

CLINICAL EVALUATION OF THE EFFICACY OF SHADDHARAN YOGA IN THE MANAGEMENT OF VIBANDHA W.S.R. CONSTIPATION

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ABSTRACT

One of the biggest challenges in interpreting both individual child situations, as well as the literature overall, is understanding what's defined as "*Vibandha* (constipation)". *Vibandha* is the burning problem in paediatric age group, causing adverse impact on child's physical and mental health; hence it is an area of concern. It is considered as one among lifestyle disorder too. The word *Vibandha* in most of the context mentioned as one of the clinical presentations of many disorders in Ayurveda, but it can be considered as separate disease entity because of the availability of broad-spectrum information and explanation available in classical texts. *Annavaha* and *Purishavaha srotas* are mainly involved in the pathogenesis of *Vibandha* with *Adhmana*, *katiprushta vedana*, *Varcho-Apravriti*, *Varcha-Kruchrata*, *Varcha-Chirat pravriti* as cardinal features of *Vibandha*. It was observed that *Viruddha ahara krama*, *Visham-Aahara*, *Avyayama*, *Alpa jalapana* and *Vega Sandharana*, *Shoka*, *Bhaya*, *Chinta*, etc. having more impact in the manifestation of *Vibandha* specially in children. *Vibandha* (Constipation) presents as a perpetual problem in health-care with painful and debilitating consequences, however it is preventable. Present study is useful guiding us regarding *Vibandha*, pathogenesis, treatment and regimens which can be implemented in Children with *Vibandha*.

Key Words: *Vibandha*, *Annavaha stotas*, *Purishavaha srotas*, *Vega sandharana*

INTRODUCTION

The present dissertation entitled "A Comparative clinical study to evaluate the efficacy of *Shaddharan* Yoga and Counselling in the management of *Vibandha w.s.r.* Constipation." comprises of eight parts i.e. Introduction, Objectives, Methodology, Review of Literature (includes disease review and drug review), Observations, Statistics & Results, Discussion, Conclusion and whole work is summarized in the last part Summary. 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 *Shaddharna* 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 describes the 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. The final section of the dissertation is the Summary, in which the entire work is summarised. This section provides a comprehensive overview of the entire investigation. In the present investigation, individuals were evaluated using pre- and post-treatment assessment criteria. The Signs and Symptoms of *Vibandha* exhibited statistically significant results.

MATERIALS AND 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.

The current clinical research is an attempt to determine the efficacy of *Shaddharan* yoga in the management of *Vibandha* w.s.r. Constipation.

Study Design

An open label clinical trial.

Study type: Interventional study. Level of study: OPD Level Control: Not Controlled Timing: 18 months of duration No. Of group: three

Sample Size: 45

Study Duration: 2 months

End point: Efficacy and Safety

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.

Appropriate data management and analysis plan and methods

Diagnostic criteria

Procedure was thoroughly explained to the Children's Parents/guardian and consent were acquired before proceeding with the study.

Methods of Selection of Study Subject

- Hard stool with straining and Sensation of incomplete evacuation
- Chronological age is between 4 - 15 years.
- The behaviour is clinically significant as manifested by either a frequency of 2-3 a week or more.

Inclusion Criteria

- Children was selected for the Age group 04-16 years and of either gender
- Children manifesting the symptoms of *Vibanda*, viz, *Udarashoola*, *Antrakoojana*, *Atopa*, *Trikvedana*, *Anaaha*.
- Parents who are willing to give consent

Exclusion criteria

- Children below 04 years and above 16 years.
- Children suffering from Chronic Debilitating Infections Diseases
- Children with any congenital anomalies or with anatomical deficits of gastro- intestinal system was not included in the study.
- Neurological disorders And Structural Anomalies of anal canal was expelled.
- Children having constipation secondary to any of other disorders like hypothyroidism,
- *Hirshsprung's* Disease
- Children with Worm infestation was excluded.

Withdrawal criteria

- If Children are not willing to continue the treatment or irregular follow ups
- Children unable to tolerate the treatment.
- Any unknown adverse drug reaction of treatment on Children.

CRITERIA OF ASSESSMENT

During trial and follow up, registered subjects were assessed on the following parameters

- Subjective Parameters; All Children registered for present trial was looked for any change in their growing feeling of wellbeing if any, produced after the course of treatment.
- Objective Parameter; The criteria of assessment of treatment were based on improvement in cardinal and associated symptoms of *Vibandh w.s.r.* Constipation.

Cardinal symptoms

Vibandh

Associated Symptoms; *Udarashoola, Antrakoojana, Atopa, Trikvedana, Anaaha.*

Criteria of Assessment:

A. Investigations (if required) Blood: CBC, Hb%, BT.CT.

Urine: Routine and Microscopic examination. Stool: Routine and Microscopic examination.

Criteria for overall effect of therapy:

Percentage of relief in symptoms and signs with respect to each of the Children was done as follow as and classified as per the definition of cured, markedly improved, and improved and unchanged.

Percentage of Relief	Effect
More than 75 %	Excellent improvement
51-75 %	Markedly improved
26-50 %	Improved
Less than 25 %	No improvement

Using these methods of examination, the criteria of assessment as described earlier were recorded meticulously. After completion of the study all this data were subjected to scientific statistical analysis method.

Data Collection:

- Primary data – The method used for data collection is observation method, and the tools used to collect the data were predominantly structured in case paper.
- Secondary data – The secondary data were collected from the various sources like Web search books, video case study.

Data were collected with the help of history taking and examination. It was done once a week for a month and noted in follow up table.

Statistical Analysis

Data Management and Analysis Procedure:

Collected data were presented in the form of tables, charts and graphs.

Observation was drawn strictly on basis of data collected and it were presented in appropriate forms like tables and graphs.

Appropriate tests were applied to collected data.

- For within the group analysis of assessment criteria other than smell Wilcoxon signed Ranks test were applied at 5% level of significance.
- For between the group analysis of assessment criteria other than smell Anova test were applied at 5% level of significance.

OBSERVATION & RESULTS

The subjective, objective parameters and laboratory findings, prior and after the clinical trial were completed, compounded, statistically analysed and conclusion were drawn on the basis of results.

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.

Among 45 children, 55.56% of children was having rice as predominant food, 40% are with legumes diet, 42.22% with h/o dairy products and 51.11% of children with fruits and vegetables intake.

The present study entitled “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.

When results were compared for group A, before treatment and after treatment for variable *Vibandha* with Wilcoxon Sign rank test, Extremely Significant results were obtained with Z value= 3.40 & P=0.006. Since mean difference is more in patients treated with *Shaddharana* yoga tablet it is concluded that it is highly effective to reduce *Vibandha*.

When results were compared for group B, before treatment and after treatment for variable *Vibandha* with Wilcoxon Sign rank test, Non-Significant results were obtained with Z value=

1.73 & $P=0.08$. Since mean difference is less in patients treated with placebo drug with counselling it is concluded that it is not effective to reduce *Vibandha*.

When results were compared for group C, before treatment and after treatment for variable *Vibandha* with Wilcoxon Sign rank test, Significant results were obtained with Z value= 3.09 & $P=0.001$. Since mean difference is more in patients treated with placebo drug without counselling it is concluded that it is effective to reduce *Vibandha*.

When results were compared for group A, before treatment and after treatment for variable *Udara Shoola* with Wilcoxon Sign rank test, Extremely Significant results were obtained with Z value= 4.08 & $P=0.00006$. Since mean difference is more in patients treated with *Shaddharana* yoga tablet it is concluded that it is highly effective to reduce *Udara Shoola*.

When results were compared for group B, before treatment and after treatment for variable *udara shoola* with Wilcoxon Sign rank test, very Significant results were obtained with Z value= 2.66 & $P=0.007$. Since mean difference is more in patients treated with placebo drug with counselling it is concluded that it is effective to reduce *Udara Shoola*.

When results were compared for group C, before treatment and after treatment for variable *udara Shoola* with Wilcoxon Sign rank test, very Significant results were obtained with Z value= 3.29 & $P=0.0009$. Since mean difference is more in patients treated with placebo drug without counselling it is concluded that it is effective to reduce *Udara shoola*

When results were compared for group A, before treatment and after treatment for variable *Antra kujana* with Wilcoxon Sign rank test, Extremely Significant results were obtained with Z value=3.57 & $P=0.0003$. Since mean difference is more in patients treated with *Shaddharana* yoga tablet it is concluded that it is highly effective to reduce *Antra kujana*.

When results were compared for group B, before treatment and after treatment for variable *Antra kujana* with Wilcoxon Sign rank test, non-significant results were obtained with Z value= 1.93 & $P=0.053$. Since mean difference is less in patients treated with placebo drug with counselling it is concluded that it is not effective to reduce *Antra kujana*.

When results were compared for group C, before treatment and after treatment for variable *Antra kujana* with Wilcoxon Sign rank test, non-significant results were obtained with Z value= 1.85 & $P=0.06$. Since mean difference is less in patients treated with placebo drug without counselling it is concluded that it is not effective to reduce *Antra kujana*

When results were compared for group A, before treatment and after treatment for variable *Atopa* with Wilcoxon Sign rank test, Extremely Significant results were obtained with Z value=3.39 & $P=0.0006$. Since mean difference is more in patients treated with *Shaddharana* yoga tablet it is concluded that it is highly effective to reduce *Atopa*.

When results were compared for group B, before treatment and after treatment for variable *Atopa* with Wilcoxon Sign rank test, non-significant results were obtained with Z value= 1.41 & $P=0.157$. Since mean difference is less in patients treated with placebo drug with counselling it is concluded that it is not effective to reduce *Atopa*.

When results were compared for group C, before treatment and after treatment for variable *Atopa* with Wilcoxon Sign rank test, very Significant results were obtained with Z value= 2.71 & P=0.006. Since mean difference is more in patients treated with placebo drug without counselling it is concluded that it is effective to reduce *Atopa*

When results were compared for group A, before treatment and after treatment for variable *Anaaha* with Wilcoxon Sign rank test, Extremely Significant results were obtained with Z value=3.55 & P=0.0003. Since mean difference is more in patients treated with *Shaddharana* yoga tablet it is concluded that it is highly effective to reduce *Anaaha*

When results were compared for group B, before treatment and after treatment for variable *Anaaha* with Wilcoxon Sign rank test, non-significant results were obtained with Z value= 1.38 & P=0.165. Since mean difference is less in patients treated with placebo drug with counselling it is concluded that it is not effective to reduce *Anaaha*

When results were compared for group C, before treatment and after treatment for variable *Anaaha* with Wilcoxon Sign rank test, Quite Significant results were obtained with Z value= 2.00 & P=0.045. Since mean difference is more in patients treated with placebo drug without counselling it is concluded that it is effective to reduce *Anaaha*

When results were compared for group A, before treatment and after treatment for variable *trik-vedana* with Wilcoxon Sign rank test, Extremely Significant results were obtained with Z value= 3.77 & P=0.0001. Since mean difference is more in patients treated with *Shaddharana* yoga tablet it is concluded that it is highly effective to reduce *trik-vedana*.

When results were compared for group B, before treatment and after treatment for variable *trik-vedana* with Wilcoxon Sign rank test, Significant results were obtained with Z value= 2.00 & P=0.045. Since mean difference is more in patients treated with placebo drug with counselling it is concluded that it is effective to reduce *trik-vedana*.

When results were compared for group C, before treatment and after treatment for variable *trik-vedana* with Wilcoxon Sign rank test, Significant results were obtained with Z value= 2.00 & P=0.045. Since mean difference is more in patients treated with placebo drug without counselling it is concluded that it is effective to reduce *trik-vedana*.

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

CONCLUSION

Shaddharan yog tablet in a dose of 500 mg twice a day with warm milk is effective in the management of *Vibandha* (Constipation) in children aged 4-16 years. 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. Internal administration of medicine is found to have significant improvement in the disease along with dietary modification of the child. Hereby repeated measure *Annova* 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.

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