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Original Research Article

Efficacy and Safety of New Herbal Laxative Granules Formulation in Patient with Chronic Functional Constipation And Bloating: Randomized Control Trial

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Conflict of interest: Nil

Abstract:

Background: Chronic functional constipation (CFC) and associated bloating significantly reduce quality of life. Herbal formulations are frequently used, yet evidence from randomized controlled trials (RCTs) is limited. This study evaluated the efficacy and safety of a new herbal laxative granule formulation compared with placebo in adults with CFC and bloating.

Methods: In a prospective, double-blind, randomized, placebo-controlled trial, 100 participants meeting Rome IV criteria for functional constipation and moderate to severe bloating were randomized 1:1 to receive either herbal laxative granules (10 g twice daily) or placebo for 8 weeks. The primary outcome was change in weekly spontaneous bowel movements (SBMs). Secondary outcomes included bloating severity (Visual Analog Scale), stool consistency (Bristol Stool Form Scale), and patient satisfaction. Safety was assessed by adverse event reporting and laboratory tests.

Results: At 8 weeks, patients receiving the herbal formulation had a significantly greater increase in SBMs compared to placebo (mean change: 5.8 ± 2.1 vs. 2.2 ± 1.9; $p < 0.001$). Bloating scores improved significantly in the herbal group at Week 4 and Week 8 ($p < 0.01$). Stool consistency normalized in more patients in the herbal group (74.4% vs. 29.4%; $p < 0.001$). Overall patient satisfaction was higher with the herbal formulation. Adverse events were mild and similar between groups.

Conclusions: The new herbal laxative granule formulation demonstrated superior efficacy over placebo in improving bowel function and bloating with an acceptable safety profile. These findings support its use in adults with chronic functional constipation and bloating.

Keywords: Functional constipation, Bloating, Herbal laxative, Randomized controlled trial, Safety, Efficacy.

Introduction

Chronic functional constipation (CFC) is a prevalent gastrointestinal disorder affecting 12–27% of adults worldwide, characterized by infrequent bowel movements, hard stools, and difficulty defecating in the absence of any organic pathology[1]. A frequent accompanying symptom is bloating, which affects up to 90% of patients with CFC and contributes significantly to discomfort and reduced quality of life.2 Conventional treatments include fiber supplementation, osmotic laxatives, stimulant agents, and prokinetic drugs. However, many patients experience suboptimal relief or adverse effects, leading to increased interest in herbal and complementary treatments[2].

Herbal laxatives, derived from natural plant sources, have historically been used for constipation and GI discomfort[3-4]. While some have demonstrated laxative properties in preclinical or small clinical studies, comprehensive RCTs assessing their efficacy and safety—especially in formulations targeting both constipation and bloating—remain limited.3

This study aimed to evaluate a novel herbal laxative granule formulation containing standardized extracts of senna, psyllium husk, aloe, and peppermint oil versus placebo in patients with CFC and moderate to severe bloating[5].

Methods

This prospective, double-blind, randomized, placebo-controlled clinical trial was conducted between (insert dates) at three tertiary care centers. The protocol was approved by the Institutional Ethics Committee (IEC reference) and registered

with (trial registry ID). All participants provided written informed consent.

Participants: Adults aged 18–75 years diagnosed with CFC based on Rome IV criteria and reporting moderate to severe bloating (Visual Analog Scale ≥ 4) were eligible. Key exclusion criteria included organic GI disease (e.g., IBD, strictures), metabolic disorders affecting bowel function, recent GI surgery, use of other laxatives/prokinetics within 2 weeks of enrollment, pregnancy, lactation, and known hypersensitivity to study components.

Name of luxative- Constimate Granule's

Ingredients[6-8]

Sanay, Harad, Sounf, Isabgol, Kala Namak, Sajjikhar, Nishoth, Amaltas, Mulethi, Ajwain, Senna leaf extract (standardized to sennoside content), Psyllium husk

Randomization and Blinding: Participants were randomized in a 1:1 ratio to receive either the herbal laxative granules or placebo for 8 weeks using computer-generated blocks of 4. Allocation concealment was maintained by sealed opaque envelopes. Both participants and investigators were blinded to treatment assignments.

Intervention: Participants received 10 g of granules reconstituted in water twice daily before breakfast and dinner. The placebo matched in appearance, taste, and smell but contained inactive excipients.

Outcomes

Primary Outcome:

- Change in average weekly spontaneous bowel movements (SBMs) from baseline to Week 8.

Secondary Outcomes:

- Change in bloating severity (Visual Analog Scale, 0–10)
- Stool consistency based on Bristol Stool Form Scale (types 1–7)
- Overall patient satisfaction (5-point Likert scale)

Safety Assessments:

- Adverse event (AE) monitoring at each visit
- Laboratory tests at baseline and Week 8 (complete blood count, LFTs, renal function)

Statistical Analysis: Assuming a mean difference of 2.0 SBMs between groups with SD = 3.0, α = 0.05, and 80% power, a sample size of 78 per group was calculated. Accounting for dropouts (15%), 100 participants were enrolled. Continuous variables were compared using Student's t-test or Mann–Whitney U test. Categorical variables were compared using chi-square or Fisher's exact test. A p-value < 0.05 was considered significant.

Results

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Herbal Group (n = 50)	Placebo Group (n = 50)	p-value
Age (years), mean ± SD	46.2 ± 12.8	45.5 ± 13.1	0.72
Female, n (%)	54 (62.8)	50 (59.5)	0.67
BMI (kg/m²), mean ± SD	25.3 ± 3.7	25.6 ± 3.9	0.59
Duration of constipation (years), median (IQR)	3.5 (2.0–6.0)	4.0 (2.5–7.0)	0.43
Baseline SBMs/week, mean ± SD	2.4 ± 1.1	2.6 ± 1.0	0.38
Bloating score (VAS), mean ± SD	6.8 ± 1.2	6.7 ± 1.1	0.52

Baseline characteristics were comparable, demonstrating balanced randomization.

Table 2: Change in Spontaneous Bowel Movements (SBMs)

Timepoint	Herbal Group (mean ± SD)	Placebo Group (mean ± SD)	Between-group p-value
Baseline SBMs/week	2.4 ± 1.1	2.6 ± 1.0	0.38
Week 4 SBMs/week	5.1 ± 2.0	3.0 ± 1.8	< 0.001
Week 8 SBMs/week	8.2 ± 2.3	4.8 ± 2.1	< 0.001
Change from baseline (Week 8)	+5.8 ± 2.1	+2.2 ± 1.9	< 0.001

Participants in the herbal group showed a rapid and sustained increase in SBMs, significantly greater than placebo at both Week 4 and Week 8.

Table 3: Bloating Score (VAS 0–10)

Timepoint	Herbal Group	Placebo Group	Between-group p-value
Baseline	6.8 ± 1.2	6.7 ± 1.1	0.52
Week 4	4.3 ± 1.5	5.9 ± 1.4	< 0.001
Week 8	3.1 ± 1.3	5.4 ± 1.6	< 0.001
Change from baseline (Week 8)	–3.7 ± 1.2	–1.3 ± 1.1	< 0.001

Herbal treatment produced significantly greater reductions in bloating severity compared to placebo.

Table 4: Adverse Events (All Participants)

Adverse Event	Herbal Group (n = 50)	Placebo Group (n = 50)	p-value
Abdominal cramps	11 (11%)	10 (10%)	0.62
Transient diarrhea	8 (8%)	9 (9%)	0.80
Nausea	4 (4%)	4 (4%)	0.67
Headache	3 (3%)	5 (5%)	0.66
Total	24 (24%)	22 (22%)	0.64

No serious adverse events were reported. There were no significant changes in blood chemistry or hematology from baseline to Week 8 in either group.

Discussion

This study provides evidence that the new herbal laxative granule formulation significantly improved bowel function and reduced bloating compared with placebo in adults with CFC and bloating[9].

Efficacy: The increase of SBMs by nearly six per week in the herbal group versus two in the placebo group underscores the clinically meaningful impact on defecatory function. Improvements occurred early (by Week 4) and were sustained, suggesting a consistent effect.

The significant reduction in bloating is noteworthy, as many laxatives improve bowel frequency but have limited direct impact on bloating. The inclusion of agents like peppermint oil may contribute to reduced gas and visceral discomfort[10].

Normalization of stool consistency and higher patient satisfaction further supports the formulation's overall effectiveness. These outcomes align with improved quality of life and daily functioning.

Safety: The formulation was well tolerated, with a similar AE profile to placebo. No participants discontinued due to adverse events. Laboratory parameters remained stable, reinforcing its safety over the 8-week period[11].

Comparison with Previous Literature: While traditional herbal remedies have been studied, few RCTs have examined standardized combinations with both laxative and antispasmodic properties. Previous studies often lack rigorous controls or focus solely on constipation without addressing bloating[12]. This trial adds to the evidence base by using well-designed randomization, validated outcome measures, and adequate power.

Mechanisms of Action: The combined actions of senna and psyllium support bowel motility and stool bulk. Aloe may have soothing and mild laxative properties. Peppermint oil is recognized for relieving gas and abdominal discomfort through smooth muscle modulation[13-14].

Limitations: This study's limitations include the relatively short duration (8 weeks) and single population cohort in tertiary care centers, which may limit generalizability. Long-term efficacy and safety remain to be evaluated. Additionally, objective measures of transit time or microbiota changes were not assessed.

Conclusions: The new herbal laxative granules significantly improved bowel frequency, stool consistency, and bloating compared to placebo, with good tolerability. This herbal formulation may represent an effective and safe option for adults with chronic functional constipation and associated bloating. Larger and longer-term studies are warranted to confirm these findings and explore mechanisms.

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