

ASSOCIATION BETWEEN IRRITABLE BOWEL SYNDROME SUBTYPE AND PAIN REDUCTION FOLLOWING INDIVIDUALIZED HOMOEOPATHIC TREATMENT: A DESCRIPTIVE SECONDARY ANALYSIS OF A RANDOMIZED TRIAL

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ABSTRACT

Background: Irritable bowel syndrome (IBS) is a disorder of gut–brain interaction associated with abdominal pain and altered bowel habits. Clinical presentations are commonly classified as constipation-predominant (IBS-C), diarrhoea-predominant (IBS-D), or mixed (IBS-M). Describing outcomes across these subtypes may help identify questions for future research.

Objective: To describe changes in abdominal pain scores by IBS subtype among participants who received individualized homoeopathic treatment using centesimal (CM) or LM potencies in a randomized clinical trial.

Methods: This descriptive secondary analysis used data from 52 participants, with 26 in each treatment group. Participants were classified as IBS-C, IBS-D, or IBS-M. Pain was measured before and after treatment using the Numeric Pain Rating Scale (NPRS). Pain reduction was defined as the pretreatment score minus the post-treatment score. Subgroup means and standard deviations were summarized, and an exploratory model assessed the treatment-group-by-subtype interaction.

Results: There were 18 participants with IBS-C, 10 with IBS-D, and 24 with IBS-M. Mean pain reduction in the CM group was 3.00, 3.00, and 3.17 points for IBS-C, IBS-D, and IBS-M, respectively. The corresponding means in the LM group were 4.78, 5.20, and 4.75 points. The LM-minus-CM differences were 1.78, 2.20, and 1.58 points, respectively. The treatment-group-by-subtype interaction was not statistically significant ($p = 0.534$).

Conclusion: Mean pain reduction was numerically greater in the LM group in each subtype, but the analysis did not show statistical evidence that the difference between treatment groups varied by IBS subtype. The findings are exploratory and should not be interpreted as definitive evidence of subtype-specific treatment effects.

KEYWORDS: Irritable bowel syndrome; IBS subtype; Numeric Pain Rating Scale; homoeopathy; centesimal potency; LM potency; secondary analysis.

INTRODUCTION

The Irritable bowel syndrome is a disorder of gut–brain interaction in which recurrent abdominal pain occurs alongside changes in stool frequency or form. Diagnosis relies on symptom-based criteria, including the Rome framework, after appropriate clinical assessment [1,2]. IBS is not a uniform presentation: bowel habits are used to distinguish constipation-predominant IBS (IBS-C), diarrhoea-predominant IBS (IBS-D), and mixed IBS (IBS-M) [2].

Current understanding of IBS describes a multifactorial condition involving bowel motility, visceral sensitivity, gut microbiota, immune processes, psychosocial influences, and communication between the gut and brain [3,4,5]. These overlapping factors contribute to clinical variability. Reporting outcomes by subtype can therefore be useful for describing patterns and generating hypotheses, although small subgroup samples make estimates less precise.

Complementary and alternative approaches, including homoeopathy, have been studied in people with IBS. Reviews of the literature have noted limitations in the amount and quality of available evidence, and further well-designed research is needed before firm conclusions can be drawn [6,7,8]. Clinical studies have also examined individualized homoeopathic treatment and other homoeopathic interventions in IBS [9,10,11].

The parent randomized trial compared individualized treatment using centesimal and LM potency scales. The present secondary analysis focuses on a narrower question: whether the observed pattern of abdominal pain reduction differed descriptively among IBS-C, IBS-D, and IBS-M participants in the two treatment groups. The analysis uses existing clinical outcomes; it did not measure genetic, genomic, microbiome, inflammatory, or other molecular biomarkers [12,13,14,15].

MATERIALS AND METHODS

Study design and participants

This was a descriptive secondary analysis of data collected during a single-blind randomized controlled trial of individualized homoeopathic treatment for IBS. The analysed sample comprised 52 participants: 26 assigned to the CM

group and 26 to the LM group. The parent study used Rome IV-based clinical classification and followed participants for approximately three months. For the present analysis, participants were categorized as IBS-C, IBS-D, or IBS-M.

Treatment groups

Participants in the CM group received individualized homoeopathic medicines in centesimal potencies, with progression from 30C to 200C and 1M according to clinical response. Participants in the LM group received individualized medicines using the LM potency scale, beginning at LM 0/1 and progressing according to the study protocol and clinical response. Treatment was individualized in both groups. This secondary analysis was not designed to compare individual remedies or isolate the effect of any specific medicine.

Outcome measure

Abdominal pain was assessed with the Numeric Pain Rating Scale (NPRS), ranging from 0 to 10. Pain reduction was calculated as:

Pain reduction = pretreatment NPRS – post-treatment NPRS

A larger positive value represents a greater decrease in the reported pain score. The NPRS is used in clinical pain assessment, although the interpretation of score changes depend on the clinical setting and population [12].

Statistical analysis

Participant counts, means, and standard deviations were summarized by treatment group and IBS subtype. The difference between group means was calculated as the LM mean minus the CM mean. An exploratory linear model included treatment group, IBS subtype, and their interaction. The interaction term was used to assess whether the treatment-group difference appeared to vary across subtypes. Given the small subgroup sizes, this analysis was considered exploratory; the results should not be treated as definitive evidence of subtype-specific efficacy.

Ethical considerations

The parent study received approval from the Institutional Ethics Committee of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital, Pune (Protocol No. BVDUHCMC/2024/03; 10 July 2024). Written informed consent was obtained from participants. The parent trial was registered with the Clinical Trials Registry–India (CTRI/2024/11/077304). Institutional confirmation that the approved consent and protocol cover this secondary analysis should be obtained before submission if required by the institution or target journal.

RESULTS

Distribution of participants by IBS subtype

The analysis included 52 participants. IBS-M was the most common subtype (24/52; 46.15%), followed by IBS-C (18/52; 34.62%) and IBS-D (10/52; 19.23%). Each subtype was represented equally in the two treatment groups.

Table 1. Distribution of participants by IBS subtype and treatment group

IBS subtype	CM group, n	LM group, n	Total, n (%)
IBS-C	9	9	18 (34.62)
IBS-D	5	5	10 (19.23)
IBS-M	12	12	24 (46.15)
Total	26	26	52 (100)

The equal subtype distribution across groups supports a straightforward descriptive comparison. Nevertheless, the number of participants in each subgroup—especially IBS-D—was small and limits the precision of the estimates.

Pain reduction by IBS subtype

In the CM group, mean pain reduction ranged from 3.00 to 3.17 NPRS points. In the LM group, subgroup means ranged from 4.75 to 5.20 points. The LM group had a higher mean reduction in each of the three subtypes.

Table 2. Mean NPRS pain reduction by IBS subtype

IBS subtype	CM (n)	CM mean ± SD	LM (n)	LM mean ± SD	Difference (LM – CM)
IBS-C	9	3.00 ± 0.71	9	4.78 ± 0.67	1.78
IBS-D	5	3.00 ± 1.00	5	5.20 ± 0.84	2.20
IBS-M	12	3.17 ± 0.72	12	4.75 ± 0.62	1.58

Values are NPRS points. Differences are descriptive differences between subgroup means.

For IBS-C, the mean reduction was 3.00 points in the CM group and 4.78 points in the LM group, a difference of 1.78 points. For IBS-D, the corresponding values were 3.00 and 5.20 points, a difference of 2.20 points. For IBS-M, they were 3.17 and 4.75 points, a difference of 1.58 points. Although the numerical difference was largest in IBS-D, only five participants per treatment group were included in that subgroup. This estimate may be strongly influenced by individual observations and should not be interpreted as proof of a stronger response in IBS-D.

Treatment-group-by-subtype interaction

In the exploratory factorial model, the treatment-group main effect was statistically significant ($F(1,46) = 77.12, p < 0.001$). The main effect of subtype was not statistically significant ($F(2,46) = 0.27, p = 0.763$). The treatment-group-by-subtype interaction was also not statistically significant ($F(2,46) = 0.64, p = 0.534$).

The interaction result means that this analysis did not identify statistical evidence that the difference in mean pain reduction between treatment groups varied by subtype. It does not demonstrate equivalence between subtypes, nor does it prove that the treatment-group difference is identical across them.

DISCUSSION

This secondary analysis described pain reduction by IBS subtype among participants receiving individualized homeopathic treatment in CM or LM potencies. Mean NPRS reduction was numerically higher in the LM group across IBS-C, IBS-D, and IBS-M. The descriptive between-group differences ranged from 1.58 to 2.20 points.

The purpose of the present analysis was to explore how the observed outcome was distributed across subtypes, rather than to repeat the parent trial's overall treatment comparison. The subgroup pattern was directionally similar across the three clinical presentations. However, the treatment-group-by-subtype interaction was not statistically significant; the data therefore do not provide evidence that IBS subtype modified the difference between groups.

IBS is a heterogeneous condition involving multiple interacting physiological and psychosocial processes [3,4,5]. Subtype-based reporting may help researchers identify questions for future studies, but the small sample in this analysis limits the conclusions that can be drawn. The IBS-D subgroup contained only five participants in each treatment arm, making its mean especially uncertain. A larger study with a prespecified sample-size calculation for interaction testing would be needed to assess whether subtype modifies outcomes with adequate precision.

These findings should be viewed alongside the broader evidence on homeopathy for IBS. Previous clinical studies and systematic reviews have described limitations in the evidence base, including small samples and methodological uncertainty [7,8,9,10,11]. The present analysis is a descriptive use of data from one randomized trial. It does not independently establish efficacy, resolve wider evidence limitations, or identify a biological mechanism.

No genetic, genomic, microbiome, inflammatory, or other molecular outcomes were collected for this analysis. Accordingly, the findings cannot be used to infer genetic susceptibility, molecular pathways, or biological explanations for the observed clinical pattern. Investigating clinical-molecular associations would require suitable biological samples, validated laboratory methods, prespecified outcomes, and a study design appropriate to those questions.

Strengths and limitations

The analysis describes outcomes using the same pain scale across three clinically defined IBS subtypes, and the subtype counts were balanced between treatment groups. Important limitations include its secondary and exploratory nature, small subgroup sizes, particularly for IBS-D, reliance on a subjective pain score, single-centre setting, and follow-up of approximately three months. The analysis was not prospectively powered to test whether subtype modifies treatment response. It also cannot establish a mechanism of action or separate the influence of potency scale from other elements of individualized care.

CONCLUSION

In this descriptive secondary analysis of 52 participants with IBS, mean NPRS pain reduction was numerically greater in the LM group than in the CM group across IBS-C, IBS-D, and IBS-M. The treatment-group-by-subtype interaction was not statistically significant. The findings should be interpreted as exploratory and do not establish subtype-specific treatment effects. Larger, prospectively planned studies are needed to determine whether IBS subtype meaningfully modifies clinical outcomes.

DECLARATIONS

Ethics approval and consent to participate: The parent study received approval from the Institutional Ethics Committee of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital, Pune (Protocol No. BVDUHCMC/2024/03; 10 July 2024). Written informed consent was obtained from all participants.

Trial registration: Clinical Trials Registry–India: CTRI/2024/11/077304.

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Conflicts of interest: The authors declare that they have no competing interests.

Data availability: The data used in this secondary analysis are derived from the parent clinical study. De-identified data may be requested from the corresponding author, subject to institutional approval, participant-consent conditions, and applicable data-sharing requirements.

Author contributions: PP: conceptualization of the secondary analysis, data organization, interpretation, and drafting of the manuscript. SM: academic supervision, critical review, and revision of the manuscript. Both authors should review and approve this contribution statement and the final manuscript before submission.

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