) Loss of appetite (Annadvesh)

GRADE 0	Normal	Takes food normally
GRADE 1	Mild	Less intake compared to routine diet
GRADE 2	Moderate	Sometimes takes food properly but most of the times avoid
GRADE 3	Severe	Avoid food anytime

3)Swaroop

GRADE 0	Normal
GRADE 1	Semisolid,unformed
GRADE 2	Semiliquid
GRADE 3	Watery

4) Amavastha

GRADE 0	Nirama
GRADE 1	Sama

5)Pureesha gandha

GRADE 0	Prakrita purisha gandha
GRADE 1	Visra gandha
GRADE 2	Kunapa gandha

6)Varna

GRADE 0	Light brown
GRADE 1	Whitish yellow
GRADE 2	Yellowish green
GRADE 3	Greyish

7) Quantity of water intake (Trushna)

GRADE 0	Normal
GRADE 1	Mildly increase
GRADE 2	Moderately increased
GRADE 3	Too thirsty

8) Mutrapravathi

GRADE 0	4-7 times/24hr
GRADE 1	2-3times/24hr
GRADE 2	Less than 2 times/24hr

3. Discussion

Atisara (diarrhea) is the most commonly encountered disease in clinical practice. Diarrhoea is the third leading cause of childhood mortality in India, and is responsible for 13 % of all deaths/year in children under 5year of age. Many types of diarrhoea have been discussed by various *acharyas* among which *vataj*, *pittaj*, *kaphaj atisar* are common. In *atisara chikitsa* following should be considered:-

If avastha is *ama* or *pakwa*.

A) *Amatisara-1*).Alpa dosha- langhana,deepana

2) *Madhyama dosha-pachana*

3) *Bahudosha-pravartan*

B) *Pakwaatisar-1*).Pravahika-isabgole

2) *Varchakshay-dhanya yush,tandula,mamsarasa,bilwa*

3) *Gudabhramsha-snehan,swedan*, at its place.

The *Bilwa Amra kwath* mentioned in *atisaradhikara in Vangasena Samhita* administered in syrup form is *agnideepana*, *amapachana* and is also *purishasangrahaneeya*, so this digests *Ama* results in *srotoshodhan,vikrutvata* gets its *prakrutgati* and causes *upashaya* in *atisara*.

In this study the *apakwa bilwa majja* part is used , as the pulp of unripe bilwa fruit is astringent,digestive and stomachic and useful in *atisara*. The unripe fruit of bilwa having *Kashaya,tikta rasa and laghu,ruksha in guna* it is *deepana pachana,sangrahitik*.

Bilwa being a *sangrahi drug* which stimulates *agni* and digests *ama* and by virtue of its *ushnaguna* it causes *dravasoshana* and thereby reduces the *atipravrutti lakshan* in *atisar*.It reduces *agnimandya due to tikta katurasa,ushna virya* and *laghu guna* causes *amapachan*.Bilwa considered to be the best *sangrahitik* and *deepaniya* drug being *vatakaphahara*.

The unripe fruit of aegel marmelos containing aegeline, xanthotoxol, tannin shows antidiarrheal property by inhibiting intestinal motility and secretion. Its doesnot permit the pathogens to establish themselves, since the adherence of pathogen to the gut epithelium is the foremost stage of disease process, inhibition of adherence could be a very important aspect in the antidiarrheal aspect.

The *apkwa amra* having *rochana, deepana, snehana and saraka* in functions, *Amra patra* is good for *chardinigrhana*. The *phala* is *madura rasa* diuretic & laxative. In this study the *pakwa amrabeeja* is used as the *amra beej* having *Kashaya, madura rasas & stambhana* in action. The mango seed kernel also acts good in diarrhea, as it is *Kashaya rasa,having guna like ruksha,laghu causes agnideepan, amapachana , ruksha guna* helps in *mala drava shoshan* and thus causes *mala stambhana*.

Apakwa amra being a *stambhana* drug which aggravates *vata* by virtue of its *ruksha, shita, Kashaya rasa* and *laghupaaka* properties stops the expulsion of *malas*.

The seed kernel of mangifera indica containing chemical constituent mangiferin, which is a polyphenolic antioxidant

and a glucosyl xanthone. It has strong antioxidant, anti lipid production, immunomodulation, cardiotoxic and also show growth inhibition of these 5 pathogenic organisms E coli, S typhi, vibrio cholera, S sonnei.

In short it can be said that both the drugs are anti infective in the gut preventing growth and colonization of pathogenic organisms thus preventing the infective diarrhoea. These drugs also inhibit intestinal motility and increases the fluid absorption from gut thus it prevents the secretory diarrhoea.

The assessment of *atisara* is done by using eight parameters i.e. Frequency of diarrhea in 24 hrs (*Atisarvega*), Loss of appetite (*Annadvesh*), *Swaroop*, *Amavastha*. *Pureeshagandha*. *Varna*, Quantity of water intake (*Trushna*), *Mutrpravathi*. Total 45 patients were studied for this short term project Patients were screened and registered from OPD of Bharati Ayurveda Hospital and Research center.

The whole demographical and experimental data was then analyzed using Paired t test. After application of these test and with the help of tabulated data interferences were tried to be drawn based on the analysis obtained. The data was collected and on presumed performa.

Effect of Bilwa Amra Yoga on Dravamalavega

The patients were followed up for total of 7 days and the days of follow up were day 0 (day of registration) day 3, day 5, day and 7. On the day of registration it was found that 60% children having grade 2 dravamalavega i.e 5-8 vegas in 24 hr reduced to grade 0 i.e normal bowel movement on 5th day of follow up.

In this study grade 1 *daravamalavega* present in 14 patients before treatment which is reduced to 2 patients after treatment. Grade 2 *dravamalavega* present in 27 patients before treatment reduce to grade 0 after treatment. *dravamalavega* reduced to grade 0 found on 21 patients on the 3rd day, 38 patients on the 5th day, 43 patients, i.e 95.56% improvement on the 7th day.

The mean grade of *DRAVAMALAVEGA* on 0th day was 1.777 which were decreased to 0.62 at 3rd day. The mean increment in score was 65% which is significant as observed by paired t test (as p value < 0.05) thus it can be said that there is significant increment on *DravaMalavega* in *Atisara*.

Early improvement in frequency of diarrhoea is found on 3rd day of followup. Complete relief from loose motion found on 5th - 7th day.

Kashaya rasa, *ushna guna of bilwa* & *Kashaya rasa and ruksha guna of amrabeja* both act as *stambhaka* (i.e. drugs which increase vata by their *ruksha, shita, Kashaya, and laghupaaka* properties). and thereby reduces the *atipravrutti lakshan in atisar*.

Effect Bilwa Amra Yog on Swaroopa of Stool

It is shown that out of 45 patients on 1st day of registration there is 16 number of patients registered with grade 2 i.e semisolid form of stool, and 13 patients with grade 3 i.e watery stools, on 3rd day of followup grade 2 and grade 3

shows mild improvement on Swaroopa of stool. There is significant improvement found in consistency of stool day i.e normal bulky stool on 7th day of followup.

The mean grade of *SWAROOP* on 0th day was 1.933 which was decreased to 0.95 at 3rd day. The mean increment in score was 50.57% which is significant as observed by paired t test (as p value < 0.05) thus it can be said that there is significant increment on *SWAROOP* in *Atisara*.

There is 89.66 % & significant result in improving *Swaroop* of stool. The drug *bilwa* having *ushna guna*, & *tikta Kashaya rasa* & *amra* also having, *tikta rasa*, here *bilwa* act as *sangrahik* i.e drugs which possess *deepana, pachana* properties and also dry up the moisture of the wastes of the body) causes *shoshan* of *aapdhatu* which is *drava, sara, ardra, kled, sheet & guru*.

Effect of Bilwa Amra Yoga On Amavastha of Stool

In this study out of 45 patients there are only 16 number of patients with grade 1 i.e *samaj* registered on 1st day of registration. By 5th day of follow up there are 15 number of patients with grade 0 i.e *niramaj*. On 7th day of follow up there is 100% improvement. The mean grade of *AAMAVASTHA* on 0th day was 0.355 which was decreased to 0.022 at 5th day. The mean increment in score was 93.75% which is significant as observed by paired t test (as p value < 0.05) thus it can be said that there is significant increment on *AAMAVASTHA* in *Atisara*. The study shows 100% improvement in curing the *amavastha* of stool. Due to *jataragnimandya* in *amashaya* leads to formation of *Ama*. Here both *bilwa* and *amra* possessing, *tiktara* and *laghu, rukshagunaushnaveerya* helps in *amapachana* and *agnideepana* so it helps in removing the *amabvastha*.

Effect of Bilwa Amra Yog on Gandha of Stool

On 1st day of registration grade 2 i.e. *kunapaganda* of stool seen in 12 patients which reduced to *prakrut-ganda* stool i.e become grade 0 on 4th day. In this study there is 91.11% significant result in reducing *gandha* of stool. Due to *ama*, food components remain undigested and unabsorbed they accumulate in *pakwashaya* leads to *durganda* of stool. The mean grade of *GANDHA* on 0th day was 0.8 which was decreased to 0.422 at 3rd day. The mean increment in score was 47.22% which is significant as observed by paired t test (as p value < 0.05) thus it can be said that there is significant increment on *GANDHA* in *Atisara*.

Due to the *tikta, ruksha laghu guna* of *bilwa* and *amra* which helps in *agnideepna* and *amapachana* the foul smelling *purisha* get cured by improving *jatharagni* and removing *ama*.

Effect of Bilwa Amra Yog on Varna of Stool

On 1st day of registration 19 patients out of 45 registered with grade 2 *varna* of stool i.e yellowish white, which got reduced to grade 0 i.e. light brown coloured stool On 7th day of follow up. The mean grade of *VARNA* on 0th day was 1.911 which was decreased to 0.8889 at 3rd day. The mean increment in score was 53.49% which is significant as observed by paired t test (as p value < 0.05) thus it can be said that there is significant increment on *VARNA* in *Atisara*. There is 93.02% significant results in improving *varna* of stool. *Pittadosha* is responsible for production of colour, so

pitta vitiation leads to abnormal colour of stool. *Amra* having *madura Kashaya*, *tikta rasa sheeta virya* reduces *vikruta pitta*, *drug bilwa majja* also having *tikta Kashaya rasa* which alleviate *pitta* vitiation Both drugs are *agnideepana* in action, so by *pitta shamaka karma* stool gets *prakrutapurisha varna*.

Effect of Bilwa Amra Yog on Mutrapravarthi

The mean grade of MUTRA PRAVARTHI on 0th day was 0.733 which was decreased to 0.266 at 3rd day. The mean increment in score was 63.64% which is significant as observed by paired t test (as p value<0.05) thus it can be said that there is significant increment on MUTRA PRAVARTHI in *Atisara*. Also here 78.79% improvement found at 5th day of treatment which is increased to 90.91% at 7th day on MUTRA PRAVARTHI in *Atisara*. i.e. result is satisfactory as there is good urine output. The *amla rasa* and *sheeta virya* of *amrabeeja* which increases the volume intake & also *vatanashakaction* of *bilwamajja* corrects the *vatagati* and improves *mutrapravarthi*. *Amapachana* helps in reduction of excess fluid loss through *purisha* and *jataragnivardana*, because of these there is good intake of fluids & the hydration will be maintained.

Effect of Bilwa Amra Yog on Appetite

The mean grade of LOSS OF APPETITE on 0th day was 1.2 which was decreased to 0.55 at 3rd day. The mean increment in score was 53.7% which is significant as observed by paired t test (as p value<0.05) thus it can be said that there is significant increment on LOSS OF APPETITE in *Atisara*. Also here 81.48% improvement found at 5th day of treatment which is increased to 87.04% at 7th day on LOSS OF APPETITE in *Atisara*. i.e. *Bilwaamrayoga* was effective on improving appetite. In this study there is 87.04% significant results on improving appetite. Due to *tikta rasa ushna veerya* of *bilwa* & *tikta-amlarasa* of *amrabeeja*, increases the *deepana*, *pachana* properties which leads to *jataragni vardhana* which leads to improvement in appetite

4. Conclusion

- 1) *Atisara* is one of most common diseases in children predominantly in *ksheeraannadaavastha*. This disease is a result of *agnimandya*. It is an acute disease with severe complication that require immediate attention & action for control. *Atisara* which is recently developed and that is devoid of any *upadrava* is *sadhya*
- 2) The *chikitsa* of *atisara* differs from its *ama* or *pakwaavastha*. The common treatment includes the use of either *sangrahamaushadis* or *stambhanaaushadis* along with *agnideepana*. In general, 4 different types of pathogenesis exist for diarrheal diseases. Dehydration is the commonest & the most dreadful complication of diarrhoea. Maintaining hydration & preventing dehydration is the primary aim of the treatment of diarrhoea
- 3) *Bilwa phala majja* exerts different types of action depending upon its state, ripe or unripe. The unripe fruit is digestive, stomachic & useful in treatment of diarrhoea as it exerts a *sangrahi* property whereas the ripe fruit is a mild laxative. The seed kernels of mango are anti diarrhoeal and antihelminthic

- 4) Sugar based syrup can be considered as an *upakalpana* of *kwath* and can be substituted to *kwath* for oral administration. Sugar based syrups are palatable and more easily accepted by children as a part of medicine.
- 5) Incidence of *atisara* in children is independent of sex. Age or sex has no influence on the type of *atisara* acquiring in children.
- 6) Rotavirus vaccination is said to prevent diarrhoeal disorders in children, but no such inference could be drawn in this study. This could be further studied by the stool sampling specifically of rotavirus. This incidence of all 3 single *doshajatisara* was nearly similar in all rotavirus vaccinated children. This infers that *atisara* in Ayurveda is not of specific infective agents.
- 7) The combination of *bilwa phalamajja* & *amrabeeja majja* is effective in reducing the *dravamalavga* in *atisara* in 3 days
- 8) The consistency of stool improves gradually & steadily over a period of 7 days with the use of trial drug. The trial drug is *amapachak* & this is inferred from the finding that there was no *samapurish* after 7 day of treatment. The trial drug is more than 90% of which attained *pakwastha* by the 5th day.
- 9) The foul smell reduced gradually with decrease in *ama* by the 5th day & thus can be stated that *ama* is responsible for the foul smell of *purisha*. The trial drug can be inferred to be *amapachan* on the finding that there was gradual improvement in the appetite of the children on the 5th and 7th day.
- 10) *Bilwamajja* & *amramajja* being *kashay* in *rasa&katu* in *vipak* have shown maximum effect on *pittajatisara* & *kaphajaatisara*. By virtue of its *rasa* & *vipaka* the trial drug reduces the *amavastha* leading to reduction in the *durganda* of the stool & increment in appetite.
- 11) The trial drug also reduces the frequency of liquid stools and improves the consistency thus reducing the chance of *upadrava* that might arrive due to *atisar*. The trial drug is safe and no untoward events were reported during the complete study period. The drug does not lose its potency atleast for 1 year as has been tested after the completion of the clinical trial. Thus it can be inferred that shelf life of the trial drug is of atleast 1 year as it does not undergo any physical disintegration or biological contamination.
- 12) Longitudinal studies on a larger sample are required to validate and re-confirm the results.

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