

RANDOMIZED OPEN-LABELLED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF LAVANGADI CHURNA IN GRAHANI WITH SPECIAL REFERENCE TO IRRITABLE BOWEL SYNDROME

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ABSTRACT

Background & Objectives: Grahani was described as an Annava Srotovikara with Mandhagni as an important underlying factor and altered bowel movements as a characteristic manifestation. Based on the symptomatology and absence of detectable structural abnormalities, the condition was correlated in the study with Irritable Bowel Syndrome (IBS). The present study was undertaken to clinically evaluate the efficacy of Lavangadi Churna in Grahani with special reference to IBS and to compare its effect with Bruhad Gangadhara Churna. **Methods:** A randomized, open-labelled, parallel-group, active-controlled clinical study was conducted in 30 subjects fulfilling the study criteria. Subjects were randomly allocated into Group A (n=15), receiving Lavangadi Churna, and Group B (n=15), receiving Bruhad Gangadhara Churna. Both interventions were administered orally for 30 days followed by a 15-day drug-free follow-up. Subjective parameters included Baddha Mala

Pravrutti, Drava Mala Pravrutti, Muhur Muhur Mala Pravrutti, Udara Shoola, Amayukta Mala Pravrutti, Flatulence and Quality of Life. Assessments were performed on Day 0, Day 30 and Day 45. Within-group analysis was used the Friedman repeated-measures analysis of

variance on ranks, while between-group comparison used the Mann-Whitney U test. Effect size was assessed using Kendall's W for Friedman analysis and $r = Z/\sqrt{N}$ for other non-parametric analyses. **Results:** Group A showed statistically significant improvement in all assessed subjective parameters after treatment, with highly significant changes reported for Baddha Mala Pravrutti and Amayukta Mala Pravrutti, and significant changes in Drava Mala Pravrutti, Muhur Muhur Mala Pravrutti, Udara Shoola, Flatulence and Quality of Life. Several improvements remained statistically significant during follow-up. Group B also showed significant or highly significant improvement across the assessed parameters. Between-group comparisons at Day 30 and Day 45 were non-significant for all parameters. The parameter-wise overall improvement ranged from 60% to 87% in Group A and from 50% to 89% in Group B. **Conclusion:** In the present study, both Lavangadi Churna and Bruhad Gangadhara Churna produced significant improvement in the assessed subjective parameters of Grahani with special reference to IBS. No statistically significant difference was observed between the groups at Day 30 or Day 45. The study therefore reported Lavangadi Churna as clinically comparable to Bruhad Gangadhara Churna for the assessed parameters.

KEYWORDS: Grahani, Irritable Bowel Syndrome, Lavangadi Churna, Bruhad Gangadhara Churna, Agnimandya.

1. INTRODUCTION

Grahani was described as one of the Annavaha Srotovikaras in which Mandhagni was an important underlying pathology and altered bowel movements are a characteristic manifestation. Considering the clinical presentation described in the study, Grahani was correlated with Irritable Bowel Syndrome (IBS), a condition characterized by altered bowel habits associated with abdominal pain in the absence of detectable structural abnormalities.

Contemporary management described in the study included patient counselling, dietary modification, stool-bulking agents, antispasmodics, antidiarrhoeal drugs, antidepressants, antiflatulent therapy and modulation of gut serotonin receptors. Which shows adverse effects associated with some pharmacological approaches, including xerostomia, urinary hesitancy and retention, blurred vision, drowsiness and drug dependency.

From the Ayurvedic perspective, Agnimandya was considered an important factor in the Samprapti of Grahani; hence, Agnivardhana, Deepana and Pachana approaches were

relevant. Lavangadi Churna was selected as the trial formulation. Bruhad Gangadhara Churna, described as a proven formulation in Grahani with special reference to IBS, was selected as the control intervention. Lavangadi Churna contained 19 ingredients, with predominance of Katu and Kashaya Rasa, Laghu and Ruksha Guna, Ushna Veerya and Katu Vipaka, along with Deepana, Pachana and Sangrahi actions.

2. RESEARCH QUESTION

Whether oral administration of Lavangadi Churna is effective in Grahani with special reference to Irritable Bowel Syndrome?

3. AIM AND OBJECTIVES

Aim: To clinically evaluate the efficacy of Lavangadi Churna in the management of Grahani with special reference to Irritable Bowel Syndrome.

Primary Objective: To clinically evaluate the efficacy of Lavangadi Churna in Grahani with special reference to Irritable Bowel Syndrome and compare its efficacy with Bruhad Gangadhara Churna based on subjective parameters in the institutional clinical set-up.

Secondary Objective: To undertake a detailed literary review of Grahani with special reference to Irritable Bowel Syndrome.

4. HYPOTHESIS

- Null hypothesis (H0): There is no significant difference between the efficacy of Lavangadi Churna and Bruhad Gangadhara Churna in Grahani with special reference to Irritable Bowel Syndrome.
- Alternative hypothesis (H1): The efficacy of Lavangadi Churna is better than Bruhad Gangadhara Churna in Grahani with special reference to Irritable Bowel Syndrome.
- Alternative hypothesis (H2): The efficacy of Bruhad Gangadhara Churna is better than Lavangadi Churna in Grahani with special reference to Irritable Bowel Syndrome.

5. MATERIALS AND METHODS

5.1 Study Design and Ethical/Trial Registration Details

The study was a randomized, open-labelled, parallel-group, active-controlled clinical study. Thirty subjects diagnosed with Grahani with special reference to Irritable Bowel Syndrome were selected and randomly allocated into two groups of 15 subjects each. Randomization

was performed using a randomization table generated through www.randomizer.org. The trial was registered prospectively in the Clinical Trials Registry–India (CTRI) on 01/12/2025 with registration number CTRI/2025/12/118321.

5.2 Source of Data

Literary source: Ayurvedic classical literature, contemporary textbooks, authentic digital sources and reputed journals were referred to gather information regarding the disease and drugs.

Sample source: A total of 30 subjects fulfilling the inclusion criteria were selected from the OPD/IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Kanakapura Road, Bengaluru. Subjects were also selected through referral sources and special camps.

5.3 Sample Size and Randomization

The sample size was estimated using the stated RCT formula and was calculated as 118 subjects. As the research formed part of the postgraduate academic curriculum and due to time constraints and lack of feasibility, a standard sample size of 30 subjects was taken. Thirty subjects were randomized into Group A (n=15) and Group B (n=15).

5.4 Drug Source

Drug	Source / Manufacturer	Batch	Manufacturing	Expiry
Lavangadi Churna	Ingredients procured from authentic sources; identified and approved by PG Studies in Dravyaguna; preparation done in Department of Rasashadtra and Bhaishajya Kalpana, SSCASRH, Bengaluru	Not stated	23/08/2025	23/08/2027
Bruhad Gangadhara Churna	Baidhyanath GMP-certified Pharma; obtained from Sarvahitha Ayurvedalaya Pvt. Ltd., Bengaluru	T02	07/2024	06/2027

5.5 Diagnostic Criteria

Subjects who had the following signs and symptoms was considered for selection in this study

- Baddha Mala Pravrutti.
- Drava Mala Pravrutti.
- Muhur Muhur Mala Pravrutti.
- Ama Mala Pravrutti.
- Established diagnosis of Grahani.
- Established diagnosis of IBS (at least Rome-category IV), as stated in the PPT.

5.6 Inclusion Criteria

- Subjects of either gender aged 21–60 years.
- Subjects fulfilling the study diagnostic criteria.
- Subjects willing to participate with written informed consent.

5.7 Exclusion Criteria

- Subjects with inflammatory bowel disease, intestinal tuberculosis or other inflammatory conditions of the intestine, such as Crohn's disease and ulcerative colitis.
- Subjects with malabsorption syndrome.
- Pregnant and lactating women.
- Subjects with diabetes mellitus.
- Subjects diagnosed with microscopic colitis, active coeliac sprue, chronic pancreatitis or pancreatic insufficiency.
- Subjects with any other condition interfering with the course of disease or treatment.

5.8 Intervention and Posology

Feature	Trial Group – Group A	Control Group – Group B
Sample size	15	15
Intervention	Lavangadi Churna	Bruhad Gangadhara Churna
Dosage	6 g BD	6 g BD
Anupana	Warm water (Q.S.)	Warm water (Q.S.)
Time of administration	BD, before food	BD, before food
Treatment period	30 days	30 days
Drug-free follow-up	15 days	15 days
Total study duration	45 days	45 days
Route	Oral	Oral

5.9 Assessment Criteria and Schedule

The subjective assessment included Baddha Mala Pravritti, Drava Mala Pravritti, Muhur Muhur Mala Pravritti, Udara Shoola, Amayukta Mala Pravritti, Flatulence and Quality of Life using the IBS-QOL score.

Assessment point	Assessment
Day 0	Pre-test assessment of subjective parameters
Day 30	Post-test assessment of subjective parameters
Day 45	Follow-up assessment of subjective parameters

5.10 Statistical Analysis

The recorded data were presented in tables, diagrams and charts. Statistical analysis was performed using SIGMASTAT software version 3.1. Data passing the normality test were subjected to parametric tests, whereas data not passing normality were analysed using non-parametric tests. Non-parametric data were presented as Median (25th–75th percentile). For within-group comparison, the Friedman repeated-measures analysis of variance on ranks test was used. For between-group comparison, the Mann-Whitney U test was employed. Clinical effect size was assessed using Kendall's W for data generated through the Friedman test and $r = Z/\sqrt{N}$ for other analyses. $P > 0.05$ was interpreted as non-significant, $P \leq 0.05$ as significant and $P \leq 0.01$ as highly significant.

6. RESULTS

6.1 Study Flow and Safety

Thirty-two subjects were screened. Two subjects were excluded for not meeting the inclusion criteria. Thirty subjects were randomized, with 15 subjects allocated to each group. All 30 subjects received the allocated intervention, completed the follow-up and were included in the analysis. No dropouts occurred. No adverse drug reaction was reported in either group and no rescue medication was administered.

6.2 Baseline Observations

Among the study participants, 50% belonged to the 21–30-year age group; 56.66% were female; 73.33% belonged to Sadharana Desha; 100% were Hindu; 60% were graduates; 56.66% were salaried employees; 66.66% belonged to the upper-middle socioeconomic class; 100% were married; 63.33% consumed a mixed diet; 80% consumed coffee; 56.66% had a

sedentary lifestyle; 56.66% had a family history; 63.33% had Vata Shleshmala Prakriti; and prominent Nidana included Snigdha Ahara Sevana (60%) and Avyayama (56.70%).

6.7 Baddha Mala Pravrutti

Group	Day 0	Day 30	Day 45
Group A	0.000 (0.000–1.000)	0.000 (0.000–0.750)	0.000 (0.000–0.000)
Group B	0.000 (0.000–1.000)	0.000 (0.000–0.000)	0.000 (0.000–0.000)

Within-group analysis showed significant reduction in both groups at Day 30 and Day 45. Between-group difference was non-significant ($p = 0.770$).

6.8 Drava Mala Pravrutti

Group	Day 0	Day 30	Day 45
Group A	1.000 (1.000–2.000)	0.000 (0.000–1.000)	0.000 (0.000–0.750)
Group B	1.000 (1.000–2.000)	0.000 (0.000–1.750)	0.000 (0.000–0.000)

Within-group analysis showed significant reduction in both groups at Day 30 and Day 45. Between-group difference was non-significant ($p = 0.618$).

6.9 Muhur Muhur Mala Pravrutti

Group	Day 0	Day 30	Day 45
Group A	1.000 (1.000–2.000)	1.000 (0.000–1.750)	0.000 (0.000–1.000)
Group B	1.000 (1.000–2.000)	1.000 (0.000–1.000)	0.000 (0.000–0.750)

Within-group analysis showed significant reduction in both groups at Day 30 and Day 45. Between-group differences were non-significant ($p = 0.648$ at Day 30 and $p = 0.786$ at Day 45).

6.10 Udara Shoola

Group	Day 0	Day 30	Day 45
Group A	1.000 (1.000–2.000)	0.000 (0.000–1.000)	0.000 (0.000–0.750)
Group B	1.000 (1.000–2.000)	0.000 (0.000–1.000)	0.000 (0.000–0.000)

Within-group analysis showed significant reduction in both groups at Day 30 and Day 45. Between-group difference was non-significant ($p = 0.803$).

6.11 Amayukta Mala Pravrutti

Group	Day 0	Day 30	Day 45
Group A	1.000 (0.000–1.000)	0.000 (0.000–1.000)	0.000 (0.000–0.000)
Group B	0.000 (0.000–1.000)	0.000 (0.000–0.750)	0.000 (0.000–0.000)

Within-group analysis showed significant reduction in both groups at Day 30 and Day 45. Between-group difference was non-significant ($p = 0.574$).

6.12 Flatulence

Group	Day 0	Day 30	Day 45
Group A	0.000 (0.000–1.000)	0.000 (0.000–0.750)	0.000 (0.000–0.000)
Group B	0.000 (0.000–1.000)	0.000 (0.000–0.000)	0.000 (0.000–0.000)

Within-group analysis showed significant reduction in both groups at Day 30 and Day 45. Between-group difference was non-significant ($p = 0.517$).

6.13 Quality of Life (IBS-QOL)

Group	Day 0	Day 30	Day 45
Group A	49.300 (29.050–49.825)	18.400 (11.750–27.775)	18.400 (11.750–27.775)
Group B	36.000 (27.375–45.625)	14.700 (10.675–20.225)	15.400 (10.300–19.100)

Within-group analysis showed significant reduction in both groups at Day 30 and Day 45. Between-group difference was non-significant ($p = 0.618$).

6.14 Summary of Statistical Analysis

Parameter	Group A Day 0–30	Group A Day 30–45	Group B Day 0–30	Group B Day 30–45	Between groups
Baddha Mala Pravrutti	Highly significant	Non-significant	Significant	Significant	Non-significant
Drava Mala Pravrutti	Significant	Non-significant	Significant	Significant	Non-significant
Muhur Muhur Mala Pravrutti	Significant	Significant	Significant	Significant	Non-significant
Udara Shoola	Significant	Non-significant	Significant	Non-significant	Non-significant
Amayukta Mala Pravrutti	Highly significant	Non-significant	Highly significant	Non-significant	Non-significant
Flatulence	Non-significant	Non-significant	Highly significant	Non-significant	Non-significant
Quality of Life	Significant	Non-significant	Significant	Non-significant	Non-significant

6.15 Parameter-wise Overall Effect.

Parameter	Group A	Group B
Baddha Mala Pravrutti	66%	60%
Drava Mala Pravrutti	75%	89%
Muhur Muhur Mala Pravrutti	71%	73%

Udara Shoola	72%	89%
Amayukta Mala Pravrutti	66%	50%
Flatulence	87%	84%
Quality of Life	60%	62%

6.16 Effect Size

Parameter	Group A 0–30	Group A 30–45	Group B 0–30	Group B 30–45
Baddha Mala Pravrutti	0.95 (Large)	0.95 (Large)	0.92 (Large)	0.80 (Large)
Drava Mala Pravrutti	0.97 (Large)	0.95 (Large)	0.90 (Large)	0.70 (Large)
Muhur Muhur Mala Pravrutti	0.90 (Large)	0.80 (Large)	0.89 (Large)	0.60 (Large)
Udara Shoola	0.97 (Large)	0.90 (Large)	0.97 (Large)	0.90 (Large)
Amayukta Mala Pravrutti	0.95 (Large)	0.92 (Large)	0.91 (Large)	0.80 (Large)
Flatulence	0.92 (Large)	0.80 (Large)	0.91 (Large)	0.60 (Large)
Quality of Life	0.81 (Large)	0.62 (Large)	0.90 (Large)	0.60 (Large)

Which shows large effect sizes for all listed parameters within both groups across the treatment and follow-up intervals. For between-group comparisons, effect size was negligible/no effect for most parameters and small for Flatulence and Quality of Life.

7. DISCUSSION

7.1 Ayurvedic and Contemporary Correlation

The study considered IBS in the context of Grahani, where impaired Agni and altered bowel function form important components of the Ayurvedic understanding. The intervention was selected on the premise that correction of Agnimandya through Deepana and Pachana actions might had helped in Samprapti Vighatana. Clinically, both groups demonstrated improvement in bowel pattern, abdominal pain, associated stool abnormalities, flatulence and quality of life.

7.2 Probable Mode of Action of Lavangadi Churna

Lavangadi Churna was as a polyherbal formulation contain Lavanga, Suddha Karpura, Ela, Twak, Nagakesara, Jatiphala, Usheera, Nagara, Krishna Jeeraka, Krishna Agar, Tugakshiri, Jatamamsi, Nilotpala, Pippali, Chandana, Tagara, Vala, Kankola and Sita. The formulation was described as having Madhura, Tikta and Katu Rasa, Laghu and Tikshna properties, Ushna Veerya and Katu Vipaka, with Deepana, Pachana and Sangrahi actions.

Lavanga contained caryophyllene and humulene, which were described as having antispasmodic and anti-inflammatory actions. Suddha Karpura contained borneol and linalool and was described as analgesic and antimicrobial. Ela contained terpinyl acetate and flavonoids and was described as carminative and mildly anti-inflammatory. Twak contained cinnamic acid and was described as influencing intestinal serotonin-related mechanisms. Nagakesara contained mesuol and xanthenes and was described as anti-inflammatory and antispasmodic.

Jatiphala was described as containing eugenol and macelignan with smooth-muscle-relaxant, local anaesthetic, antioxidant and antimicrobial effects. Usheera was described as containing sesquiterpenoids and vetivones with anti-inflammatory and spasmolytic effects. Nagara was described as containing volatile compounds and zingibain with effects on gastrointestinal motility and abdominal cramping. Krishna Jeeraka was described as containing phenolic compounds and flavonoids with antioxidant and anti-inflammatory activity.

Krishna Agarū was described as containing chromone derivatives and sesquiterpenes with antispasmodic and antioxidant effects. Tugakshiri was described as providing mucilage with a demulcent effect. Jatamamsi was described as containing coumarins with anti-inflammatory effects. Nilotpala was described as having calming and antispasmodic effects. Pippali was described as containing volatile oils that might have helped relieve bloating and abdominal discomfort.

Chandana was having constituents that suppress inflammatory mediators. Tagara was described as containing iridoid compounds with smooth-muscle-relaxant effects. Vala contained essential oils such as β -eudesmol and terpenes and was described as antispasmodic. Kankola was described as providing anti-inflammatory and analgesic effects. Collectively, the formulation's described Deepana, Pachana and Sangrahi actions.

7.3 Comparison with Bruhad Gangadhara Churna

Within-group analysis demonstrated statistically significant improvement in several parameters in both groups. However, between-group comparisons at Day 30 and Day 45 were non-significant for all assessed parameters. The effect-size comparison between groups was reported as negligible or no effect for most parameters and small for Flatulence and Quality of Life. Thus, the study data did not demonstrate a statistically significant or clinically

meaningful difference between Lavangadi Churna and Bruhad Gangadhara Churna for the assessed outcomes.

8. SAFETY AND CONFIDENTIALITY

No adverse drug reaction was reported in either group and no rescue medication was administered during the study. data would be kept confidential and preserved for a period of five years.

9. LIMITATIONS

The principal limitation evident from the study design was the small sample size of 30 subjects, which limits generalization to a larger population. estimated sample size was 118, but 30 subjects were included because the study formed part of the postgraduate academic curriculum and there were time and feasibility constraints.

10. SCOPE FOR FURTHER STUDY

- Larger clinical studies might had been undertaken to establish more conclusive results.
- Future studies may evaluate a treatment protocol combining Shodhana and Shamana approaches for better management of Irritable Bowel Syndrome.
- Further studies may include assessment using stool culture.

11. CONCLUSION

In the present randomized, open-labelled, controlled clinical study, both Lavangadi Churna and Bruhad Gangadhara Churna produced significant improvement in the assessed subjective parameters of Grahani with special reference to Irritable Bowel Syndrome. Lavangadi Churna showed significant or highly significant improvement in bowel-pattern abnormalities, abdominal pain, Amayukta Mala Pravrutti, flatulence and Quality of Life, with several improvements persisting during the drug-free follow-up. Bruhad Gangadhara Churna also produced significant improvement in the assessed parameters.

Between-group comparisons at Day 30 and Day 45 were non-significant for all assessed parameters. The effect-size analysis likewise showed no meaningful clinical difference between the two groups for most parameters, Lavangadi Churna was reported as clinically comparable to Bruhad Gangadhara Churna in the management of Grahani with special reference to Irritable Bowel Syndrome, and the null hypothesis was accepted.

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