

**“CLINICAL ASSESSMENT OF THE EFFECT OF SHADDHARAN YOGA ON VIBANDHA W.S.
EXAMINATION OF THE DEGREE OF IT'S EFFICACY ON CONSTIPATION”**

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ABOUT THE ARTICLE

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ABSTRACT

Present study comprises a total of eight sections. The first section offers an Introduction and Assumptions for the present study, while the second section describes the Aims and Objectives for the present study. The third section is devoted to a Review of Literature, including a historical overview of Vibandha. Vibandha is elaborately explained in terms of its Nidana, Rupa, Sampradyti, Chikitsa, and Pathya Apathya. Review of Constipation according to present scientific knowledge, including causes, kinds, and treatment procedures that must be customised for Constipation. It also addresses the drug evaluation of the drug being tested, namely Shaddharma yoga. The fourth section discusses Materials and Methods, which consists primarily of the hypothesis, study design, diagnostic criteria, assessment criteria, IEC, preparation of the drug and drug analysis report, and the fifth section describe estimation of sample size for the current study. The overall observations gathered in this study are reported in tabular format in the fifth section. Statistics and study results are discussed in the sixth section of the report. The effects of therapy on a variety of indications and symptoms have been statistically examined and methodically provided in tables with brief explanations of each discovery. In the seventh section of the thesis entitled Discussions, the results of the investigation are discussed. This study's observations are summarised in the eighth section under Conclusions. And the final section is Summary. In the present investigation, individuals were evaluated using pre- and post-treatment assessment criteria. The Signs and Symptoms of Vibandha exhibited statistically significant results.

KEYWORDS: Vibandha, Shaddharma yoga, Constipation, Pathya-apathya

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INTRODUCTION

As the most vulnerable or disadvantaged members of society, children experience a high incidence and recurrence of gastrointestinal diseases. Changes in human lifestyle, as reflected in dietary and behavioural patterns, play a crucial influence in the emergence of various diseases that directly or indirectly affect children. Constipation affects children on a regular basis. Understanding the underlying

pathophysiology is crucial for the optimal therapy of persistent constipation. Age influences the manifestation and treatment of constipation. This article intends to provide the reader with a comprehensive overview of the diagnosis, investigation, and pharmacological and nonpharmacological management of chronic constipation in children. We detail the clinical history characteristics and how the pathology can interfere with normal physiology.

In today's paediatric practise, there are a significant number of patients with G.I.T.- related problems. These include Appetite loss, Chronic stomach pain, Chronic flatulence, Constipation, Diarrhea, and Failure to flourish, among others. For which parents seek a pediatrician's opinion. In addition, childhood is the period of greatest growth and development. Normalcy during this period promotes healthy Growth and Development. Any factors affecting the child's growth during this time will also effect the child's activities, social behaviour, immunity, concentration, and academic achievement.

The words Vibandha/Vibaddha/Baddha purisha, which signify one of the states of Srotodusti, particularly in Purishavaha srotas, literally mean Sanga meaning full or partial obstruction of purishvaha Srotas. The distinctive indications of their vitiation include the voiding of a little quantity of faeces with difficulty, a very scybalous stool accompanied by sound and discomfort, and the voiding of a small quantity of faeces with difficulty. All of the signs indicate that vitiated Vata is involved in the pathophysiology of Vibandha. Vibandha is one of the most common clinical diseases characterised by difficulty defecating, infrequent bowel motions, and firm stool in youngsters. The majority of youngsters suffer from constipation due to either ingesting insufficient fibre and water, or due to their lifestyles having been disrupted. Sometimes, overzealous toilet training in infancy can be stressful for children, leading to chronic constipation later in life. Vibandha as is typically caused by vata prakopak ahara, vihara, and noncompliance with Astha ahaar vidhi viseshayatana in children. This shall include changes in dietary habits, lifestyle, social structure, and constant mental stress that result in disturbances of the Annavaha and Purishvaha srotas vikara such as Vibandha, Adhmana, Anaha, Atopa, etc., and these symptoms persist for a longer period of time and lead to more distressing features. Vibandha Constipation can result in a vicious cycle characterised by frequent digestive problems, excessive food stagnation, and weak peristalsis. Children with extensive faeces retention (vibandha) and resulting nutritional issues. In addition, it might have a negative impact on the physical and mental development of children. Ayurveda's focus on preventative medicine, including care for children, is not novel.

When the classical writings were examined, just a few allusions to Vibandha were discovered. The list is as follows:

- In Astanga Hridya, Acharya Vagbhata describes Vibandhi as an organ of Mahasroras, which is the seat of Agni (i.e. Pachaka Pitta), and which receives and stores food.⁴
- Charakacharya used the term Koshta to describe the digestive process. According to him, food is driven into the Kosthaby Pranavayu¹.

- In Astanga Hridyah, Acharya Vagbhata describes the location of Vibandhas Pakwashaya Dwara, which is at the entrance to Pakwashaya².
- According to Acharya Sushruta, Pitta and Antragni are the same digestive entities³.
- Pachaka Pitta with Samana-vayu is discussed in relation to digestion in Vagbhata Samhita⁴.

Vibandha produces suffering by depriving the child of usual activities, producing disinterest, abdominal discomfort, loss of appetite, and fear of defecation, which in turn causes sadness and fear of defecation. Occasionally, it may also induce various additional disorders. Therefore, it is of the utmost importance to treat Vibandha promptly and prevent further complications in children caused by Vibandha.

The tailored therapy ideas should target both the disease's origin and pathophysiology. There is an impetus to investigate the Ayurveda-prescribed medications and to identify viable answers to the problem of constipation in children. One such formulation is Shaddharan yog, as the mainstay of treatment should consist of Agnideepana and Vatanulomana, which exert their effects by virtue of their Prabhava. When administered with Luke-warm milk, Anulomana provides additional benefits.

Efforts are undertaken to collect and analyse the available material regarding Vibandha concepts according to Ayurveda and contemporary literature. The purpose of the present study was to investigate and document the efficacy of oral administration of 500 mg of shaddharan yog twice daily, after meals with warm milk, for 45 days, in the management of Vibandha in terms of symptom reduction. In the dissertation, data collection, observation, interpretation of the results collected, and the mechanism of action of the drug were discussed.

AIMS AND OBJECTIVES

Keeping all these facts in mind the present study has been undertaken with the following aims and objectives –

1. To study the concept of Vibandh (constipation) in Ayurvedic text and modern literature.
2. Assuring and educating the parents regarding the disorder and development of the child [parent counselling].
3. To compare and assess the efficacy of drugs ie and Shaddharan yoga in the management of the disorder.
4. To study the role of instructions [counselling] formulated in controlling the disorder.

MATERIALS & METHODS

Clinical trials enable us to evaluate the citation of our hypotheses logically, objectively, critically, and

scientifically in order to verify their legitimacy. It is a valuable commodity that, when properly employed, will aid our classics in gaining a firm foothold in the current era of "Evidence Based Study."

Any research that does not include statistical analysis is akin to a "tree without roots." As a result, any scientific theory should ideally be supported by clinical data and statistics. The realities established by evidences derived after analysis, investigation, perception, inspection, and test are supported by precise clinical information and compelling thoughts about study in a clinical trial.

Grouping

The selected Children was randomly categorized into 3 groups viz. Shaddharan yoga groups with parent counselling (Group A) and Control parent counselling (Group B) and Control/ Placebo group only (Group C).

- Shaddharan yoga group with parent counselling: 15 Children of this group was administered with oral medication of Tablet Shaddharan yoga in the dose as per the age of child for duration of 45 days along with parent counselling.

- Placebo group with parent counselling: 15 Children of this group was given orally Capsule containing Wheat flour and sugar with parental counselling for a period, as mentioned above.

Group C- Placebo group without parent counselling: 15 Children of this group were given orally Capsule containing Wheat flour and sugar without parental counselling for a period, as mentioned above.

Every drug is taken in equal quantity, and then triturated (Bhavana) by Goumutra for three times. In the process, firstly whole combination is triturated by Goumutra, then the preparation is allowed to dry. After the proper drying and mixing again second time trituration of Goumutra is carried out. After this process again the preparation is allowed to dry followed by third titration of Goumutra. After proper drying the drug is now ready as SHADDHARAN YOGA. It was made into 500 mg tablets in tablet making machine. Group B & C/ PLACEBO GROUP: Here the placebo drug was given i.e. wheat flour with sugar in tablet form.

Methods of Selection of Study Subject:

1. Hard stool with straining and Sensation of incomplete evacuation.
2. Chronological age is between 4 - 15 years.

OBSERVATIONS

DESCRIPTIVE STATISTICAL ANALYSIS

The study was conducted according to the materials and methods discussed and many observations regarding various factors related to Constipation were made during the course of the study. The distribution based on socio-demographic characteristics such as age, gender, economic status etc., were well documented, tabulated and interpreted to reach conclusions. The data was tabulated using descriptive statistics and graphs were drawn.

Distribution of trial patients

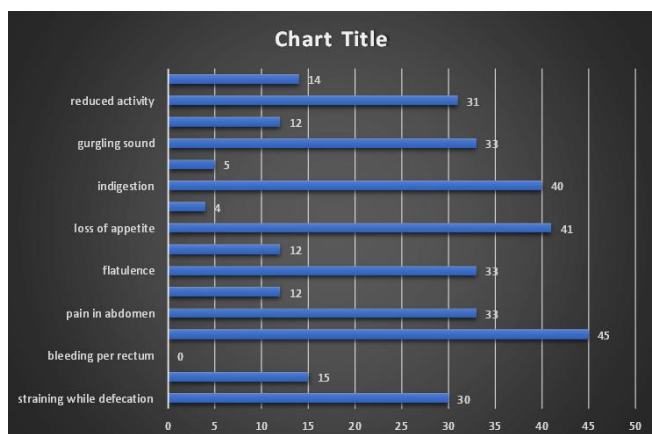
Patient Registrations	Total	%
Registered	45	100
Drop Out	0	0
Total	45	100

45 children were registered for the study, among them 45

Coexisting complaints	Ans	Total	%
Straining while defecation	Yes	30	66.67
	No	15	33.33
Bleeding per rectum	Yes	0	0
	No	45	100
Pain in abdomen	Yes	33	73.33
	No	12	26.67
Flatulence	Yes	33	73.33
	No	12	26.67
Loss of appetite	Yes	41	91.11
	No	4	8.89
Indigestion	Yes	40	88.89
	No	5	11.11
Gurgling sound	Yes	33	73.33
	No	12	26.67
Reduced activity	Yes	31	68.89
	No	14	31.11
Total		45	100

children completed the study, no one were considered as dropouts.

Distribution of study population by co-existing complaints



RESULTS

The present study originally conducted as “A Comparative clinical study to evaluate the efficacy of Shaddharan Yoga and Counselling in the management of Vibandha w.s.r. Constipation.” was carried out in total 45 patients divided equally in three groups. The patients were tested in this clinical trial for drug efficacy to evaluate the treatment of Shaddharan yoga tablet in the management of Vibandha. All the cases were noted on the basis of statistical result. All the subjective parameters and objective parameters were put to statistical test and results were obtained.

RESULTS	P-VALUE
Not Significant	>0.05
Significant	<0.05
Quite Significant	<0.01
Very Significant	<0.001
Extremely Significant	<0.0001

Wilcoxon signed-rank test is used to compare two related samples, matched samples, or to conduct a paired difference test of repeated measurements on a single sample to assess whether their population mean ranks differ.

DISCUSSION

There were no dropouts among the 45 children who were enrolled in the study, since all of them completed it.

In the study population of 45 participants, 46.66% of the children were between the ages of 4 and 8 years, 35.56 % were between the ages of 8 and 12 years, and 17.78% were between the ages of 12 and 16 years. The highest incidence of constipation occurs between the ages of 3 and 7 due to the

fact that children in this age range are picky eaters (junk foods) and consume no/little fibre and less water, as demonstrated by the current study.

In the study population of 45 individuals, 46.67 percent were male and 53.33 percent female. According to the findings of scientific studies, the notion that one gender is more likely to suffer from constipation than the other is false. In this sample population, a maximum of

73.33 percent of youngsters practised Hinduism, 22.22 percent practised Islam, 2.22 percent followed Christianity, and 2.22 percent belonged to other religions. Children of all religions are susceptible to constipation.

Overall, 62.22 percent of study participants consumed meat (including red meat, poultry, seafood, and other animal flesh), eggs, and vegetarian diets, whereas 37.77 percent followed a vegetarian diet exclusively. Regular consumption of meat, which is high in fat and requires more time for digestion, were the cause.

According to the Social Status distribution of the study population, 24.44% were wealthy. 15.56% of participants self-identified as upper middle class, 33.33% as lower middle class, and 26.67% as poor. Nutritional sufficiency, particularly in children, is proportional to economic position. A child with a low socioeconomic status has a greater likelihood of malnutrition, nutritional problems, constipation, etc., and other undesirable health concerns. Insufficient education and improper nutrition exacerbate the issue.

The distribution of the diets of the study participants reveals that, on average, 31.11% ate meals on time, i.e. breakfast in the morning, lunch in the afternoon, and dinner in the evening, whereas 68.89% had no routine and ate meals at random times. Regular timing of food consumption with a suitable amount of time between meals allows food to be effectively digested, hence maintaining the body's metabolism. In this study, the majority of subjects had inconsistent sleep patterns, which lowers the metabolism and can contribute to constipation and other gastrointestinal disorders.

Maximum 44.44% of individuals consumed junk food more than twice per week, whereas 31.11% consumed less than twice but more than once per week, and 24.44% had junk food once per week. Modern children are picky eaters (junk foods), and all of these foods are heavy in fat and low in fibre. This exacerbates constipation.

Considering the frequency of water consumption, a maximum of 46.67% drank 500-1000 ml of water daily, 51.11 % drank less than 500 ml of water daily, and 2.22% drank more than 1000 ml of water daily. Insufficient water consumption is the second leading cause of functional constipation. The

recommended water consumption will result in stools that are softer and simpler to pass.

Maximum 53.33 percent of milk consumers drank less than 200ml per day; 37.78 percent drank 200-300 ml per day; 6.67 percent drank 300-400 ml per day; and the remaining 2.22 percent drank more than 400ml per day. Constipation was observed in children who consumed primarily milk. Cow milk protein allergy (CMPA) has been suggested as one of the common reasons of constipation, which is characterised by hard stools, painful defecation, and anal fissures. Cow milk contains a high concentration of calcium, which, upon digestion, is converted into calcium curds, i.e. casein (a protein that is indigestible by human enzymes), it is constipating and contains a high concentration of phosphate receptor binding agents, which prevents the binding of iron, resulting in constipation.

13.33% experienced constipation symptoms for less than three months, 15.56 % for four to six months, 28.89 % for six to nine months, and 42.22 % for more than nine months.

55.56% of 45 children had rice as their primary food, 40% had a diet containing legumes, 42.22% had a diet containing no dairy products, and 51.1% consumed fruits and vegetables. Inadequate fibre consumption is a significant factor in the appearance of constipation. Cereals (rice, corn), bread, vegetables, fruits, and whole grains are common examples of foods that are high in dietary fibre. Less or no consumption will result in decreased stool volume, decreased osmotic load, and slowed colon transit (unable fermentation of fibre does not create short chain fatty acids).

Hereby repeated measure Anova test is used to analyse the changes in the symptom of vibandha in all the three groups. Accordingly, results were interpreted using F value and P value for significance. Groupwise paired comparison showed non-significant results in Group B & C whereas when compared with Group A Significant results were seen. This implies Shaddharan yoga tablet is more effective than the groups treated with Placebo drug.

CONCLUSION

1. Shaddharan yog tablet in a dose of 500 mg twice a day with warm milk is effective in the management of Vibandha(Constitution) in children aged 4-16 years.
2. Therapy showed marked improvement in the symptoms of Vibandha such as Mala katinata, Sa shoola and kashta mala pravarthana, Udarashoola, Atopa/Adhmana, Anaaha, Antra kujana, Trik vedana, etc
3. Internal administration of medicine is found to have significant improvement in the disease along with dietary modification of the child.
4. Hereby repeated measure Anova test is used to analyse the changes in the symptom of vibandha in all the three groups. Accordingly, results were interpreted using F value and P value for significance. Groupwise paired comparison showed non-significant results in Group B & C whereas when compared with Group A Significant results were seen. This implies Shaddharan yoga tablet is more effective than the groups treated with Placebo drug.

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