

A Clinical Study of Nagaradi Yoga in Childhood Atisara (Diarrhea)

Ajeet Singh Yadav¹, P.S. Upadhyay²

¹Junior Resident, Dept. of Kaumarbhritya / Balrog, FOAy, IMS, BHU, Varanasi

²Asst. Professor, Dept. of Kaumarbhritya / Balrog, FOAy, IMS, BHU, Varanasi

Corresponding Author: P.S. Upadhyay

ABSTRACT

Aim of study: The aim of study was to evaluate effect of “Nagaradi Yoga” by a random clinical trial in the children suffering from Atisara (Diarrhea). Nagaradi Yoga is a herbal formulation which contains *Nagar (Zingiber officinale)*, *Ativisha (Aconitum heterophyllum)*, *Mustaka (Cyperus rotundus)*, *Indrayava (Holarrhena antidysenterica)* and *Balaka (Pavonia odorata)*. This yoga is indicated in childhood Atisara (diarrhea) by Vrindmadhav, Chakradatta and Bhaishhya Ratnavali under Balarogadhikar. These drugs have been described to have anti-diarrheal properties and antimicrobial properties in scholarly article as well in text.

Material & methods: - For clinical study, a total number of 20 cases including male and female child were registered. Test drug was given in dose 8-10 mg/kg/dose thrice in a day. Test drug was prepared in syrup form in concentration of 400 mg/5ml. All the treated cases were assessed at each follow up, Ist follow up on 1st day (after 8 hrs of treatment), IInd follow up on 3rd day, IIIrd follow up on 7th day and IVth follow up on 14th day. Efficacy of drugs was assessed clinically on the basis of score provided as per the scoring table and also on the basis of investigations.

Observation & Result: - Signs and symptoms of Atisara (diarrhea) persist maximum up to 3rd follow up, and on 3rd follow up significant improvement in clinical signs and symptoms were observed.

Conclusion: - Research drug showing positive result and improving different sign & symptom of atisara. This drug decreases frequency of stool, improving consistency of stool, decrease mucus and foul smell of stool. It also decreases abdominal distention, abdominal pain, vomiting, fever and perianal rashes.

Keywords: Atisara, Abdominal pain, Diarrhea, Nagaradi Yoga and Vomiting etc.

INTRODUCTION

Diarrhea is a most common disease in children. It is preventable as well as treatable disease. A significant proportion of diarrheal disease can be prevented by safe drinking-water, adequate sanitation and proper hygiene. Diarrheal disease is the one of the most important cause of malnutrition in under five years old children. [1] Infectious types of diarrhea are considered as second most common cause of morbidity and mortality worldwide. [2] Diarrhea still continues to be a major cause of

hospitalization and death in under five years old children and has severe economic consequences. [3] Overall prevalence being significantly higher in children below 2 years as compared to those 2-5 years. [4] Diarrhea also plays a major contributory factor in childhood malnutrition. The two most important consequences of diarrhea in children are malnutrition and dehydration. Malnutrition and diarrhea form vicious cycle, since malnutrition increases the risk and severity of diarrhea. [5]

Diarrhea is the result of infection acquired through the fecal-oral route or by ingestion of contaminated food or water. Diarrhea is associated with poverty, poor environmental hygiene and sanitation. Most common Enteropathogens that causes diarrhea 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*.^[6]

This study was planned for assessment of clinical efficacy of Nagaradi Yoga, which contains Nagar (*Zingiber officinale*), Ativisha (*Aconitum heterophyllum*), Mustaka (*Cyperus rotundus*), Indrayava (*Holarrhena antidysenterica*) and Balaka (*Pavonia odorata*). Nagaradi Yoga is indicated in childhood Atisara (diarrhea) by Vrindmadhav,^[7] Chakradatta^[8] and Bhaishjya Ratnavali^[9] under Balarogadhikar. Nagaradi Yoga used in the form of syrup base to improve the palatability for children.

MATERIALS AND METHODS

The clinical interventional trials are of paramount importance in the field of medical sciences, as the data generated by appropriate clinical trial is the most reliable evidence for further use of the formulation in human population. In this clinical study, total numbers of 20 patients were registered from Kaumarbhritya /Balroga O.P.D / I.P.D, S.S. Hospital, Ayurveda wing, I.M.S, B.H.U, after proper screening on the predesigned Performa. These cases were

selected on the basis of following exclusion and inclusion criteria.

Inclusion criteria:

- Age between 6 month to 14 years
- Both male and female children
- Case of acute and persistent diarrhea (mild to moderate)
- Occasionally vomiting
- Diarrhea with no dehydration / mild dehydration
- Associated with or without blood
- Associated with or without mucus / foul smell
- With or without abdominal distension
- With mild pain in abdomen or without pain

Criteria for exclusion:-

- Children age below 6 months and above 14 years
- Not accepting orally
- Persistent vomiting
- Severe dehydration
- Associated with Cholera, Shock, Septicemia, Meningitis

The investigations used during the study are Hematological routine investigation (Hb, TLC, DLC, ESR), Serum Electrolyte, Serum Urea, Serum Creatinine and Stool (R/M) & (C/S), Ova/ Cyst, Fungal hyphae and Reducing substance.

Materials and methods

Plant Materials

The dried rhizomes of Nagar (*Zingiber officinale*), Ativisha (*Aconitum heterophyllum*), Mustaka (*Cyperus rotundus*), dried seed of Indrayava (*Holarrhena antidysenterica*) and dried whole plants (*panchanga*) of Balaka (*Pavonia odorata*) were collected from Haridwar, Uttarakhand. The plant was identified and authenticated by the Professor N. K. Dubey, Department of Botany, Banaras Hindu University, Varanasi, with the voucher specimen number as-

***Zingiber officinale* Roscoe** (Voucher specimen no. Zingiber, 2018/2)

Aconitum heterophyllum Wall. ex Royel (Voucher specimen no. Ranunculus, 2018/1)

Cyperus rotundus L.- (Voucher specimen no. Cypera, 2018/1)

Holarrhena antidysenterica (Roth) Wall. ex A.DC. (Voucher sp. Apocyna. no. 2018/1)

Pavonia odorata Willd. (Voucher specimen no. Malva. 2018/1)

Drug dose: Syrup Nagaradi Yoga given in 8-10 mg/kg/dose thrice in a day for 14 days. Every effort was made to get information from the patient's mother/nearest attendant at each follow up.

Scoring Criteria of Stool:

| Stool characteristics | Score | | |
|-----------------------|--------------------|------------------------------|-------------------------------|
| | 1 | 2 | 3 |
| Frequency | 1-3/day | 4-9/day | ≥10/day |
| Consistency | Soft, Formed | Semi loose | Watery |
| Color | Normal (Yellowish) | Abnormal (greenish/Blackish) | Abnormal (Red or black stool) |
| Foul smell | Normal stool smell | Mild offensive | Highly offensive |
| Mucous | Absent | Occasionally present | Frequently present |
| Blood | Absent | Streaks present | Mixed in stool |

Scoring Criteria of Signs and Symptoms:

| Signs and Symptoms | Score | | |
|-----------------------|---------|------------------|-----------------------|
| | 0 | 1 | 2 |
| Appetite | Reduced | Normal | - |
| Perianal rashes | Absent | Present | - |
| Distention of Abdomen | Absent | Mild | Moderate |
| Pain in Abdomen | Absent | Mild | Moderate |
| Vomiting | Absent | 1-3/day | >3/day |
| Fever | Absent | Mild (99-101 °F) | Moderate (101-103 °F) |

Table No. 1: Distribution of cases as per sex

| Sex | F | M |
|--------------------------|----------|-----------|
| No. & % of Cases (n= 20) | 11 (55%) | 9 (45.0%) |

Table no. 1 shows that out of 20 cases the percentage of children suffering from *Atisara*, the female children were 55% and male are 45%.

Table No. 2: Age wise distribution of case in diarrhea

| Age | 6 month to 2 yrs | >2yrs to 5 yrs | > 5 yrs to 10 yrs | >10 yrs to 14 yrs |
|-------------------------|------------------|----------------|-------------------|-------------------|
| No. & % of Cases (n=20) | 10 (50.0%) | 6 (30.0%) | 4 (20.0%) | 0 (0.0%) |

Table no. 2 shows that out of 20 cases, maximum number children suffering from *Atisara* were belongs to age from 6 month to 2 year.

Table No. 3: Distribution of cases as per the Socio Economic Status (SES):

| SES | Low | Middle | High |
|-------------------------|-----------|-----------|-----------|
| No. & % of Cases (n=20) | 9 (45.0%) | 8 (40.0%) | 3 (15.0%) |

Table no. 3 shows that the maximum number children suffering from *Atisara*

were belongs from low and middle Socio-Economic Status.

Table No. 4: Incidence of diarrhea as per season:

| Season | Winter | Summer | Rainy |
|-------------------------|---------|------------|-----------|
| No. & % of Cases (n=20) | 2 (10%) | 10 (50.0%) | 8 (40.0%) |

Table no. 4 shows seasonal variation of diarrheal cases. Maximum cases are found in summer season (50.0%).

Table No. 5: Distribution of cases as per duration of diarrhea:

| Duration of diarrhea | Acute diarrhea (less than 7 days) | Sub-acute diarrhea (7-14 days) | Chronic diarrhea (more than 14 days) |
|-------------------------|-----------------------------------|--------------------------------|--------------------------------------|
| No. & % of Cases (n=20) | 16 (80.0%) | 3 (15.0%) | 1 (5.0%) |

Table no. 5 shows maximum number of cases of diarrhea have acute onset (less than 7 days).

Table No. 6: Distribution of cases as per the Prakriti:

| Prakriti | V | P | K | PK | VK | PV | VPK |
|-------------------------|--------|---------|--------|---------|---------|---------|----------|
| No. & % of Cases (n=20) | 1 (5%) | 2 (10%) | 0 (0%) | 5 (25%) | 3 (15%) | 3 (15%) | 1 (5.0%) |

Table no. 6 shows that the percentage of diarrheal cases in different types of prakriti. Maximum number of cases were belongs to PV and PK prakriti.

Table No. 7: Intra-group correlation of stool frequency

| Group | Frequency of stool (Score) | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Friedman test) |
|--------|----------------------------|-----------|------------|------------|------------|-------------|---|
| (n=20) | 3 | 0 | 0 | 0 | 0 | 0 | $\chi^2=67.86$ p=0.000 |
| | 2 | 20 | 20 | 13 | 0 | 0 | |
| | 1 | 0 | 0 | 7 | 20 | 20 | |

Stool frequency: 1=1-3 times/day, 2= 4-9 times /day, 3=>10 times/day

Table No. 7 shows that, in within group comparison (Friedman test), frequency of stool on subsequent follow up is reduced and this difference was statistically significant (p<0.01).

Table No. 8: Intra-group correlation of stool consistency:

| Group | Consistency of stool (Score) | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Friedman test) |
|--------|------------------------------|-----------|------------|------------|------------|-------------|---|
| (n=20) | 3 | 4 | 0 | 0 | 0 | 0 | $\chi^2=76.65$ p=0.000 |
| | 2 | 16 | 20 | 1 | 0 | 0 | |
| | 1 | 0 | 0 | 19 | 20 | 20 | |

Consistency of stool: 1= Formed and soft, 2=Loose stool, 3= Watery stool

Table no. 8 shows that the within-group comparison (Friedman test), improvement in Consistency of stool from watery or loose to formed and soft stool was found statistically significant (p<0.01) from registration to final follow-up.

Table No. 9: Intra-group correlation of Color of stool

| Group | Color of stool (Score) | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Friedman test) |
|--------|------------------------|-----------|------------|------------|------------|-------------|---|
| (n=20) | 3 | 0 | 0 | 0 | 0 | 0 | $\chi^2=20.000$ p=0.000 |
| | 2 | 5 | 5 | 0 | 0 | 0 | |
| | 1 | 15 | 15 | 20 | 20 | 20 | |

Color of stool- 1= Normal (yellowish), 2= Greenish/Blackish, 3=Red/black/White

Table No. 9 shows that, the change in stool color from abnormal to normal from registration to successive follow ups. Within-group comparison (Friedman test) of stool color was statistically significant (p<0.01).

Table No. 10: Intra-group correlation of Foul smell of stool

| Group (n=20) | Foul smell of stool (Score) | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Friedman test) |
|--------------|-----------------------------|-----------|------------|------------|------------|-------------|---|
| | 3 | 15 | 2 | 0 | 0 | 0 | $\chi^2=62.886$ p=0.000 |
| | 2 | 2 | 15 | 5 | 0 | 0 | |
| | 1 | 3 | 3 | 15 | 20 | 20 | |

Foul smell of stool- 1= Normal, 2= Offensive, 3= Highly offensive

Table no. 10 shows that in within-group comparison (Friedman test), significant reduction in foul smell from highly offensive or offensive smell to normal was observed from registration to successive follow ups which was statistically significant (p<0.01).

Table No. 11: Intra-group correlation of Mucus in Stool

| Groups (n=20) | Mucus in stool (Score) | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (friedman test) |
|---------------|------------------------|-----------|------------|------------|------------|-------------|---|
| | 3 | 17 | 10 | 0 | 0 | 0 | $\chi^2=70.121$ P=0.000 |
| | 2 | 2 | 9 | 14 | 1 | 0 | |
| | 1 | 1 | 1 | 6 | 19 | 20 | |

Mucus in stool: 1 = Absent, 2 = Occasionally present, 3 = Frequently present

Table no. 11 shows that, in within-group comparison (friedman test), significant reduction in mucus from frequently or occasionally mucus to absent mucus was observed from registration to successive follow ups which was statistically significant ($p < 0.01$).

Table No. 12: Intra-group correlation of Pain in abdomen

| Group | Pain in Abdomen | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Cochran's Q) |
|--------|-----------------|-----------|------------|------------|------------|-------------|---------------------------------------|
| (n=20) | Present | 7 | 3 | 0 | 0 | 0 | Q=22.353 p=0.000 |
| | Absent | 13 | 17 | 20 | 20 | 20 | |

Table No. 12 shows that the change in pain of abdomen from present to absent was observed from registration to successive follow ups. Within-group comparison (Cochran's Q test) shows statically significant ($p < 0.01$).

Table No. 13: Intra-group comparison of distension of abdomen:

| Group | Distension of abdomen | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Cochran's Q) |
|--------|-----------------------|-----------|------------|------------|------------|-------------|---------------------------------------|
| (n=20) | Present | 13 | 11 | 0 | 0 | 0 | Q=47.243 p=0.000 |
| | Absent | 7 | 9 | 20 | 20 | 20 | |

Table no. 13 shows that the change in distension of abdomen from present to absent was observed from registration to successive follow ups. Within-group comparison (Cochran's Q test) show statically significant ($p < 0.01$).

Table no. 14: Intra-group correlation of Appetite

| Group | Appetite | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Cochran's Q) |
|--------|----------|-----------|------------|------------|------------|-------------|---------------------------------------|
| (n=20) | Reduced | 20 | 20 | 20 | 6 | 0 | Q=67.556 p=0.000 |
| | Normal | 0 | 0 | 0 | 14 | 20 | |

Table no. 14 shows that the improvement in appetite from reduced to normal was observed in all groups from registration to successive follow ups. Within-group comparison (Cochran's Q test) of appetite shows statically significant ($p < 0.01$).

Table No. 15: Intra-group correlation of Perianal Rashes

| Groups | Perianal Rashes | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Cochran's Q) |
|--------|-----------------|-----------|------------|------------|------------|-------------|---------------------------------------|
| (n=20) | Present | 11 | 10 | 10 | 1 | 0 | Q=37.806 p=0.000 |
| | Absent | 9 | 10 | 10 | 19 | 20 | |

Table no. 15 shows that the improvement in perianal rashes from present to absent was observed from registration to successive follow ups. Within-group comparison (Cochran's Q test) of perianal rashes was statically significant ($p < 0.01$).

Table No. 16: Intra-group correlation of Vomiting:

| Group | Vomiting | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Cochran's Q) |
|--------|----------|-----------|------------|------------|------------|-------------|---------------------------------------|
| (n=20) | 1 | 12 | 6 | 0 | 0 | 0 | Q=38.400 p=0.000 |
| | 0 | 8 | 14 | 20 | 20 | 20 | |

Vomiting: 0 = Absent, 1=Less than three times /day

Table no. 16 shows that the improvement in frequency of vomiting from present to absent was observed from registration to successive follow ups. Within-group comparison (Cochran's Q test) of vomiting was statically significant ($p < 0.01$).

Table No. 17: Intra-group correlation of fever:

| Groups | Fever | Day-0 (R) | Day-1 (F1) | Day-3 (F2) | Day-7 (F3) | Day-14 (F4) | Within group comparison (Cochran's Q) |
|--------|--------|-----------|------------|------------|------------|-------------|---------------------------------------|
| (n=20) | Mild | 4 | 3 | 0 | 0 | 0 | Q =13.818 p=0.008 |
| | Absent | 16 | 17 | 20 | 20 | 20 | |

Table no. 17 shows, that the significant changes in fever from present to absent was observed from registration to successive follow ups. Within-group comparison (Cochran's Q test) of fever show statically significant ($p < 0.01$).

RESULT AND DISCUSSION

Efficacy of drugs was assessed clinically on the basis of score provided as per the scoring table and also on the basis of investigations. In this study the incidence of Atisara is found more in females as compared to male. Maximum cases belong to age between 6 months to 1 years. Signs and symptoms of Atisara persist maximum up to 3rd follow up. Almost all the clinical features were subsided on 4th follow up.

CONCLUSION

This research drug showing positive result and improving different sign & symptom of Atisara. This drug decreases frequency of stool, improving consistency of stool, decrease mucus and foul smell of stool. It also decreases mild to moderate abdominal distention, abdominal pain, vomiting, fever and perianal rashes. On the basis of result of clinical trial, research drug found effective in management of childhood atisara (diarrhea).

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