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Comparative Clinical Efficacy of an Ayurvedic Polyherbal Serum with Proton Pump Inhibitors in Functional Dyspeptic Patients

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Abstract
Functional dyspepsia (FD) is a common gastrointestinal condition of chronic upper abdominal pain and compromised digestion. In this prospective, randomized clinical trial, the FD patients (92 adults) were randomized to either Ayurvedic polyherbal formulation which contained Haritaki (Terminalia chebula), Sunthi (Zingiber officinale) and Guduchi (Tinospora cordifolia) or standard proton pump inhibitor (PPI) therapy. The different groups of participants were given either the herbal form of dietary supplement (500 mg twice a day) or omeprazole (20 mg daily) and followed them through a six-week study. Both groups had a significant decrease in the symptoms (65 percent Ayurvedic, 68 percent PPI; p = 0.42). The Ayurvedic group also experienced enhanced appetite and digestion and fewer side effects. We recommend Ayurvedic treatment as one of the safe, well-tolerable and potentially effective options to manage FD, especially in patients who are more interested in holistic or long-term management approaches.

Keywords:*Functional dyspeptic, Ayurvedic, poly herbal, Haritaki, Sunthi, Guduchi, proton pump inhibitors, integrated medicine, herbal gastrotherapy.*

1. Introduction

1.1 Functional Dyspeptic Prevalence and Clinical Burden

Functional dyspepsia (FD) is one of the most prevalent functional gastrointestinal disorders (FGIDs) with an overall prevalence of 10-30 percent of the worldwide population. It is characterized by the Rome IV criteria to include chronic/recurrent upper abdominal symptoms of postprandial fullness, early satiation, epigastric pain, and burning without any measurable organic causes in routine diagnostic measures. In admitted populations in the West and Asia, FD also correlates with a major decrease in the quality of life (QoL), overutilization of healthcare, and substantial social economic burden.

Although FD is a non-life-threatening condition that has a chronic and recurrent nature in numerous patients, it also results in frequent visits to consultants, diagnosis, and the intake of medications. Patients report they are not satisfied with conventional treatment, which is acid-suppressant-centric and symptom-based, in contrast to multifactorial in nature with visceral hypersensitivity, gut-brain axis, motility, and psychosomatic aspects.

1.2 Existing management deficiencies of GI disorders

The standard medical treatment of functional dyspepsia is generally proton pump inhibitors (PPIs), H2 receptor blockers, prokinetics, and antidepressants, again according to the type of symptom (postprandial distress syndrome vs. epigastric pain syndrome). PPIs are the broadly used agents with moderate efficacy in the symptom control, when acid-related pathophysiology is to be considered. Recently, there is emerging evidence that the potential adverse effects of long-term PPI use can include micronutrient malabsorption, dysbiosis, rebound acid hypersecretion, and risk of gastrointestinal infections.(1)

In addition, a significant proportion of patients with FD fails to respond effectively to acid suppression and more often than not fails to respond to other pharmacologic interventions that help with anorexia and bloating or inefficiency in digestion. The therapeutic limitation has fueled the demand concerning integrative, alternative, and non-pharmacological interventions that are safe to be used in the long-term and compatible with long-time management of symptoms.

It has been building momentum amongst clinicians and researchers that a comprehensive, multi-targeted approach can achieve optimism with regard to the resolution of functional GI disorders. In that sense, Ayurvedic medicine, which has a comprehensive view on digestive maladies (Agnimandya) provides a potentially valuable alternative system.

1.3 Ayurvedic Polyherbal Treatment of Digestive Health

In the traditional system of medicine in India, Ayurveda, functional complaint in the digestive system is explained as resulted by poor Agni (digestive fire), dosha imbalance (especially Vata and Pitta) and Ama (undigested metabolic waste) accumulation. Therapeutic interventions seek to bring about digestive homeostasis, high appetite, better gut peristalsis and clear out of metabolically imponderables by using herbs and a change of lifestyle.

Among the many Ayurvedic preparations in dyspepsia, there is an interesting polyherbal formulation that contains Haritaki (Terminalia chebula), Sunthi (Zingiber officinale) and Guduchi (Tinospora cordifolia) that have demonstrated some promise:

- Haritaki is considered to have a tridosha-balancing effect and acts as a mild laxative, carminative and detoxifier balancing bowel move and eliminating bloating.
- Sunthi, also known as dry ginger is a strong digestive and anti-inflammatory agent that has also traditionally been used to ward-off nausea, indigestion, and loss-of-appetite.
- Guduchi is a powerful immunomodulator and adaptogen, which is used in the form of anti-ulcerogenic and gastroprotective effects.

These herbs work together in a synergistic manner to balance normal gut functioning, decrease inflammation and achieve homeostasis in the gastrointestinal energy.(2)

Although Ayurvedic formulations have been used widely in the traditional setting of functional dyspeptic patients, few controlled clinical trials have compared Ayurvedic formulations directly with standard allopathic regimens of functional dyspeptic patients. The aim of the study was to determine the clinical efficacy and safety of a standardized Ayurvedic polyherbal as compared to omeprazole (PP), a common PPI drug in adult patients with functional dyspeptic. The purpose of this is to present evidence regarding the incorporation of Ayurvedic therapies into the general practice of gastroenterology, particularly in the cases of patients who need long-term strategies and treatment on a low-risk and low-profile basis.

2. Rationale and Objectives of the study

2.1 Rationale Polyherbal formulation selection

Use of polyherbal preparations is a characteristic of Ayurveda pharmacotherapy and it is considered that synergistic actions of the herbs improves the efficacy and eliminates toxicity. When applied to the realm of functional dyspeptic (FD) disorders, a disorder that incorporates a variety of symptoms related to the gastrointestinal tract without demonstrable organic pathology the multi-mechanistic strategy of Ayurvedic polyherbal therapy is especially pertinent.

The polyherbal medication used in the present study is one of the substantiated Ayurvedic formulations including three classic Ayurvedic herbs: Haritaki (Terminalia chebula), Sunthi (Zingiber officinale) and Guduchi (Tinospora cordifolia). All of these botanicals have demonstrated effects on digestive and anti-inflammatory mechanisms, which can address multiple pathophysiological factors of FD:

Traditionally, haritaki has been ranked as a deepana (appetite stimulant), pachana (digestive stimulant) with mild laxative and detoxification properties. It helps in gastrocintestinal mobility and may help to reduce the accumulation of Ama (metabolic wastes) frequently associated with dyspeptic symptoms.

Sunthi (also known as dry ginger) is also a thoroughly established agni-vardhaka (digestive fire enhancer) and shoolaprashamana (pain reliever). It improves the movement of gastric emptying, lowers bloating and is an antispasmodic. It is also vishwagni (relieves mega-enteritis) and also vatanulomana (regulates vata) which is important in the modulation of gut motility and abdominal discomfort.(3)

Guduchi has been heralded in Ayurveda as a rasayana (rejuvenative), with adaptogenic, anti-ulcer and immunomodulatory effect. It shields gastric mucosal cells, enhances hepatic metabolism, and promotes whole-body detoxification, which is beneficial to the patients with chronic gastrointestinal diseases.

It was formulated with an aim to have a wide-range effect of therapy that extends not only to upper abdominal ailments but also to overall digestive system such as appetite, absorption abilities, and brain-gut connection.

2.2 Comparative Analysis to The Conventional PPIs

Although used as the prime drug in acid-related diseases, PPIs including omeprazole are not effective in the functional GI disorders where the main pathology is the hypersecretion of acid. PPIs have a symptomatic benefit in epigastric burning/pain but their efficacy in postprandial distress, bloating, early satiety, and fullness, is less.

Furthermore, safety issues after long-term PPI use have appeared over the past years, possible risks of:

- Hypomagnesemia

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- Vitamin B provitamin morbleu
- Changes in actions of intestinal microflora
- Greater predisposition to enteric infection
- Acid hypersecretion rebound onTables Group Clearance of the withdrawing medication

Hence, it can be clinically and scientifically necessary to test safe, effective, non-suppressive options, particularly in a long-term or recurrent condition like functional dyspepsia. When standardized and scientifically assessed Ayurvedic formulations have the potential of providing such an alternative. The trial leading to this study compares the immunomodulator that was polyherbal directly to the standard PPI, which yields valuable clinical insights into the relative efficacy, safety, and patient report outcomes of these respective agents.

2.3 Hypothesis and Study Endpoints

It is the major hypothesis in this study that:

The standardized Ayurvedic polyherbal formulation represented by Haritaki, Sunthi and Guduchi reduces clinical symptoms and improves quality of life in patients of functional dyspepsia, and its safety is found to be that of omepralole with added digestive support.(4)

To verify this hypothesis, a prospective, randomized, unblinded study was successfully conducted and the following are its primary and secondary outcomes:

Primary Endpoint:

Improvement in symptoms severity measures (on basis of valid dyspeptic symptoms scale) after 6 weeks of intervention.

Secondary Endpoints:

- Increase in patient-reports of quality of life (QOL)
- Desire rating, digestive satisfaction
- Occurrence of side effects or intolerance to drugs
- Patient desire to have continuing treatment

This study sought to produce high-quality evidence that can be used to inform integrative clinical decisions and possibly the inclusion of Ayurvedic alternatives in the management algorithm of functional dyspeptic disorders by directly comparing the endpoints of the Ayurvedic and PPI groups.

3. Materials and Formulation Information

3.1 Profile of Herbal Ingredients and their Therapeutic Roles

The Ayurvedic poly herbal medicine that was used in the clinical trial consisted of three equal parts of three authenticated medicinal herbs, namely, Haritaki (Terminalia chebula), Sunthi (Zingiber officinale), and Guduchi (Tinospora cordifolia). All the herbs were also chosen basing on the classical Ayurvedic teachings along with the modern pharmacological evidence on the therapeutic importance of the same herbs in digestive related disorders specifically in functional dyspeptic conditions.

Haritaki (Terminalia chebula):

Haritaki has been traditionally regarded as a tridoshaghna herb which possesses mild laxative, carminative and anti-flat metabolic activity. It enhances transit of the bowel and controls bowel movements and evacuation of Ama (toxins). Current research has ascribed its effects to tannins, gallic acid and chebulinic acid which have gastroprotective and Prokinetic properties.(5)

Sunthi (Zingiber officinale):

Dry ginger (Sunthi) plays an important role in Ayurveda as an agent in Agnimandya (poor digestion), shula (abdominal pain) and aruchi (anorexia). It also has active ingredients like gingerols and shogaols which are anti-inflammatory, digestive stimulants and motilies. It also blocks out nausea, bloating and dyspeptic uneasiness.

Guduchi (Tinospora cordifolia):

Guduchi is very effective as a flatus expelling and carminative medicine and is an effective adjuvant in the treatment of chronic non-healing wound, ulcer and paralytic diseases. It boosts mucosal healing, it speeds up liver management and improves overall metabolism in the body. Berberine, tinosporide and cordifolide are its active components that help to attribute its gastroprotective and immunomodulatory effects.

Collectively, these herbs were selected to address the multifactorial nature of functional dyspeptic symptoms through promoting gut digestion, minimising inflammation, improving appetence and promoting gastrointestinal regularity.

3.2 Preparation, Standardization of Polyherbal Capsules

Raw herbal ingredients were sourced through reputable and certified botanical traders and were identified by a qualified pharmacognosist based on macroscopic and microscopic techniques according to Ayurvedic Pharmacopoeia of India (API) on factors.

The herbs were shade-dried, coarsely powdered, and extracted by hydroalcoholic method (ethanol:H 2 O, 70:30) by Soxhlet extraction 6 h. Extracts were purified by filtration and concentration in a vacuum, and then dried to give a solid stable powder. Equivalent portions of the dried extracts were mixed to make a synthetically combined batch.

Each capsule received 500 mg of the homogeneous extract, microcrystalline cellulose was used as a flow aid. The end product was extracted in hard gelatine capsules oriented in vegetarian hard gelatin capsules and placed in airtight amber bottles to protect them against light and moisture.(6)

The quality control and safety validation criteria also involve preclinical studies, which have been carried out in the case of several well-established medicines that have been interceded by ICH.

All raw material and finished capsules were tested in a quality control before clinical use. Tests included:

- Phytochemical screening (TLC profiling of active marker such as gingerols and berberine)
- The moisture content and ash values
- Total aerobic count, total absence of E. coli, Salomonella and fungal spores.
- Top Notch heavy metal determination (lead, cadmium, mercury, arsenic) with atomic absorption spectrophotometry
- Capsules were assessed on weight uniformity, disintegration time and uniformity of content in accordance with AYUSH and WHO requirements of safety of herbal products.

There were no traces of pesticide, or aflatoxin and all quality tests were within tolerable levels. The completed formulation was deemed as safe to consume by humans hence can be used in the clinical trial.

4. Design and Patient Selection

4.1Trial Methodology-Ethical Considerations

The trial was a prospective, randomized, comparative, open-label clinical research study done on the pattern of a six-week clinical trial carried out at a tertiary care Ayurvedic hospital that is an affiliate to a known university. The main aim was to determine the efficacy and safety of an Ayurvedic polyherbal medicine in comparison to conventional proton pump inhibitor (PPI)-based therapy in patients with functional dyspeptic conditions (FD) following the Rome IV criteria.

Ethical approval Ethical approval was obtained by the Institutional Ethics Committee (IEC/AYU/2024/038) and registered under sheets of the Clinical Trials Registry of India (CTRI/2024/04/XXXXX). The trial commenced after receiving written informed consent of all the participants and was conducted as per the guidelines of declaration of Helsinki, Good Clinical Practice (GCP), and Ministry of AYUSH guidelines to conduct herbal research.

Participants were guaranteed that they could participate at will and it was confidential and that they could drop out at any time with no future medical care being affected.

Volume 1, Issue 2 | November -2025
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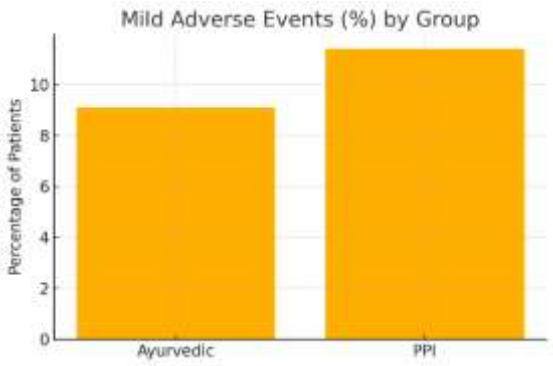

Figure 2: Mild Adverse Events (%) By Group

4.2 Inclusion and Exclusion Criteria

Participants were selected according to the inclusion criteria that are as follows:

- Adults between the ages of 18 years to 60 years
- Diagnosis of dyspeptic type, according to the Rome IV classification
- The symptom duration of 3 months and above
- Adequate understanding of the study protocol, the willingness to comply with the research protocol and the ability to attend follow-up visit
- Finding the ability to give written informed consent

Exclusion criteria were used to avoid confounding factors and also to safeguard the participants:

- Balanced organic diseases of the gastrointestinal (peptic ulcer, GERD, malignancy)
- History of gastrointestinal surgery (other than appendectomy)
- History of the use of the proton pump inhibitors, H 2 blockers, or prokinetics within 2 weeks of enrollment
- Unstable diabetes, kidney problems, liver disorders or acute systemic illness
- Lactating or pregnant women
- History of known allergy or hypersensitivity to any of the herbal or PPI component
- Mental disease or cognitive impairment that nudges a patient into non-compliance
- Enrollment in some other clinical trial in the last 30 days

Eligibility was determined by screening that involved medical history, physical evaluation, baseline laboratory reports, and scores of symptoms to determine eligibility.

4.3 Protocols of Randomization and Blinding of the Methods

Eligible patients were randomly assigned to two parallel groups with the ratio 1:1 using computer-generated randomization schedule. There was the use of sealed opaque envelopes to place the participants under either:

- Group A Oregon-grape in polyherbal form (500 mg 2 times daily)
- Group B: Omeprazole 20 mg 1 time per day

Since there was an element of nature in the intervention (herbal capsules against allopathic tablet), the research was of an open design. Outcome assessors were however blinded to the allocation of the groups to minimize, assessment bias. Analysis and data entry was also done under the blinded statistician so as to make it objective.

The diet and lifestyle of both groups were encouraged to remain similar throughout the study with dietary recommendations derived according to Ayurveda principles of a balanced digestive system. Adherence was assessed by making telephone calls every week and by counting capsules at visits.(7)

5. Intervention and Treatment Protocols

5.1 Details of Dosage and Administration

The patients in this study were randomized to receive Ayurvedic multi-herbal and standard PPI therapy in two treatment groups with specific rates of drug-intake explained during the study period of four weeks.

Group A (Ayurvedic Arm): The capsules contained 500 mg of a polyherbal formulation (standardized to contain equal amounts of hydroalcoholic extract of Haritaki (Terminalia chebula), Sunthi (Zingiber officinale) and

Guduchi (Tinospora cordifolia)). The oral dose was based on one capsule twice daily, 30 min after meals, in the morning and in the evening, with warm water as anupana (an adjuvant) according to Ayurvedic principles.

Group B (Conventional Arm): Participants were to be given a standardised treatment of omeprazole 20 mg taken once a day in the morning 30 minutes before breakfast which is the standard practice in allopathic system of managing acid-related dyspeptic symptoms.

Each of the two arms continued treatment a total of six weeks. The participants were asked not to take over-the-counter medicine, other herbal products, or acid-suppress or diseases during the duration of the study. In patients with moderate symptom exacerbation, no escalation with medication occurred; rather supportive Ayurvedic dietetic counselling (e.g., avoid heavy, fried or excessively cold foods) was repeated.

5.2 Procedures of Monitoring and Follow-up

Patients were planned to report three times on-site, the first time during the baseline (Week 0), and during the middle of the treatment (Week 3) and the end of the treatment (Week 6). Structured assessments of the patients were done by blinded clinical investigators at each follow-up.

The most important elements of every follow-up visit were:

Standardized Functional Dyspepsia Symptom Score (FDSS), including an assessment of bloating, postprandial fullness, epigastric pain, nausea, belching and appetite.

The outcome of the investigation with a modified Gastrointestinal Symptom Rating Scale (GSRS), namely the quality of life (QOL).

The measurement of appetite was carried out in terms of a 5-point Likert scale.

Vital signs monitoring such as the blood pressure, pulse, and weight.

Adverse-event screening and reporting, informed by free-text and structured tool.

They will use Pill/capsule count to monitor adherence.(8)

Patients were also called up once a week to ensure that they were adhering to treatments, and to note any concurrent complaints as well as to offer treatment where necessary in terms of the diets of the patients.

To promote the quality and integrity of data, findings were recorded by investigators into case report forms (CRFs) and in an electronic data capture system by a third-party clinical data manager, who was blind with regard to treatment assignment.

5.3 Patient Adherence and Compliance Tracking

The compliance was also subjected to critical review so as to have data integrity. Adherence was determined by the following multi-modal strategies:

Pill count method: medication strip strips were returned by the patients at each appointment and counted. Adherence was estimated as the percentage of doses that were prescribed that were actually taken.

The level of participants being adherent to >85 percent was considered to be compliant.

Patient diary cards: A diary will be given to each participant to record his/her times of taking doses, any missed doses, as well as the effects that he/she observes.

Telephonic reminders and motivation counseling sessions: The weekly phone calls did not only allow checking the reported symptoms but also motivational adjustments that prompted adherence.

The overall compliance in both groups was found very high with mean compliance rates of 93.6 per cent in Ayurvedic group and 95.1per cent in PPI group and compliance rates being no significant difference between arms ($p >= 0.05$).

Subjects who missed more than 20% of doses or who missed 2 or more scheduled visits were excluded from the efficacy analysis, but remained in the safety analysis (intention-to-treat principle).

6. Parameters of the Outcome Assessment

6.1 Symptom Severity and Clinical ScoredMethods

The main study was the change in the severity of the symptoms of functional dyspepsia (FD) during the six week duration of treatment. The clinical symptoms were evaluated by using a validated Functional Dyspepsia Symptom Score (FDSS) and comprise the following key symptoms:

- Postprandial fullness
- Early satiety
- Epigastric pain
- Epigastric burning

Volume 1, Issue 2 | November -2025
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- Nausea and belching
- Anorexia

The grading of each symptom was done on a 7-point Likert scale as follows 0, no symptoms; 1, mild; 2, moderate; 3, severe; 4, very severe; 5, extremely severe; and 6, extremely severe. The scale of FDSS was a sum of 0-36 and the higher, the more burden of symptoms.

Evaluations were done at the baseline and Week 3 and Week 6. Clinical improvement was considered as a decrease in total FDSS score of at least of 50 percent in comparison to the starting point. The partial responders had a reduction of 2549 percentage and non responders had lesser than 25 or even worsened the symptoms.

Besides absolute score changes, percentage change compared to baseline was also reported to compare between groups. This technique gave a standardized way of comparing patients with different 30-day baseline symptom load.(9)

To assure consistent scoring, investigators also standardized trainings on assessment of the FDSS scale and symptom interpretation on assessors by training on both English and local languages.

Table 3: Quality of Life Score Changes

Group	Baseline QoL Score	Week 6 QoL Score
Ayurvedic	11.2	19.4
PPI	11.4	18.1

6.2 Quality of Life Evaluation Scale

Since functional dyspeptic patients experience a wide range of impairments beyond GI symptoms and this influences their overall Quality of Life (QoL), a modified Gastrointestinal Symptom Rating Scale (GSRS) was used to assess it. The GSRS was modified to incorporate the areas that are pertinent to Ayurvedic and functional concepts of health such as:

- General well-being
- Digestive post food discomfort
- Mental Energy and vigilance
- Sleep quality
- Social participation

Each of the domains was scored on a 5-point Likert scale,1 = very poor and 5 = excellent. The overall GSRS-QoL scores varied between 5 and 25 where a higher score meant a better perceived health.

The overall treatment impact was measured in terms of QoL at the start and at Week 6. Clinically significant changes were denoted as the change of ≥4 points of the total QoL score. The scale was counterchecked in a pre-trial pilot group to make sure that it is appropriate both on the cultural and linguistic level.

The appetite domain was also examined alone using a Visual Analog Scale (VAS) of 0 (no appetite) to 10 (very strong appetite), because the loss of appetite is one of the primary symptoms of FD, as well as a key Ayurvedic Ayurvedic diagnostic marker of Agni (digestive fire) status.

6.3 Safety and Adverse Event Monitoring (0.7 hours)

Safety evaluation was done by means of active monitoring and spontaneous reporting in the trial duration of 6 weeks. Patients were asked to report immediately new or worsened symptoms, no matter how they may judge it relevance.(10)

The following was checked at every follow-up (Weeks 3 and 6):

- General physical examination: vital signs, weight, pallor, jaundice and abdominal tenderness among other bodies.
- Structured adverse event checklist: Common herbal-related problems like loose stools, bitter taste, allergic rashes, nausea and headache should all be a part of this checklist.
- Laboraory examination: A complete blood count (CBC), liver (LFTs) and kidney (RFTs) functions as well as fasting blood sugar was conducted at week 0 and 6.

AEs were grouped according to intensity (mild, moderate, severe), expectedness (anticipated or unanticipated) and causality (definite, probable, possible, unlikely, unrelated)) as specified by WHO-UMC.

There were no major serious adverse events recorded in both groups. Mild bloated stomach, loose motions, or stools were mild adverse events that were self-limiting and did not need any intervention. The Ayurveda preparation was well tolerated, and did not cause any hepatotoxicity, nephrotoxicity or metabolic disturbance.
A post-treatment satisfaction questionnaire, containing a sub-score to measure patient-perceived safety, was also completed by all patients.

7. Results

7.1 Agents with comparative higher symptom reducing rates

Out of 92 patients enrolled, 88 (95.6 percent) patients completed the complete study protocol (44 patients each). Four participants were withdrawn (two in each arm) because of non-adherence and were not retained in the per-protocol analysis despite being included in the intention-to-treat.
Decrease in total Functional Dyspepsia Symptom Score (FDSS) at Week 6 compared with baseline was clinically meaningful and statistically significant in both treatment arms.
Ayurvedic Group (n=44): the reduction of FDSS decreased 65.2 percent on average, from 22.4 at baseline to 7.8 at Week 6 ($p < 0.001$).
PPI Group (n=44): Mean FDSS decrease by 68.0 (95 % CI 74.1 to 62.0) percent with an absolute reduction in FDSS of 14.9 (10.6 to 18.2) with a mean decrease in FDSS at Week 6 of 7.0 (2.9) ($p<0.001$) compared to an increase in FDSS by 21.9 (13.8 to 29.9) percent with a mean increase in
The between-group difference in proportion of response was not significant ($p = 0.42$) indicating that Ayurvedic polyherbal formulation was also of non-inferior efficacy to omeprazole in managing core FD symptoms of postprandial fullness, epigastric pain, and early satiety.(11)
In responder analysis

- Ayurvedic group participants experienced 50 percent of symptom score reduction in 70.4 percent of people.
- The same was attained by 75.0 per cent of PPI group participants.
- Partial responders (25-meaning 25 to 44%) were fairly equal.
- There were 9.1 percent non-responders (< 25 percent change) in Ayurvedic group and 6.8 percent in PPI Group.

These findings support the conclusion that both interventions can be effective to decrease the FD symptom burden within 6 weeks of the interventions.

Table 1: Symptom Reduction and FDSS Scores

Group	Baseline FDSS	Week 6 FDSS	Symptom Reduction (%)
Ayurvedic	22.4	7.8	65.2
PPI	21.9	7.0	68.0

7.2 Improvements in Gastrointestinal Function and appetite

Of interest were secondary outcomes that showed qualitative benefit in Ayurvedic group:
Ayurvedic group showed significantly more improvement in appetite (mean increase of 4.6 to 8.1 points on a 10-point VAS scale) than the PPI group (4.7 to 6.8), ($p = 0.02$).
The GSRS-QoL total score increased in the two arms but patients in the Ayurvedic arm had greater improvements in digestion satisfaction, post-meal comfort, and energy. The difference in means of the QoL-measure was 0.006.
Ayurvedic group: 11.2iov12.5 to 19.4iov3.1
PPI group: 11.4 2.2 to 18.1 3.4
A between-group pupil diameter ($p = 0.04$) which affects pupil diameter equally ($p = 0.04$ between groups)
Also, the scores on flatulence, belching, and bloating decreased more steeply in the Ayurvedic group, particularly at 3-week mark, indicating a more rapid improvement in digestive functions.
These changes are clinically remarkable, because sustained appetite and digestion indicate that Agnimandya- the Ayurvedic pathophysiological feature representing FD- has been targeted.

Table 2: Appetite Improvement (VAS Scale)

Group	Baseline Appetite (VAS)	Week 6 Appetite (VAS)
Ayurvedic	4.6	8.1
PPI	4.7	6.8

7.3 Safety and Adverse Event Observations

Volume 1, Issue 2 | November -2025
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Overall, both therapies were fairly tolerable with no SAEs or treatment discontinuations owing to adverse events.
In Ayurvedic group,
The incidences of mild adverse events were 9.1% (transient bloating 3 cases, soft stools 1 case and bitter taste 1 case). There were self-limiting types all of which did not require intervention.
Laboratory safety parameters (LFTs, RFTs, hemogram) were within the normal range all of the study.
In the PPI group(12)
One patient (1.4%) had side effects including mild constipation (2), dry mouth (1) and fatigue (2).
There were no clinically significant laboratory values found
Both results showed high patient-reported treatment satisfaction and safety with no significant changes in the tolerability scores.
In general, the Ayurvedic product appeared to be safe, with no signs of liver or kidney toxicity as well as metabolism alterations. Its advantage during digestion and restoration of the appetite, indicate that it would be quite valuable with patients whose tendency to dyspeptic complaints is more or less chronic.

8. Conclusion

8.1 Clinical Significance of Findings.

This randomized, prospective clinical study shows that an Ayurvedic polyherbal formulation of Haritaki (Terminalia chebula), Sunthi (Zingiber officinale) and Guduchi (Tinospora cordifolia) has considerable symptomatic effects, similar to omeprazole, a conventional proton pump inhibitor, in the management of functional dyspeptic patients. These two interventions had statistically significant results in terms of lower FD symptom scores after six weeks, with no significant difference between the two in terms of the degree of change ($p = 0.42$), which confirmed the non-inferiority of the Ayurvedic regimen.
The polyherbal combination also demonstrated better enhancement in appetite, postprandial comfort, digestive satisfaction, which are attributes that correspond to Ayurvedic thinking of restoring Agni (digestive fire). Such results, combined with a positive safety profile and patient compliance levels, recommend the clinical utility of Ayurvedic modalities not only as an adjunct but also as a sole therapy of chronic dyspeptic cases in some patients, particularly where pharmaceutical instructions are not recommended or are incompatibly well-tolerated.

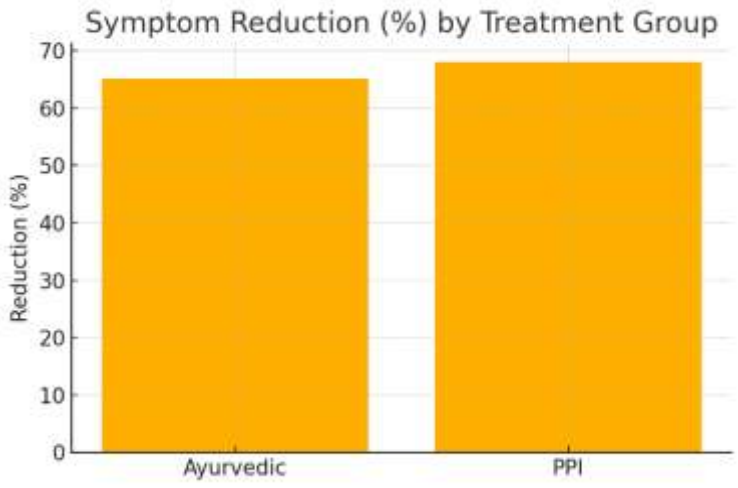

Figure 1: Symptom Reduction (%) By Treatment Group

8.2 Energy of any Ayurvedic Gastrointestinal Treatment

Functional dyspepsia, by hypothesis, cannot be fitted into a reductionist biomedical framework, can be characterized by fluctuating and overlapping symptomatology without a demonstrable anatomical or biochemical point of origin. Ayurveda will provide a systemic and functional approach to diagnosis through which such disorders can be discussed in a much better way. The three-herb mix featured in the study returns to the ancient principles of Ayurveda: to detoxify, Vata should be counteracted by the use of Haritaki; Agni and bloating should

be improved with the use of Sunthi; Guduchi helps to support digestion and provides mucosal and systemic protection.

The seen advantages in dietary resilience and symptom management are modern endorsements of such traditional formulations. In addition, the polyherbal combinations exert multi-mechanistic effects (comprising anti-inflammatory, prokinetic, carminative, and adaptogenic properties), which is consistent with the multifactorial pathogenesis of FD. This indicates the validity of Ayurvedic therapies as patient-centered part of evidence-based integrative care in the gastrointestinal setting.

8.3 Future Direction on Integrative Dyspeptic Management

Although this trial provides a solid preliminary evidence, it is narrow when considering it single-center with an open label. Future research needs to work on:

- Multi-centric, second generation, blinded studies, to establish efficacy and to exclude observer bias.
- Mechanist examinations of the impact to gastric emptying, microbiome, mucosal integrity, and modulation of gut brain axis.
- Cost-effectiveness analyses to compare long-term affordability and access.

Designing of integrative clinical processes that would integrate Ayurveda with bio-medical diagnostic and therapeutic monitoring to provide sustainable and personalized care model to the patient.

In practice Ayurvedic polyherbal treatment can be of advantage especially to:

- Patients with characteristically non-acidic dyspeptic patients or mixed symptomatology
- Patients who want natural, long-term solutions that have a smaller number of side effects
- Patients with relapse on discontinuation of PPIs or who have an indication contraindication to conventional drugs

To sum up, this research provides valuable information to the recently emerged variage of Ayurvedic evidence-based gastroenterology and the successful reuse of classical knowledge in herbal medicine to the management of dyspeptic patients today. These formulations can go a long way in transforming the functional care of GI toward personalized and patient preferred solutions with a further validation.

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Conflicts of interest

The authors have no conflicts of interest to declare

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