



A RANDOMIZED CONTROLLED CLINICAL TRIAL TO EVALUATE THE EFFECT OF ABHAYARISHTA AND POLYETHYLENE GLYCOL IN VIBANDHA (CONSTIPATION)

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ABSTRACT

Introduction: Vibandha (Constipation) is not a disease. However, it is a common symptom of *Purishavaha Srotas*, presented as *Mala-kricchata*, *Baddhakoshtata* in children. Causes are improper diet, toilet training, faulty lifestyle, etc. considering all the habitual changes in today's generation, there is a need to study these symptoms. **Aim:** Present study is aimed at evaluating the efficacy of *Abhayarishta* and polyethylene glycol in Vibandha (constipation) in school-going children. **Objective:** To assess the efficacy of the trial and control drug on various subjective parameters and objective criteria as Bristol scale. **Material and Method:** Present study is designed as a randomized controlled clinical study, 30 people will be divided into two groups. *Abhayarishta* will be administered to group A (trial drug) and in group B (standard drug) Polyethylene glycol will be administered, twice a day with warm water post meal. Assessment will be recorded on the

3rd, 7th, and 14th day. **Observation & Result:** Changes will be observed in subjective parameters-Udarshoola (abdominal pain), Kshudhamandya (lack of appetite), Frequency of defecation, Flatulence, and Bristol's Scale. **Conclusion:** After the experiment is completed, outcome of the study will be derived with the help of qualitative and quantitative statistical tests.

KEYWORDS: *Vibandha, constipation, Mala-kricchata, Baddhakoshtata, Purishavaha Srotas, Children, Abhayarishhta.*

INTRODUCTION

Constipation is a symptom, not a disease. But nowadays children exhibit this symptom quite frequently. *Vibandha* is the Ayurvedic term for *Apravrutti*, according to *Shabdakosh*.^[1] The common causes are changes in food habits (Increased consumption of fast food), inadequate toilet training, altering sleep patterns, and also as a result of the working mother's disturbed routine.^[2] By considering all habitual changes in today's generation, there is a need to study this symptom although it is not a disease. Functional constipation is a common problem in childhood, with an estimated prevalence of 3% worldwide. *Annavaha* and *purishvahastrotas* are mainly involved in *Vibandha*. In patients of *Malavstambha*, there is a disturbance of *Purish*, *Purishkriya* including *Dosh* and *Agni*. Amongst several functions of *Apanvayu*, excretion of feces and micturition are important functions. If *Apana Vayu* is disturbed by any cause, it will interrupt the normal function of excretion which will give rise to the symptom called *Malavibandha*.^[3] *Acharya* described *Vibandha* as a *Lakshana* in certain *Vyadhi* like *Anaha*, *Arsha*,^[4] *AamaJwara*, *Udar Roga*,^[5] *Gulma*,^[6] and in many other conditions. *Vibandha* can be co-related with constipation according to its clinical manifestation. Constipation starts in the 1st year of life in 17 to 40% of cases.^[7] Beyond the neonatal period, the commonest cause of constipation is functional and it is called idiopathic constipation, functional fecal retention, and fecal withholding.^[8] Different treatment modalities are available but the most commonly used are laxatives. But the use of laxatives is associated with side effects such as bloating, abdominal cramps or pain, nausea, vomiting, etc. Theoretically, there are multiple causes for constipation but out the commonest is an improper diet of the child. It includes excessive daily intake of milk, eating junk foods, and filling the tummy with wafers, chips, biscuits, etc. inadequate fiber and low residue leads to loss of appetite, hence decreased intake of food and frequent intake of laxatives can cause further constipation.

If constipation is not treated early, it may lead to chronic abdominal pain, fecal incontinence & complications like enuresis, fecal soiling, anxiety, etc. It is because of the high prevalence rate, the financial load, and the negative consequences on quality of life. Makes constipation a major public health issue. Therefore, there is a need to find out a drug that is safer, palatable for children & more effective in treating constipation. So, an effort is made to see the effect

of *Abhayarishta* in treating constipation of children by vibhandaghna property as mentioned in *Bhaishajyaratnavali*. Osmotic laxatives are made out of polyethylene glycol. It works by retaining water in the stool, softening it, and promoting bowel movement.

AIM

The present study is aimed at evaluating the efficacy of *Abhayarishta* and polyethylene glycol in Vibandha (Constipation) in School going children.

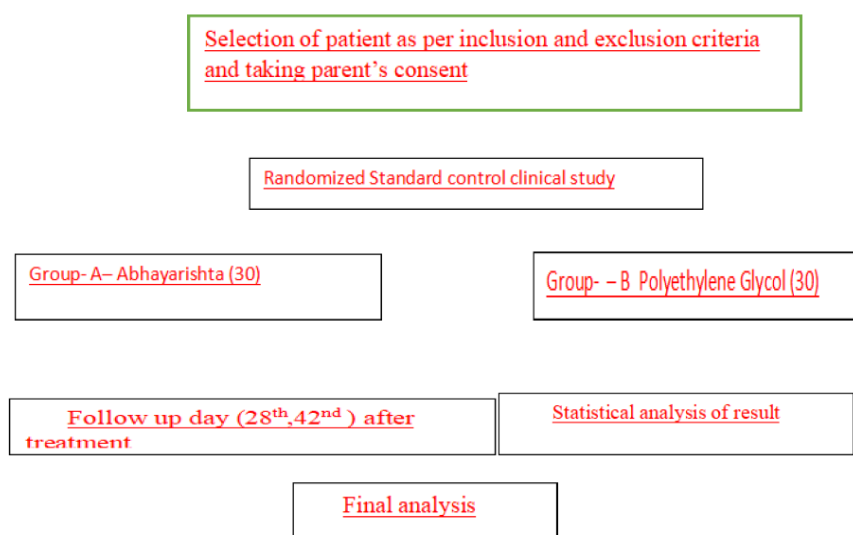
OBJECTIVES

1. To study the role of *Abhayarishta* in children with Vibandha.
2. To study polyethylene glycol in childhood constipation.
3. To compare the efficacy of *Abhayarishta* & Polyethylene glycol in Vibandha

MATERIAL AND METHOD

The present study is designed as a randomized controlled clinical study, 30 people will be divided into two groups. *Abhayarishta* will be administered to group A (trial drug) and in group B (standard drug) Polyethylene glycol will be administer, twice a day with warm water after a meal. Assessment will be recorded on 7th, 14th day during treatment and 21st, 42nd day after treatment.

Study design



Study setting: The participants will be chosen after receiving informed consent from the informer from Kaumarbhritya Department's OPD and IPD. Mahatma Gandhi Ayurved

College, Hospital, and Research Centre, Salod(H) and Specialty Camp, and Nearby Schools of Salod, Sawangi Wardha, AVBRH Hospital, Sawangi, Wardha.

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Eligibility criteria:

1. A patient having Vibandha (delay or difficulty in defecation present for two weeks or longer)
2. Children in the age group of 5-10 years, irrespective of gender.
3. Written consent of parents.

Exclusion criteria:

1. Patients suffering from any known acute or chronic medical & surgical illnesses or congenital anomaly that might interfere with the study.
2. Worm infestation, acute infections, malignancies, thyroid problems, etc.
3. Known case of Irritable Bowel syndrome, Crohn's disease.

Schedule of intervention: Diagnosed patients of Vibandha (constipation) as per inclusion criteria, participants will be recruited in the current study.

The follow-up period after treatment:

Follow-up will be taken on the 28th and 42nd day after treatment

Sample size: Total 60 patients (30 in each group A and group B)

Outcomes:

Improvement in Stool consistency along with reduced, Udarshoola (Abdominal Pain, Mal-kricchata (difficulty in defecation), flatulence, lack of appetite, and stony hard stool.

Statistical analysis: The parametric and non-parametric tests will be used for qualitative and quantitative data.

Follow-up period: 7th, 14th-day assessment during treatment and 28th & 42nd day after treatment.

Intervention:**Table 1.1**

Group	Intervention	Dose & frequency	Anupam	Followup duration & time	Followup after treatment
Group (A)	<i>Abhayarishta</i>	As per Young's rule 5 to 10 ml twice a day	Water	7 th and 14 th day	28 th &42 nd day
Group (B)	Polyethylene glycol	0.7 mg/kg/day	Water	7 th and 14 th day	28 th & 42 nd day

Data collection methods: Simple Random method

Assessment criteria**1. Udarshoola:**

- a) 0- Absent
- b) 1- Present

2. Kshudhamandya:

- a) 0- Child himself ask food and take adequately
- b) 1- Child himself ask food but not take adequately
- c) 2- Child does not ask but take considerably
- d) 3- Child does not ask and does not take food considerably even by request

3. Frequency of defecation:

- a) 0- Defecation once
- b) 1- Defecation once in alternate day
- c) 2- Defecation 2-3 times/week
- d) 3- Two or fewer defecation/week

4. Flatulence:

- a) 0- Absent
- b) 1- Present

Bristol Stool Chart

Type 1		Separate hard lumps, like nuts (hard to pass)
Type 2		Sausage-shaped but lumpy
Type 3		Like a sausage but with cracks on the surface
Type 4		Like a sausage or snake, smooth and soft
Type 5		Soft blobs with clear-cut edges
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces. Entirely Liquid

Consent: Before beginning the clinical research, written approval will be obtained from each patient (assent) and from parents whose child refuses to grant consent. During the clinical trial, each patient's confidentiality will be maintained. Consent will be obtained on their own sake.

Scope and Implications of the purposed study

Scope: The goal of this study is to assess the efficacy of Abhayarishtaa as compared to standard treatment and ensure the safety, non habitability, quick result giving formulation who suffer from constipation and thereby boost growth and development in children.

DISCUSSION

The main reason behind selecting the trial drug is easy availability. The indication against Vibandha with quick outcome due to alcohol base was the reason for choosing this experimental medication. Most of the ingredients (Haritaki, Vidanga, Madhuka, Draksha, chavya, Shunthi)^[15] of *Abhayarishta* have *kaphavata*-pacifying properties. The ingredients of *Abhayarishta* have predominantly *ushna*, *Snigdha*, and *laugh Guna*.^[9] This will lead to *Anulomana* and *Stroto shodhak* action. Pharmacological evaluation of *veerya* of drug shows

ushna veerya is dominating. It maintains the equilibrium of vataKaphadosha and Purishvahastrotas and performs Prakrut karma. Related studies were reviewed^[10,11] depicting the same samprapti vighatan. It also helps in Amapachan and alleviates the Strotorodh by Ushna Tikshna Guna.^[12,13]

Most of the ingredients (Haritaki, Vidanga, Madhuka, Draksha, chavya, Shunthi)^[14] So, that this study is planned to determine the action of Abhayarishta in children with constipation. The prevalence varies according to age groups. The peak incidence of constipation occurs between 2 and 4 years of age when potty training starts. A recent systematic review found that median constipation was shown to be common in children (12%). Constipation in neonates has been documented at rates ranging from 0.05 percent to 39.3 percent, but the prevalence is approximated at 15% based on expert opinion. Dietary factor is a major contributory component at this age.^[10] Polyethylene glycol is known as an osmotic type of laxative. It works by holding water in the stool to soften the Stool and increases bowel movement^[15] Hence, this study is planned to determine the action of Abhayarishta and polyethylene glycol in Vibandha (constipation.)

Expected result: The expected result of this study is that group A intervention is potentially more result oriented than group (B)intervention due to Agni Vardhan. It is effective in subsiding the symptom of constipation such as abdominal pain, difficulty in defecation, Agnimandya (lack of appetite), flatulence, dry, hard and irregular defecation. Normal defecation and continence maintenance is a complex procedure that necessitates rectal fullness, rectal awareness, and the capacity to propel the stool and relax the pelvic floor muscles in a coordinated manner.^[16] To sustain fecal continence, some elements work together. The anal sphincters and pectoralis muscles (the pelvic floor) as well as rectal curvatures are anatomical considerations (i.e., the recto anal angle). Passive barriers include transverse rectal folds and haemorrhoid tissue in the anal canal.^[17] Polyethylene glycol is known as an osmotic type of laxative.^[18] As Haritaki is having Chebulic acid, combined with amylase and lipase in saliva it increases the appetite.^[19] The functional properties of Haritaki are Deepaniya, Pachaniya, Anulomak, Mruduvirechaka, and Krimighna^[20,21] Group A intervention Abhayarishta will be able to sustain fecal continence more efficiently as compared to group B intervention Polyethylene glycol.

CONCLUSION

The international drug group B-(*Abhayarishta*) is equally effective as group A(polyethylene glycol).

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