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Clinical evaluation of Elle's Udarsudha Ras®, an Ayurvedic Herbal Formulation, in patients with functional dyspepsia

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ABSTRACT

Objectives: An double blind clinical study was initiated to determine if Oral syrup Elle's UdarSudha Ras®, an Ayurvedic Proprietary Herbal preparation. could reduce self-reported functional dyspepsia related gastrointestinal symptoms and improve quality of life (QOL) indicators in patients with functional dyspepsia. Methods: Forty patients with functional dyspepsia were enrolled in this 8 week, placebo controlled, double-blind clinical trial. The present study was conducted at two sites and patients were randomly assigned to either the Elle's UdarSudha Ras® or placebo group. To evaluate the efficacy of Elle's UdarSudha Ras®, the primary endpoint was a score on the total dyspepsia symptom (TDS) scale after treatment. The overall treatment effect functional dyspepsia symptom (FDSS) scale, and functional dyspepsia-related quality of life (FD-QOL) questionnaire. Laboratory tests such as liver function test, renal function test, serum lipid profile and hemogram were performed to establish the safety of the Elle's UdarSudha Ras®. Results: The 8 weeks' administration of Elle's UdarSudha has shown significantly higher reduction in the total dyspepsia symptom (p<0.001) and a significant improvement in the total dyspepsia symptom (p<0.001) than the placebo group. Patients administered with Elle's UdarSudha Ras® had a significantly higher overall treatment effect and a significant increase in the degree of improvement in scores such as epigastric burning, postprandial fullness, early satiation, functional dyspepsia-related quality of life, (p<0.001). Elle's UdarSudha Ras® has not shown any adverse events or side effects during the treatment period. Conclusion: Elle's UdarSudha Ras® treatment results in significant improvement on symptomatic relief in patients with functional dyspepsia and improves overall QoL without any adverse effects.

Keywords: Clinical study, Udarsudha Ras, Dyspepsia.

INTRODUCTION

Functional gastrointestinal disorders (FGIDs) group of disorders characterized by chronic digestive symptoms caused by a disturbance in the interactions of the gastrointestinal (GI) system and the brain which is due to dysfunction in the sensory-motor and immune systems in the gastrointestinal tract[1]. Functional dyspepsia (FD), as one of the FGID which is is associated with dysfunction in the gastroduodenal region and shows symptoms such as early satiety, pain, and fullness in the upper GI tract[2]. This is likely to result in an overall worsening of the productivity and quality of life (QOL) of patients with FD. Proton pump inhibitors, antacids, Histamine receptor-2 antagonists, and prokinetic drugs are most commonly used in the treatment of functional dyspepsia. However, Pharmacologic treatments for patients with functional dyspepsia remain unsatisfactory and might results in various adverse effects such as the atrophic gastritis, increased risk of intestinal infections, bacterial overgrowth in small intestine, and malabsorption of substances such as iron and vitamin B12[3–5]. Thus, complementary or alternative medicine approaches have been used to avoid the adverse effects of drug treatments and improve treatment outcomes[2,6,7]. Ayurvedic Herbal medicines known to have multiple pharmacological effects on functional dyspepsia symptom through different mechanisms and are considered as an appropriate alternative therapy for the management of FD[8]. Ayurvedic Polyherbal formulations are often effective in management of functional dyspepsia symptoms without side effects. The key ingredients of Ayurvedic polyherbal formulation Elle's Udarsudha Ras® (EURS), are standardized and fortified extracts of *Hordeum vulgare*, *Phyllanthus niruri*, *Phyllanthus emblica*, *Terminalia belerica*, *Terminalia chebula*, *Momordica charantia*, *Aloe barbadensis*, *Ocimum canum*, *Ocimum basilicum*, *Ocimum gratissimum*, *Ocimum album*, *Ocimum caryophyllatum*, *Elettaria cardamomum*, *Asparagus racemosus*, *Monetaria moneta* calx and *Asafoetida narthex*. The present clinical trial was designed to establish the clinical efficacy of this phytoconstituents-based product for the management of digestive ailments.

MATERIAL AND METHOD

Trial Design

The present randomized double-blind clinical trial was conducted from August 2023 to December 2023 at Phytoinc Divya Jyothi Clinic and Ganesh Clinic, Bengaluru, INDIA. The present parallel groups study was conducted by allocation ratio of 1: 1. This study protocol was approved by the Ethics Committee of the Shetty's Hospital, Bengaluru, INDIA. (Ethics committee reference number: NIP/01/2023/V1/15May 2023 Version Number 1.0) based on the International Conference on Harmonization (ICH) guidelines and the ethical principles as per Declaration of Helsinki. This clinical study was registered in the Indian Clinical Trials Registry with trial ID number CTRI/2023/07/055451.

Study objectives

The primary objectives of this clinical trial were to assess changes in functional dyspepsia symptoms such as nausea, vomiting, epigastric discomfort, belching, flatulence, heartburn, stomach fullness, abdominal distension, and so on. The adopted scoring system to assess the symptoms was 5-point Likert scale from baseline to end of the intervention. The secondary objectives of the study were to evaluate percentage responders in Elle's UdarSudha Ras® compared to placebo from baseline to end of the intervention, compliance of the subject to the Elle's UdarSudha Ras® treatment. The safety and tolerability of the Elle's UdarSudha Ras® were evaluated by monitoring of serum biochemical parameters like - lipid profile, liver function test, renal function test, haematology, adverse events, and vitals examination at baseline and end of the intervention.

Inclusion criteria

Males and females subjects between 18-65 years of age (both inclusive) who had knowledge about the clinical trial, were agreed to give written consent and being diagnosed with Functional Dyspepsia as per the ROME III criteria[9,10] i.e. the presence of postprandial distress syndrome (PDS) and epigastric pain syndrome (EPS), and dyspepsia symptoms with scores of 6 or higher on the 11-point Numerical Rating Scale (NRS) for more than 4 of the 14 days prior to enrollment were included in the study. The subjects included in the study were not consuming any medication for the treatment of gastro intestinal disorders such as Histamine receptor-2 antagonists, proton pump inhibitors and prokinetic drugs and were willing to participate in the study and signed the consent form.

Exclusion criteria

Exclusion criteria included the participants' lack of consent to participate in the study; those taking antibiotics or nonsteroid anti-inflammatory agents two weeks before the study; drug or alcohol abuse; gastroesophageal reflux disease such as heartburn and acid regurgitation; the presence of chronic digestive diseases, gastroesophageal malignancy, and peptic ulcer disease based on history, physical examination, laboratory tests (e.g., white blood cell count, C reactive protein or erythrocyte sedimentation rate); liver and kidney dysfunction based on laboratory tests; planned or current pregnancy; the history of upper GIT surgery; and serious illnesses like heart failure, epilepsy, and previous or current significant psychiatric comorbidity; the history of a severe allergic reaction to medicinal plants; Participants were restraining to take antacids, Histamine Receptor-2 antagonists, proton pump inhibitors, mucosal protectants, prokinetic agents, antidepressant and anticholinergic agents two weeks before intervention and during the intervention.

Methodology

Subjects of 18 to 65 years of age with self-reported unsatisfactory bowel habits were screened for eligibility criteria. A documented informed consent from the subject at the screening appointment attested to their involvement in the study. The subject's demographic information, medical and medication history, lab results, vital signs, and, if applicable, current medications were recorded in the case file from (CRF). Based on the inclusion and exclusion criteria, the subjects were taken into consideration for additional assessment. Randomization was used to assign study subjects to their respective groups at the baseline visit. For eight weeks, subjects in the treatment and placebo groups were given 20 ml of an Ayurvedic polyherbal formulation (EURS) twice a day after meals, respectively.

Evaluation of Outcomes

Data on the patients, their quality of life, and the intensity of their symptoms were entered into a unique form and documented at baseline, 2, 4, and 8 weeks into the treatment. Using the Functional Dyspepsia Rating Scale, the severity of the symptoms was evaluated. Patients were asked to complete the 36-item Short-Form Health Survey (SF-36) in order to assess how their treatment was affecting their quality of life [11]. As per the instructions, the SF-36 is scored using three different methods: the overall score, a score for each subscale, and a score for each of the physical and mental components. Various grading scales are employed to answer various questions on this survey, including the 5-point Likert scale, which ranges from excellent (100) to poor (0) or from yes (100) to no (0). Greater scores indicate improved health[11].

Safety and Compliance

The following side effects were noted in order to evaluate the safety of treatment regimens: mild adverse events (e.g., headache, skin redness, dizziness, itching, diarrhea, constipation, abdominal pains causing awakening, taste disturbance, dry mouth, bitterness and unpleasant changes in the mouth taste, gastrointestinal bleeding, and severe allergic reactions). If serious side effects or adverse events observed, then treatment was stopped. Serum alanine aminotransferases and aspartate aminotransferases, alkaline phosphatase, total and direct bilirubin, random blood sugar, blood urea nitrogen, and creatinine were among the laboratory tests conducted at the beginning and end of the treatment to assess safety.

Sample Size and Statistical Analyses.

Using GraphPad software, an independent statistician carried out the outcome analysis blindly. Participants who were randomly allocated and had at least one dose of the investigational medications were used to evaluate evaluate the drug's safety. The mean ± standard error of mean (SEM) is used to present quantitative variables. Mann-Whitney U test or paired sample t-test were used to evaluate the therapeutic effectiveness of Elle's Udarsudha Ras® in comparison to a placebo. Clinically significant changes in laboratory values and the frequency of

adverse events were compared between the two groups in order to determine safety. In terms of statistical significance, a $p<0.05$ was used.

The aim of our QOL analysis was to determine if there were any differences in the QOL scores over the study period. The data were analyzed using significance, which was defined as $p<0.05$, and were then given as mean values with 95% confidence levels.

RESULTS

Demographic characteristics

There were 44 subjects enrolled into study 22 in each group and 40 subjects completed the study and data is analysed (Figure 1). Two subjects from each group were not included in the final analysis. One subject from active dropped out after 2 weeks of trial due to travel to abroad and one subject has not turned up after 4 weeks of treatment. One subject from placebo group switched over to standard of care due to worsening of FD symptoms and one subject was not visited the clinic after two weeks. Each group included twenty evaluable subjects. The mean age and gender distribution of both groups were similar. The details are presented in table 1.

Table 1: Basal demographic characters of the study participants

Characteristics	EURS	Placebo
Number	20	20
Mean age (years)	47.50 ±2.15	46.45± 2.43
Sex, n (M/F)	9/11	8/12
Mean weight (kg)	71.9 ±2.360	69.17 ±2.61
Mean BMI (kg/m2)	26.93 ± 0.82	25.39 ± 0.95
Overall dyspeptic symptoms Score	22.42 ±0.39	22.60 ±0.60

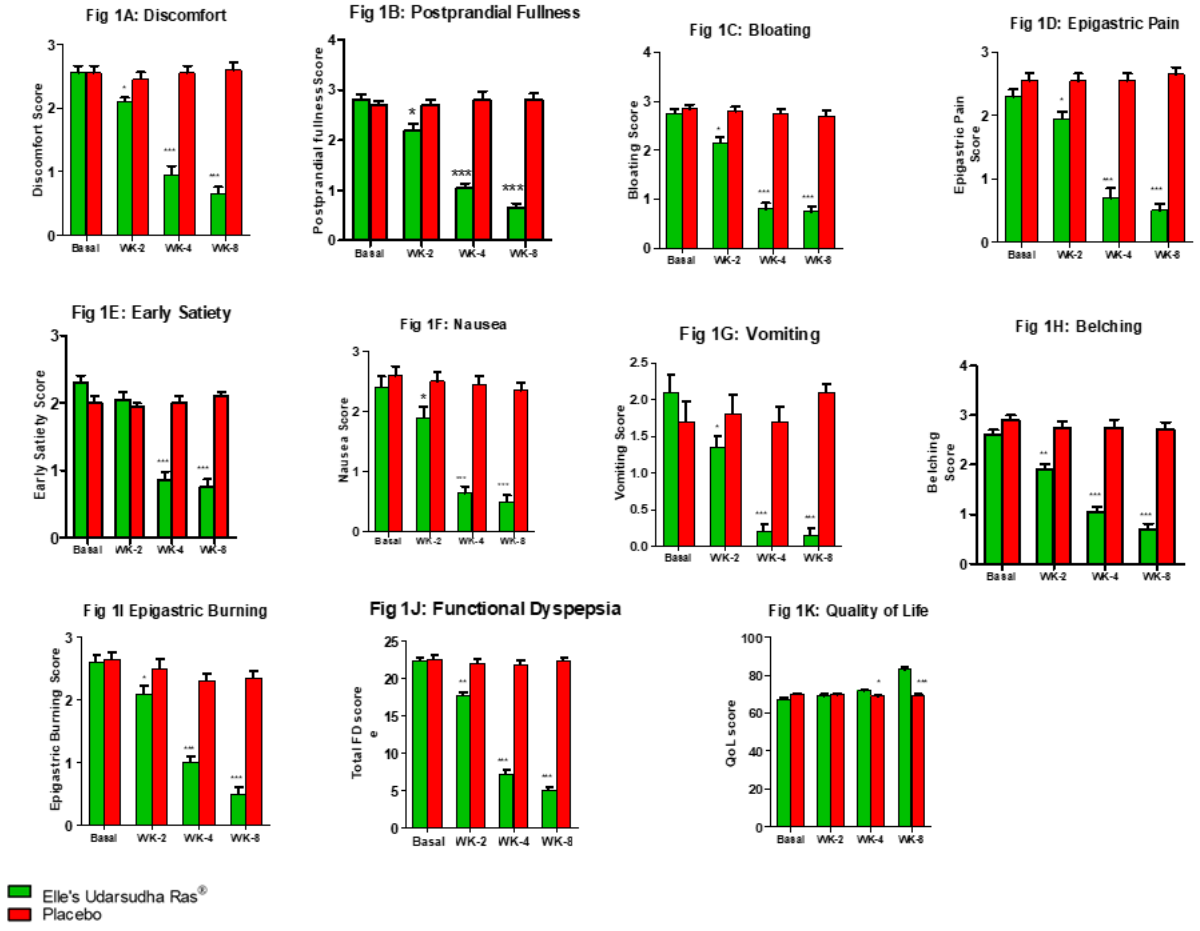

Figure 1: Effect of Elle's UdarSudha Ras® on Functional Dyspepsia symptoms and QoL in clinical subjects

Data is represented as Mean ± SEM. *$p\leq0.01$: ***$p\leq0.001$: Statistical analysis was done using the paired sample t-test and or Mann–Whitney U test

Change in clinical symptoms:

Change in epigastric discomfort between groups

At the study's baseline visit, all patient in both groups experienced mild to severe symptoms of epigastric discomfort with scores of EUS: 2.55 ±0.11 Vs Placebo 2.55 ± 0.11. After two weeks trial, patients from test group had epigastric discomfort score of 2.10 ± 0.11 whereas the patients in placebo group had epigastric discomfort score of 2.45 ± 0.06. At week 4, patients from test group had epigastric discomfort score of 0.95 ± 0.13 ($p<0.001$) whereas the patients in placebo group had epigastric discomfort score of 2.55 ± 0.11.

At week 8, patients from EUS group had epigastric discomfort score 0.65 ± 0.10. At end of the trial, patients from EUS group had epigastric discomfort score 0.65 ± 0.10 which was significantly ($p<0.001$) less as compared to placebo group i.e. 2.60 ±0.11. Thus, the Ayurvedic herbal

formulation EURS showed a significantly consistent and better effect in alleviating epigastric discomfort as compared to placebo group (Fig 1A).

Change in Postprandial Fullness between groups

At the study's baseline visit, all patient in both groups experienced mild to severe symptoms of postprandial fullness ranging from moderate to severe with scores of EUS: 2.70 ±0.10 Vs Placebo 2.80 ± 0.09. After two weeks trial, patients from test group had postprandial fullness score of 2.15 ± 0.13 whereas the patients in placebo group had postprandial fullness score of 2.70 ± 0.11. After 4 weeks, patients from test group had postprandial fullness score of 1.05 ± 0.17 whereas the patients in placebo group had postprandial fullness score of 2.80 ± 0.09. At final Visit, patients from EUS group had postprandial fullness score 0.65 ± 0.13 which was significantly less as compared to placebo group i.e. 2.80 ±0.09. The Ayurvedic herbal formulation EURS showed a significantly (p<0.001) consistent and better effect in alleviating postprandial fullness as compared to placebo group (Fig 1B).

Change in symptoms of bloating between groups

At the study's baseline visit, all the patients from both the groups had symptoms of bloating ranging from moderate to severe with scores of EUS: 2.75 ±0.09 Vs Placebo 2.85 ± 0.08. At week 2, patients from test group had bloating score of 2.15 ± 0.13 whereas the patients in placebo group had bloating score of 2.80 ± 0.09.

At week 4, patients from test group had bloating score of 0.80 ± 0.12 whereas the patients in placebo group had bloating score of 2.75 ± 0.09. At week 8, patients from EUS group had bloating score 0.75 ± 0.09 which was significantly less as compared to placebo group i.e. 2.70 ±0.10, which indicates that the Ayurvedic herbal formulation EURS showed a significantly consistent and better effect in alleviating symptoms of bloating as compared to placebo group (Fig 1C).

Change in symptoms of epigastric pain between groups

At the study's baseline visit, all the patients from both the groups had symptoms of epigastric pain ranging from moderate to severe with scores of EUS: 2.30 ±0.10 Vs Placebo 2.5 0± 0.11. At week 2, patients from test group had epigastric pain score of 1.95 ±0.11 whereas the patients in placebo group had epigastric pain score 2.55 ±0.11. At week 4, patients from test group had epigastric pain score of 0.70 ± 0.15 whereas the patients in placebo group had epigastric pain score of 2.55 ± 0.11. At final Visit patients from EUS group had epigastric pain score 0.50 ± 0.11 which was significantly less as compared to placebo group i.e. 2.65 ±0.10. In the present trial the Ayurvedic herbal formulation EUS showed a significant (p<0.001) effect in alleviating symptoms of epigastric pain as compared to placebo group (Fig 1D).

Change in symptoms of early satiety between groups

At the study's baseline visit, all the patients from both the groups had symptoms of early satiety ranging from moderate to severe with scores of EUS: 2.30 ±0.10 Vs Placebo 2.00 ± 0.01. At week 2, patients from test group had early satiety score of 2.05 ±0.11 whereas the patients in placebo group had early satiety score of 1.95 ±0.058 At week 4, patients from test group had early satiety score of 0.85 ± 0.13 whereas the patients in placebo group had early satiety score of 2.00 ± 0.08 (p<0.001). At final Visit, patients from EURS group had early satiety score 0.75 ± 0.12 which was significantly less as compared to placebo group i.e. 2.10 ± 0. 07 (p<0.001). The Ayurvedic herbal formulation EUS showed a significant (p<0.001) effect in alleviating symptoms of early satiety as compared to placebo group (Fig 1E).

Change in symptoms of nausea between groups

At the study's baseline visit, all patients from both groups had symptoms of nausea associated to gastrointestinal disorders ranging from moderate to severe scores of EUS: 2.40 ±0.18 Vs Placebo 2.60 ± 0.15. At week 2, patients from test group had nausea score of 1.90 ±0.18 whereas the patients in placebo group had nausea score of 2.50 ±0.15. At week 4, patients from test group had nausea score of 0.65 ± 0.11 (p<0.001) whereas the patients in placebo group had nausea score of 2.45 ± 0.14. At final Visit, patients from EUS group had nausea score 0.50 ± 0.11 which was significantly less as compared to placebo group i.e. 2.35 ± 0.13 (p<0.001). The Ayurvedic herbal formulation EURS showed a significant (p<0.001) effect in alleviating symptoms of nausea associated to gastrointestinal disorders as compared to placebo group (Fig 1F).

Change in symptoms of vomiting between groups

At the study's baseline visit, patients from both groups had symptoms of vomiting associated to gastrointestinal disorders ranging from mild to moderate scores of EUS: 2.10 ±0.22 Vs Placebo 1.70 ± 0.27. At week 2, patients from test group had vomiting score of 1.35 ±0.15 whereas the patients in placebo group had vomiting score of 1.80 ±0.25. At week 4, patients from test group had vomiting score of 0.20 ± 0.09 (p<0.001) whereas the patients in placebo group had vomiting score of 1.7 ± 0.19. At final visit, patients from EUS group had vomiting score 0.15 ± 0.08 which was significantly less as compared to placebo group i.e. 2.10 ± 0. 10. The Ayurvedic herbal formulation EURS showed a significant (p<0.001) effect in alleviating symptoms of vomiting associated to gastrointestinal disorders as compared to placebo group (Fig 1G).

Change in symptoms of belching between groups

In this study, all of the patients in both groups had moderate to severe complaints of belching at the baseline visit. In the EUS group score was 2.60 ±0.11 Vs Placebo 2.90 ± 0.10. At week 2, patients from test group had belching score of 1.90 ±0.12 whereas the patients in placebo group had belching score of 2.75 ±0.12. At week 4, patients from test group had belching score of 1.05 ± 0.11 whereas the patients in placebo group had belching score of 2.75 ± 0.16. At final Visit, patients from EUS group had belching score 0.70 ± 0.10 which was significantly (p<0.001) less as compared to placebo group i.e. 2.70 ± 0. 16. The Ayurvedic herbal formulation EURS showed a significant (p<0.001) effect in alleviating symptoms of belching as compared to placebo group (Fig 1H).

Change in symptoms of epigastric burning between groups

In this study, all of the patients in both groups had moderate to severe complaints of epigastric burning at the baseline visit. In the EUS group score was 2.60 ±0.11 Vs Placebo 2.65 ± 0.11 . At week 2, patients from test group had epigastric burning score of 2.10 ±0.12 whereas the patients in placebo group had belching score of 2.50 ±0.14. At week 4,

patients from test group had epigastric burning score of 1.00 ± 0.10 whereas the patients in placebo group had belching score of 2.30 ± 0.10. At end of the trial, patients from EUS group had epigastric burning 0.50 ± 0.11 which was significantly (p<0.001) less as compared to placebo group i.e. 2.35 ± 0. 10. The herbal formulation EURS showed a significant effect in alleviating symptoms of epigastric burning as compared to placebo group (Fig 1I).

Change in total FD score between groups

The current study assessed the study group's functional dyspepsia symptoms' degree of improvement by measuring the shift in the overall FD score following two, four, and eight weeks of therapy.

At baseline visit, patients from EUS group had Functional Dyspepsia score 22.42 ±0.39 Vs Placebo 22.60 ±0.60. At week 2, patients from test group had Functional Dyspepsia score of 17.74 ±0.41whereas the patients in placebo group had Functional Dyspepsia score of 22.00 ±0.62. At week 4, patients from test group had Functional Dyspepsia score of 7.25 ±0.52 which was significantly lower (p<0.001) as compared to the placebo group which had FD score of 21.85 ±0.47. At end of the trial , patients from EUS group had Functional Dyspepsia score 5.15 ±0.23 which was significantly (p<0.001) less as compared to placebo group i.e. 22.35 ±0.37. The herbal formulation EURS showed a significant effect in alleviating symptoms of Functional Dyspepsia score as compared to placebo group which was superior to that in placebo group (Fig 1J).

Total QoL score

The current study measured the study group's overall QoL score change after 2, 4, and 8 weeks of treatment to determine the extent of symptom alleviation.

At baseline visit, patients from EUS group had QoL score of 67.38 ± 0.79 Vs Placebo 69.95 ± 0.62. At week 2, patients from test group had QoL score of 69.23± 0.89 whereas the patients in placebo group had QoL score of 69.88 ± 0.73. At week 4, patients from test group had QoL score of 71.87 ± 0.69 whereas the patients in placebo group had QoL score of 69.15 ± 0.67. At end of the trial , patients from EURS group had QoL score 83.19 ± 1.16which was significantly (p<0.001) high as compared to placebo group i.e. 69.38 ± 0.55. The Ayurvedic herbal formulation EURS showed a significant effect in improving QoL score as compared to placebo group was superior to that in control group (Fig 1K).

DISCUSSION

The results of this study confirm that EURS is effective in treating digestive symptoms and improving overall quality of life in persons who report having poor bowel habits, suffering especially from functional dyspepsia. In order to alleviate the GI symptoms of patients with FD, the current study compared the effectiveness of a novel Ayurvedic herbal formulation Elle's Udarsudha Ras syrup. According to the results, the improvement of EPS, PDS, total FD, and epigastric pain scores in Ayurvedic herbal medication groups were statistically significant (p<0.001) lower as compared to placebo. Relief from symptoms was reported by patient from the second visit (two weeks) onwards.

The fact that this herbal therapy in our trial reduced symptoms more effectively than a placebo could be attributed to the various qualities of these herbs and their distinct modes of action on the gastrointestinal tract[12]. There are several pathogeneses that have been linked to the sensory, motor, and secretory dysfunction of the GI tract in FD and other FGID symptoms, including inflammation, stress, and visceral hypersensitivity[13-14]. The diverse modes of action and multiple qualities of these herbs on the gastrointestinal tract may account for the improved symptom relief observed in our study when compared to placebo[12]. For the sensory, motor, and secretory dysfunction of the GI tract in FD and other FGID symptoms, a number of pathogeneses, including inflammation, stress, and visceral hypersensitivity, have been defined[13–14]. While about the active herbal constituents of Elle's Udarsudha Ras. Various studies indicated the beneficial effect *Hordeum vulgare*[15]. *Ocimum basilicum*[16-17], *Emblica officinalis* Linn[18] in various gastro intestinal disorders such as Functional dyspepsia, non-ulcer dyspepsia[15-19]. Various Ocimum species. *Terminalia belerica*, *Terminalia chebula*, *Momordica charantia*, *Aloe barbadensis* have demonstrated beneficial effect in Functional Dyspepsia along with anti-inflammatory and antioxidant properties[19, 21-22] and *Elettaria cardamomum* known to inhibit neurogenic and inflammatory pains in gastro-intestinal and stress disorders[26]. It appears that this herbal combination may be important for treating FD, which may result from multiple mechanism of these medicinal plants work on the disease in addition to their antisecretory activity.

An examination of changes in quality of life also confirmed that EURS intake is associated with significant and clinically meaningful positive improvements in a range of mood, physical, and social domains. EURS was also well-tolerated with no significant adverse effects reported by participants.

CONCLUSION

This Ayurvedic herbal formulation, Elle's UdarSudha Ras®, considerably reduced FD symptoms and other intestinal symptoms in the current trial, outperforming a placebo. It makes sense given the range of characteristics of the plants employed in this investigation. Thus, an alternate course of treatment for FD could be Elle's UdarSudha Ras, an Ayurvedic herbal medication.

The study found Elle's UdarSudha Ras®, an Ayurvedic herbal compound, significantly improved FD symptoms and intestinal symptoms compared to Placebo due to its various plant properties, making it an alternative treatment for FD.

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Authors' statement

The following contributions to the manuscript are confirmed by the authors: Sudheendra A Deshpande: Study conception and design; Data collection; Analysis and interpretation of results. B K Joshi:Data collection; Analysis and interpretation of results. Vasudha S: Data Collection, Patient follow-up, Data Analysis and Manuscript writing; Rajesh Rathi and Basukinath Rauniyar: Preparation and Supply of Elle's

UdarSudha Ras, Critical analysis of study design, Critical revision of the manuscript. Venkataranganna M V: Study conception and design; Analysis and interpretation of results; Manuscript writing; Critical revision of the manuscript. Nithin Venkat: Data analysis and statistical analysis of the results. After reviewing the findings, all authors gave their approval to the manuscript's final draft.

Conflict of interest

There is no conflict of interest.

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REFERENCES

1. Drossman DA. Functional gastrointestinal disorders: history, pathophysiology, clinical features, and Rome IV. Gastroenterology. 2016;150(6):1262-79.
2. Talley NJ, Ford AC. Functional dyspepsia. New England Journal of Medicine. 2015;373(19):1853-63.
3. McColl KE. Effect of proton pump inhibitors on vitamins and iron. Official journal of the American College of Gastroenterology| ACG. 2009;104:S5-9.
4. Sampathkumar K, Ramalingam R, Prabakar A, Abraham A. Acute interstitial nephritis due to proton pump inhibitors. Indian journal of nephrology. 2013;23(4):304-7.
5. Yibirin M, De Oliveira D, Valera R, Plitt AE, Lutgen S. Adverse Effects Associated with Proton Pump Inhibitor Use. Cureus. 2021 Jan 18;13(1):e12759.
6. Chiarioni G, Pesce M, Fantin A, Sarnelli G. Complementary and alternative treatment in functional dyspepsia. United European gastroenterology journal. 2018;6(1):5-12.
7. Hung A, Kang N, Bollom A, Wolf JL, Lembo A. Complementary and alternative medicine use is prevalent among patients with gastrointestinal diseases. Dig Dis Sci. 2015; 60(7): 1883–8.
8. Li X, Lin Y, Jiang Y, Wu B, Yu Y. Aqueous extract of phyllanthus emblica L. alleviates functional dyspepsia through regulating gastrointestinal hormones and gut microbiome in vivo. Foods. 2022;11(10):1491.
9. Drossman DA. The functional gastrointestinal disorders and the Rome III process. Gastroenterology. 2006;130(5):1377–90.
10. Carbone F, Holvoet L, Tack J. Rome III functional dyspepsia subdivision in PDS and EPS: recognizing postprandial symptoms reduces overlap. Neurogastroenterology & Motility. 2015;27(8):1069-74.
11. Ware JE, Sherbourne CD: The MOS 36-items short-form health survey (SF-36). I- Conceptual framework and item selection. Med Care. 192; 30: 473–83.
12. Bag A, Bhattacharyya SK, Chattopadhyay RR. The development of Terminalia chebula Retz.(Combretaceae) in clinical research. Asian Pacific journal of tropical biomedicine. 2013;3(3):244-52.
13. Mearin F, Cucala M, Aspiroz F, Malagelada JF: The origin of symptoms of the brain-gut axis in functional dyspepsia. Gastroenterol. 1991; 101: 999–1006.
14. Karamanolis G, Caenepeel P, Arts J, Tack J. Association of the predominant symptom with clinical characteristics and pathophysiological mechanisms in functional dyspepsia. Gastroenterology. 2006;130(2):296-303.
15. Rashid K, Kumar CS, Haleel PM. Healthcare Benefits of Hordeumvulgare L (Barley): A Phyto-Pharmacological Review. Research Journal of Pharmacology and Pharmacodynamics. 2017;9(4):207-10.
16. Talley NJ, Ford AC. Functional dyspepsia. New England Journal of Medicine. 2015;373(19):1853-63.
17. Rafieian K, Hosseini-Asl K. Effects of Ocimum basilicum on functional dyspepsia: a double-blind placebo-controlled study. IJMS. 2005; 30: 134–7.
18. Chawla YK, Dubey P, Singh R, Nundy S, Tandon BN. Treatment of dyspepsia with Amalaki (Emblica officinalis Linn.)--an Ayurvedic drug. Indian J Med Res. 1982;76: 95–8.
19. Thompson Coon J, Ernst E. Systematic review: herbal medicinal products for non-ulcer dyspepsia. Aliment Pharmacol Ther. 2002; 16(10): 1689–99.
20. Tarasiuk A, Mosińska P, Fichna J. Triphala: current applications and new perspectives on the treatment of functional gastrointestinal disorders. Chinese medicine. 2018;13:1-1.
21. Dharsono HDA, Putri SA, Kurnia D, Dudi D, Satari MH. Ocimum Species: A Review on Chemical Constituents and Antibacterial Activity. Molecules. 2022; 27(19): 6350-73.
22. Enegide C. Ocimum Species: Ethnomedicinal uses, phytochemistry and pharmacological importance. International Journal of Current Research in Physiology and Pharmacology. 2021:1-2.
23. Bopana N, Saxena S. Asparagus racemosus--ethnopharmacological evaluation and conservation needs. J Ethnopharmacol. 2007; 110(1): 1-15.
24. Mahendra P, Bisht S. Ferula asafoetida: Traditional uses and pharmacological activity. Pharmacogn Rev. 2012; 6(12): 141-6.
25. Amalraj A, Gopi S. Biological activities and medicinal properties of Asafoetida: A review. J Tradit Complement Med. 2016;7(3):347-59.
26. Mehjabeen, Ahmad M, Noorjahan, Farah-Saeed, Bin Rehman A. The role of elettaria cardamomum (l.) maton in inflammatory, gastrointestinal and stress disorders. Int. J. Pharm. Phytopharmacol. Res. 2015;4(6):302-5.

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