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Original Article

A Prospective, Multi-centre, Open label, Single arm Study to Evaluate the Efficacy and Safety of Amlapitta Mishran Suspension in Participants with Amlapitta (Symptomatic Gastritis)

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ABSTRACT

Introduction: The multi-center clinical study was conducted to revalidate the efficacy and safety of Amlapitta Mishran Suspension in Amlapitta (symptomatic gastritis) in a larger sample size in improving Amlapitta Symptom Rating Scale Score, PPDS score, EPS score, and safety. **Methods:** The study was a multi-centric, open-labeled, single-arm, prospective clinical trial in participants with Amlapitta (symptomatic gastritis). Participants with the presence of Amlapitta (symptomatic gastritis), as diagnosed by the Amlapitta Symptom Rating Scale Score ≥ 5 were included in the study. Participants were advised to take Amlapitta Mishran Suspension in a dose of 15 ml twice daily for 14 days. The study involved three visits. The investigator recorded the Amlapitta Symptom Rating Scale (ASRS) Score, Post Prandial Distress Syndrome (PPDS) Score, and Epigastric Pain Syndrome (EPS) Score at screening visit (Visit 1), baseline visit (Visit 2) and final visit (Visit 3). The $p<0.05$ was considered statistically significant measured by paired t-test or Wilcoxon Signed Rank test. **Results:** In the multi-center study 204 participants completed the study. At final visit, a statistically significant ($p<0.001$) reduction was reported in mean Total ASRS score, PPDS score, and EPS score as compared to the baseline scores. The individual ASRS, PPDS, and EPS variables also exhibited significant reduction ($p<0.001$) at the final visit. None of the participants reported any adverse events during the study. **Conclusion:** Amlapitta Mishran Suspension treatment for 14 days effectively and safely reduced the clinical symptoms of Amlapitta (symptomatic gastritis) assessed by Amlapitta Symptom Rating Scale, Postprandial Distress Syndrome and Epigastric Pain Syndrome scores.
Keywords: Ayurveda, Gastritis, Symptom scores

INTRODUCTION

Amlapitta, described in different Ayurved scriptures, is one of the commonest conditions affecting the Annavaha Srotas (digestive system). According to Madhava Nidana, Amlapitta manifests due to increased Amlata (sourness) of Pitta Dosha[1]. Acharya Kashyap explains that the Vidagdha Pitta Dosha turns Amla (sour) in Amlapitta[2]. Amlapitta has been classified into two types: Urdhvaga Amlapitta and Adhoga Amlapitta, which affect the upper and lower gastrointestinal tract, respectively. The key symptoms of Urdhvaga Amlapitta like Avipaak (indigestion), Hrut-Kantha Daha (burning sensation in the epigastric region), Klama (tiredness), Tikta-Amla Udgar (bitter-sour belching), Gaurava (feeling of heaviness), Aruchi (anorexia) and Utklesha (nausea) have been enlisted in Madhava Nidana, based on which it is diagnosed/assessed by Ayurved practitioners[1]. Ayurved management of Amlapitta described in Yogaratnakara mainly focuses on Sama Pitta Pachana (digestion), primarily Tikta (bitter) medications, and dietary and lifestyle modifications to alleviate Pitta Dosha[3]. Many classical formulations, like Bhunimbadi Kwath, Sootashekhar Rasa, Kamadugha Vati, Avipattikar Choorna, etc., are commonly used in the Ayurved management of Amlapitta[4,5,6].

Amlapitta can be correlated to acid-peptic disorders like gastritis based on its symptomatology. Gastritis is a condition marked by inflammation, irritation, or erosion of the gastric mucosa[7]. Gastritis is commonly treated based on signs and symptoms by medical practitioners without relying on endoscopy in most cases. Functional Dyspepsia manifests as a symptom complex of gastritis without abnormal endoscopic findings. i.e., endoscopy helps to differentiate gastritis from Functional Dyspepsia[8-12]. Globally, 10-30% of adults suffer from Functional Dyspepsia[13]. A study reports that 7.6 to 49% of the Indian population suffers from dyspeptic symptoms[14]. As stated by the Rome IV criteria, Functional Dyspepsia is defined by - (i) Persistent or recurring Dyspepsia for >3 months within the past six months; (ii) No demonstration of a possible organic cause of the symptoms on endoscopy and (iii) no sign that the Dyspepsia is relieved only by defecation or of an association with stool irregularities[9]. Based on symptomatology, Functional Dyspepsia is classified into two subgroups, namely, Postprandial Distress Syndrome (PPDS) [marked by bothersome postprandial fullness and early satiation] and Epigastric Pain Syndrome (EPS) [marked by epigastric pain and epigastric burning][8,15] Meal-induced dyspeptic symptoms characterize PPDS, whereas EPS refers to epigastric pain or epigastric burning that does not occur exclusively postprandially and can even be improved by meal ingestion[16].

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According to conventional medicine, Proton Pump Inhibitor (PPI) therapy is considered the first-line therapy in Functional Dyspepsia. However, studies report that PPI therapy effectively treats Functional Dyspepsia in only 14% of patients. If anti-secretory therapy is ineffective or provides inadequate relief, cytoprotective, neuromodulator therapy, prokinetics, and fundus-relaxing therapies are considered, but their safety may be a cause of concern[17,18,19]. Hence, there is a need for safer and more efficacious alternatives.

Many Ayurved herbs and formulations are found to have acid-neutralizing, cytoprotective, and ulcer-healing potential. Amlapitta Mishran Suspension, a rational herbomineral formulation, is widely used by Ayurved Practitioners all over India to manage Acid-Peptic Disorders for > 20 years. Amlapitta Mishran Suspension is not just another product for the management of Amlapitta, but rather a comprehensive prescription offering the benefits of ingredients of Bhunimbadi Kwath (Kadha) along with Yashti (*Glycyrrhiza glabra*) and Shouktik Bhasma (Processed Seashell).

Bhunimbadi Kwath, a well-known classical formulation indicated in Amlapitta management as mentioned in Yogaratnakara contains Tikta Rasa dominant herbs like Vasa (*Adhatoda vasica*), Guduchi (*Tinospora cordifolia*), Parpata (*Fumaria indica*), Nimba (*Azadirachta indica*), Kiratatikta (*Swertia chirata*), Bhrungaraja (*Eclipta alba*), Patola (*Trichosanthes dioica*) along with Haritaki (*Terminalia chebula*), Bibhitaka (*Terminalia bellirica*), and Amalaki (*Emblica officinalis*). These ingredients are reported for their excellent anti-emetic, anti-ulcer, anti-secretory, and gastroprotective actions[8,20-28]. Significant symptomatic relief offered by Bhunimbadi Kwath in Amlapitta has also been revalidated clinically[29]. Potent anti-ulcerative activity of Yashti (*Glycyrrhiza glabra*) in an experimental rat model of indomethacin-induced gastric ulcer is reported while being safer on the liver and kidney functions than ranitidine[30]. Its healing effect in *Helicobacter pylori* infected peptic ulcers has also been reported. In rats, Shouktik (Muktashukti) Bhasma (Processed Seashell) has acid neutralizing effect and demonstrated significant anti-ulcer activity in aspirin induced ulcer model[8].

Amlapitta Mishran Suspension is documented for its dose-dependent anti-ulcer activity in indomethacin-induced gastric ulcers in rats, validating its Ayurvedic use in gastric ulcers[31]. A pilot clinical study on Amlapitta Mishran Suspension has reported a significant reduction in endoscopic scores along with a reduction in clinical symptoms of gastritis measured by the Amlapitta Symptom Rating Scale, Postprandial Distress Syndrome (PPDS) and Epigastric Pain Syndrome (EPS) scores, while being a safe medication with no adverse events in the participants with Endoscopic gastritis[8]. This study was conducted in a smaller sample size of only 30 participants, the current multi-center clinical study was conducted to revalidate the efficacy and safety of Amlapitta Mishran Suspension in Amlapitta (symptomatic gastritis) in a larger sample size. The study's objectives were to evaluate Amlapitta Mishran Suspension's efficacy in improving ASRS Score, PPDS score, EPS score, and safety.

MATERIALS AND METHODS

The study was conducted as a multi-center, open-label, single-arm clinical study in participants suffering from Amlapitta (Symptomatic Gastritis). No randomization was performed, as the study was open-label single-arm. The duration of treatment for each participant was 14 days. Participant arrival, screening, enrollment, informed consent, study procedure, and observations were conducted three days before treatment allocation.

The study was initiated after Ethics Committee approval at both sites and subsequent CTRI approval on 19.05.2022 (CTRI Registration No.: CTRI/2022/05/042670). The participant recruitment at both sites took eight months, which included the time taken for data analysis and report writing. The participant recruitment was done from May 2022 to February 2023.

The study was conducted in the respective Outpatient Department (OPD) of 2 sites viz. National Institute of Ayurveda, Jaipur and Ayurvidya Prasarak Mandal's Seth R.V. Ayurvedic Hospital, Mumbai.

Participants were included were of either gender in the age group of 18-65 years, with presence of Amlapitta (symptomatic gastritis), as diagnosed by the Amlapitta Symptom Rating Scale Score ≥ 5 [with Tikta-Amla Udgar (Sour and Bitter belching) and Hrut-Kantha Daha (Burning Sensation) Score ≥ 1], normal Electrocardiogram (ECG) report, and willing to give written informed consent. Participants excluded from the study were pregnant or lactating women, those who have previously received Amlapitta Mishran Suspension, documented *H. pylori* infection, psychiatric disorders, previous allergic reactions to any components of Amlapitta Mishran Suspension, administered with H2 receptor antagonists, muscarinic or gastrin receptor antagonists, PPI, prostaglandins or mucosal protective agents before study in 1 week, who cannot interrupt steroid, non-steroid anti-inflammatory drugs during treatment, and participants that investigators considered ineligible for this study.

The study medication, Amlapitta Mishran Suspension, manufactured according to the GMP standards, was provided by Shree Dhootapapeshwar Limited. Each bottle of Amlapitta Mishran Suspension contained 450 ml (medication sufficient for 15 days). Each participant was dispensed one bottle of Amlapitta Mishran Suspension on Visit 2 for consumption from Day 1 to Day 14. It had to be taken 15 ml twice daily before meals for 14 days.

If the participant was suffering from any other illnesses (which were not mentioned in the exclusion criteria) and for which they were receiving drugs, they were to be included in the study, provided such drugs did not interact with the study medication. The administration of such medication(s) was documented in the CRF. At each visit, the investigator obtained information about intercurrent illness/es and its concomitant drug therapy. Medication that was allowed and did not interact with the study medication was given and recorded in CRF.

If the participant's compliance with the study medication was less than 80% at the end of the study or if the participant did not take suspension for five days continuously, they were withdrawn from the study.

In the respective OPDs of both the study sites, the participants were screened for Amlapitta as per the inclusion and exclusion criteria by the investigator. The eligible participants who voluntarily agreed to participate and provided written informed consent were recruited in the study. The investigator recorded and entered all information in the CRF.

Participants came for 3 study visits (Screening - Visit 1, Baseline - Visit 2 and Day 14 - Visit 3). ECG was done on Visit 1, Blood investigations (Complete Blood Count, Liver Functions Tests and Renal Function Tests) were done on Visit 1 and Visit 3, assessment of ASRS Score, PPDS Score, EPS Score, and adverse events were done on all visits.

Participants were to be discontinued from the study if any serious adverse events/reactions occurred; Participants requested withdrawal and at the discretion of the principal investigator. The present study was conducted to confirm the previous study's findings in a larger sample size (approximately 200 participants after 8% drop out rate) suffering from Amlapitta (symptomatic gastritis) in two centers in two cities. No formal sample size calculation was done.

Data was analyzed using BlueSky Statistics Software version 10.2. Data was expressed in percentages and Mean ± SD and Median (Interquartile range – IQR). The normality of data was assessed using the Shapiro-Wilk test. Data in a group at two intervals was compared using the paired t-test or Wilcoxon signed rank test. The level of significance in the study was $p<0.05$.

RESULTS

After getting their written informed consent, 278 participants were screened for eligibility to participate in the study (Figure 1). Of these, 61 participants were not found to be eligible based on inclusion/ exclusion criteria's. Thus, 217 participants were recruited and given the study intervention/medication (Amlapitta Mishran Suspension) for 14 days as per the protocol. Of these, 204 participants completed the study. 13 participants dropped out as they were lost to follow-up.

Out of 204 participants who completed the study, 105 were female, and 99 were male. The mean age of participants was 37.14 ± 13.07 years. The mean Random Blood Sugar (RBS) level was 95.0 ± 19.19 mg/dl at the baseline.

All the 204 participants who completed the study reported ≥50% improvement in the mean Total Amlapitta Symptom Rating Scale score and 117 participants reported 100% improvement at Visit 3 (Final Visit). The mean Total Amlapitta Symptom Rating Scale (ASRS) score at Visit 2 (Baseline Visit) was 9.97 ± 2.82, which significantly reduced to 0.74 ± 1.08 ($p<0.001$) at Visit 3 (Final Visit). All the individual symptom scores in the Amlapitta Symptom Rating Scale (ASRS) exhibited statistically significant ($p<0.001$) reduction at Visit 3 (Final Visit) as compared to the Visit 2 (Baseline Visit) scores (Refer Table 1 and Figure 2).

Out of 194 participants reporting Post Prandial Distress Syndrome (PPDS) at Visit 2 (Baseline Visit), 150 participants reported 100% improvement, and 3 participants reported no improvement in the mean Total Post Prandial Distress Syndrome (PPDS) score at Visit 3 (Final Visit). The mean Postprandial Distress Syndrome score at Visit 2 (Baseline Visit) was 3.23 ± 1.25, which significantly reduced to 0.27 ± 0.57 ($p<0.001$) at Visit 3 (Final Visit). (Refer Table 2)

The scores of individual variables of PPDS viz. Bothersome Postprandial Fullness and Bothersome Early Satiation are mentioned and represented in Table 2. The individual variables of Postprandial Distress Syndrome, namely, Bothersome Postprandial Fullness and

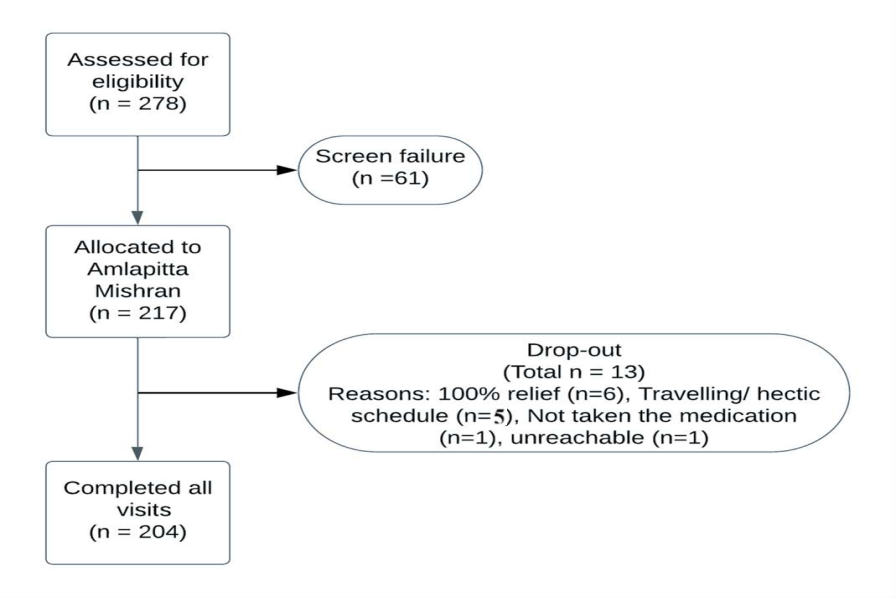

Figure 1. Participant enrollment flowchart as per CONSORT guidelines

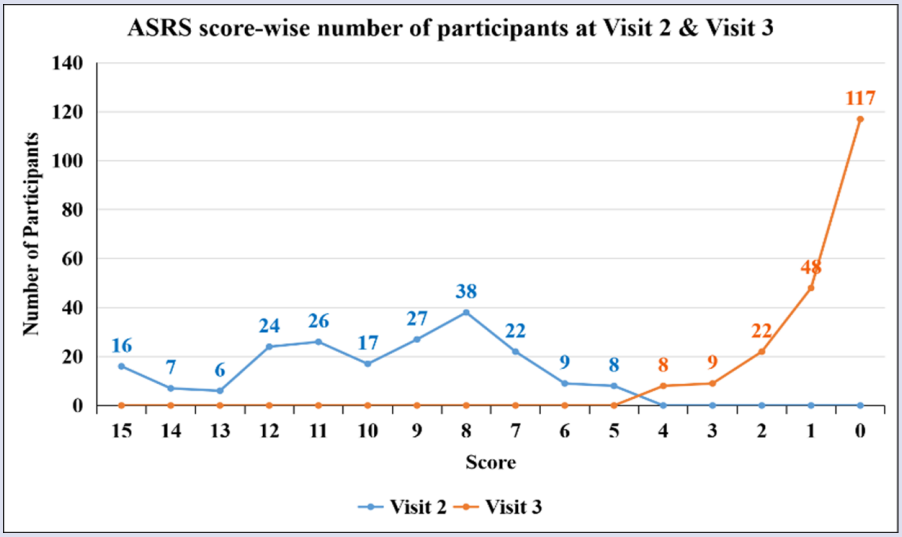

Figure 2. ASRS Score-wise number of participants at Visit 2 & Visit 3

Bothersome Early Satiation exhibited statistically significant ($p<0.001$) reduction at Visit 3 (Final Visit) as compared to the Visit 2 (Baseline Visit) scores.

All the 204 participants reporting Epigastric Pain Syndrome (EPS) at Visit 2 (Baseline Visit) reported ≥50% improvement in the mean Total Epigastric Pain Syndrome (EPS) score at Visit 3 (Final Visit). The mean Epigastric Pain Syndrome score at Visit 2 (Baseline Visit) was 3.25 ± 1.24, which significantly reduced to 0.09 ± 0.31 ($p<0.001$) at Visit 3 (Final Visit) [Refer Table 2]. Both the individual variables of Epigastric Pain Syndrome viz. Bothersome Epigastric Pain and Bothersome Epigastric Burning exhibited statistically significant ($p<0.001$) reduction at Visit 3 (Final Visit) as compared to the Visit 2 (Baseline Visit) scores.

No adverse events were observed at all time points of measurement, i.e., from Visit 1 (Screening Visit) to Visit 3 (Final Visit) in any participants.

All vital parameters, i.e., Temperature, Blood Pressure, Heart Rate, and Respiratory Rate, were within normal ranges, at all-time points of measurement. No statistically significant change ($p>0.05$) was observed in any vital parameter of any participant on any visits compared to Visit 1 (Screening Visit). All systemic examination variables (CVS, CNS, RS, and Per Abdomen) were normal at all-time points of measurement.

Hemoglobin, RBC count, HCT (PCV) ratio, and lymphocyte count were significantly higher ($p<0.001$) at Visit 3 (Final Visit) compared to Visit 1 (Screening Visit) but were not clinically significant as all values were within normal reference range. Similarly, the neutrophil count was significantly lower ($p<0.001$) at Visit 3 (Final Visit) compared to Visit 1 (Screening Visit) but was not clinically significant as the value was within the normal reference range. No statistically significant changes were found in any other blood parameters. (Refer Table 3). The compliance / adherence in taking study medication was well within the acceptable range (≥80%).

DISCUSSION

Table 1. Scores of total and individual symptoms of ASRS

No.	Scores of total and individual symptoms of ASRS	Visit	Mean ± SD	Median (IQR)
1	**Total ASRS score**	Visit 2	9.97 ± 2.82	9 (8-12)
		Visit 3	0.74 ± 1.08***	0 (0-1)
2	**Hrut-Kantha Daha (Burning Sensation)**	Visit 2	2.09 ± 0.71	2 (2 - 3)
		Visit 3	0.07 ± 0.25***	0 (0 - 0)
3	**Tikta-Amla Udgar (Bitter and Sour Belching)**	Visit 2	1.7 ± 0.73	2 (1 - 2)
		Visit 3	0.18 ± 0.38***	0 (0 - 0)
4	**Guruta (Abdominal Heaviness)**	Visit 2	1.55 ± 0.68	2 (1 - 2)
		Visit 3	0.13 ± 0.34***	0 (0 - 0)
5	**Aruchi (Anorexia)**	Visit 2	1.49 ± 0.9	1 (1 - 2)
		Visit 3	0.11 ± 0.32***	0 (0 - 0)
6	**Avipaak (Indigestion)**	Visit 2	1.31 ± 0.8	1 (1 - 2)
		Visit 3	0.13 ± 0.34***	0 (0 - 0)
7	**Utklesha (Nausea)**	Visit 2	1.1 ± 0.74	1 (1 - 2)
		Visit 3	0.06 ± 0.24***	0 (0 - 0)
8	**Klama (Tiredness)**	Visit 2	0.72 ± 0.69	1 (0 - 1)
		Visit 3	0.05 ± 0.23***	0 (0 - 0)

ASRS: Amlapitta Symptom Rating Scale, IQR – Interquartile range

$p<0.05$ was considered as significant. Values expressed as Mean ± SD and Median. Wilcoxon signed rank test was employed to test significance between the visits. ***$p<0.001$ vs. Visit 2 (Baseline Visit).

Table 2. Individual variables of PPDS and EPS Score

No.	Individual variables of PPDS and EPS Score	Visit	Mean ± SD	Median (IQR)
1	**PPDS Score (Total)**	Visit 2	3.23 ± 1.25	3 (3 - 4)
		Visit 3	0.27 ± 0.57***	0 (0 - 0)
2	**Bothersome Postprandial Fullness score**	Visit 2	1.64 ± 0.63	2 (1 - 2)
		Visit 3	0.15 ± 0.36***	0 (0 - 0)
3	**Bothersome Early Satiation score**	Visit 2	1.59 ± 1.02	2 (1 - 2)
		Visit 3	0.12 ± 0.33***	0 (0 - 0)
4	**EPS Score (Total)**	Visit 2	3.25 ± 1.24	3 (2 - 4)
		Visit 3	0.09 ± 0.31***	0 (0 - 0)
5	**Bothersome Epigastric Pain score**	Visit 2	0.51 ± 0.65	0 (0 - 1)
		Visit 3	0.02 ± 0.14***	0 (0 - 0)
6	**Bothersome Epigastric Burning Score**	Visit 2	2.74 ± 0.76	3 (2 - 3)
		Visit 3	0.07 ± 0.26***	(0 - 0)

PPDS-Postprandial Distress Syndrome, EPS-Epigastric Pain Syndrome, IQR – Interquartile range

$p<0.05$ was considered as significant. Values expressed as Mean ± SD and Median. Wilcoxon signed rank test was employed to test significance between the visits. ***$p<0.001$ vs. Visit 2 (Baseline Visit).

Table 3. Blood investigation results of the Study Participants

Blood Investigation Variable	Visit 1	Visit 3	p-value (Visit 3 vs. Visit 1)
Hb (gm/dL)	13.21 ± 1.63	13.33 ± 1.62	<0.001
RBC (million cells/µL)	4.56 ± 0.53	4.61 ± 0.58	<0.001
HCT (PCV) (%)	41.8 ± 4.45	42.52 ± 4.78	<0.001
MCV (fL)	90.33 ± 6.91	91.21 ± 9.24	0.256
MCH (pg)	29.03 ± 2.72	28.99 ± 2.98	0.06
MCHC (g/dl)	31.6 ± 2.78	31.37 ± 2.6	0.114
WBC (10^3/µl)	7468.51 ± 1582.03	7527.38 ± 1575.2	0.432
Neutrophil (%)	61.42 ± 6.46	59.5 ± 7.4	<0.001
Lymphocytes (%)	33.64 ± 6.33	34.97 ± 7.31	<0.001
Eosinophils (%)	2.58 ± 1.56	2.73 ± 1.46	-
Monocytes (%)	2.33 ± 1.68	2.34 ± 1.6	-
Basophils (%)	0.02 ± 0.14	0.01 ± 0.1	-
Platelets (*10^9 /L)	272.1 ± 88.53	270.31 ± 79.49	0.778
SGOT/AST (Units/L)	26.11 ± 10.04	24.66 ± 9.76	0.41
SGPT/ALT (Units/L)	25.29 ± 10.42	24.51 ± 12.35	0.052
Serum Bilirubin Direct (mg/dL)	0.22 ± 0.1	0.24 ± 0.14	0.09
Serum Bilirubin Indirect (mg/dL)	0.4 ± 0.24	0.41 ± 0.28	0.667
Serum Bilirubin Total (mg/dL)	0.62 ± 0.25	0.65 ± 0.3	0.194
BUN (mg/dL)	7.47 ± 2.06	7.53 ± 2.09	0.872
Serum Creatinine (mg/dL)	0.79 ± 0.16	1.12 ± 4.32	0.738

Values expressed as Mean ± SD. p<0.05 was considered as significant. Paired t-test was employed as per the normality testing of data

The symptoms of Amlapitta mentioned in Ayurved scripture resemble those of Gastritis or Functional Dyspepsia. Functional Dyspepsia manifests as the symptom complex of Gastritis wherein the endoscopic findings are normal. In most cases, general practitioners handle the symptom complex of Amlapitta, Functional Dyspepsia, or Gastritis without using endoscopy for diagnosis and treatment. Conventional medical management aims to reduce acid secretion from gastric mucosa (H_2 receptor antagonists or Proton Pump Inhibitors), mucosal barrier protection, or enhancement of gastrointestinal motility (prokinetic agents)[8]. In most cases, acid suppressants provide only partial relief from symptoms, while cytoprotective agents are becoming increasingly important in enhancing mucosal defense. It is assumed that cytoprotective agents balance the aggressive (offensive) and defensive factors[8]. The preferred treatment strategy in patients with symptomatic gastritis is the combination of acid suppression and mucosal protection.

Amlapitta Mishran Suspension, a proprietary Ayurved formulation available in the Indian pharmaceutical market for over 20 years, is widely prescribed by Ayurved practitioners to alleviate the symptoms of Amlapitta. The ingredients of Amlapitta Mishran Suspension are reported for their anti-secretory, gastroprotective, acid-neutralizing, anti-ulcer, and anti-emetic actions[8]. Ayurved practitioners consider Amlapitta Mishran Suspension a complete prescription for Amlapitta management. Of the two studies published on Amlapitta Mishran Suspension, one is an experimental study, wherein Amlapitta Mishran Suspension exhibited anti-ulcer action. Amlapitta Mishran Suspension had a significant effect on gastric ulcers in rats, resulting in a decrease in the number and severity of ulcers compared to Ranitidine[31].

The data of the first pilot clinical study on Amlapitta Mishran Suspension conducted in 2020 was published by Shetty et al[8]. In the 28 patients with endoscopic gastritis; a significant reduction was reported in mean endoscopic scores after treatment with Amlapitta Mishran Suspension for 30 days. After 30 days of treatment, 18 (64%) patients had a mean endoscopy score of 1 (no erosion). Also, the clinical symptoms of gastritis assessed by the ASRS score, PPDS score, and EPS score significantly (p<0.05) reduced after 15 and 30 days of treatment[8]. In this pilot study, 24 (85.71%) and 27 (96.43%) participants exhibited ≥50% reduction in mean ASRS score after 15 and 30 days of treatment, respectively, as compared to the baseline score. 15 (53.57%) and 25 (89.29%) participants exhibited ≥50% reduction in mean Postprandial Distress Syndrome score after 15 and 30 days of treatment, respectively, as compared to the baseline score. 16 (57.14%) and 26 (92.86%) participants exhibited ≥50% reduction in mean Epigastric Pain Syndrome score after 15 and 30 days of treatment, respectively, as compared to the baseline score.

By considering scientific data, clinical usage, and the role of general practitioners in managing Amlapitta, this study aimed to evaluate the safety and efficacy of Amlapitta Mishran Suspension in a larger sample size. This study was conducted at two sites in Mumbai and Jaipur, generating data from 204 participants. The Amlapitta Symptom Rating Scale was adopted for evaluating primary efficacy endpoint, as it is commonly used in studies on Amlapitta.[8] Also, in Ayurved OPDs and clinics, the patients of Amlapitta are evaluated on the symptoms of the Amlapitta Symptom Rating Scale. Considering the resemblance of the symptom complex of Amlapitta with Functional Dyspepsia, validated individual variables of Functional Dyspepsia viz. Epigastric Pain Syndrome and Post Prandial Distress Syndrome scores were adopted to evaluate secondary efficacy endpoints.

At the screening visit, ECG was done on all the participants to rule out the cardiac causes of chest discomfort, if any; ruling out cardiac causes is always necessary to eliminate bias and alpha error. At baseline, out of the 204 participants recruited, 105 were female, and 99 were male. The mean age of participants was 37.14±13.07 years, and their mean Random Blood Sugar (RBS) level was 95.0 ± 19.19 mg/dL.

Treatment with Amlapitta Mishran Suspension for 14 days significantly reduced the mean Total Amlapitta Symptom Rating Scale score, mean Post Prandial Distress Syndrome score, and mean Epigastric Pain Syndrome score at Visit 3 (Final Visit - After 14 days of treatment) as compared to baseline, indicating a potential symptomatic relief in Amlapitta.

The mean Total Amlapitta Symptom Rating Scale (ASRS) score of 9.97±2.82 at baseline visit significantly reduced to 0.74±1.08 (p<0.001) at Visit 3 (Final Visit). Also, all the individual symptom scores in ASRS exhibited statistically significant (p<0.001) reduction at the final visit. All the 204 participants who completed the 14-day study reported ≥50%

improvement in the mean Total ASRS score at the final visit. A 0 (100% improvement) score was reported in 117 (57.35%) participants out of 204. Score 0 (100% improvement) in the key symptoms of Amlapitta viz. Hrut-Kantha Daha and Tikta-Amla Udgar were reported by 190 (93.13%) and 168 (82.35%) participants, respectively.

The mean Post Prandial Distress Syndrome (PPDS) score of 3.23 ± 1.25 at baseline visit significantly reduced to 0.27 ± 0.57 ($p<0.001$) at Visit 3 (Final Visit). Also, both the individual variables of PPDS viz. Bothersome Postprandial Fullness and Bothersome Early Satiation exhibited statistically significant ($p<0.001$) reduction at the final visit. Of the 194 participants reporting PPDS at the baseline visit, 189 (97.42%) participants reported ≥50% improvement in the mean PPDS score at the final visit. At the final visit, 150 (77.32%) participants reported 100% improvement (Score 0). Score 0 (100% improvement) in Bothersome Postprandial Fullness and Bothersome Early Satiation was reported by 162 (83.94%) out of 193 participants and 144 (85.21%) out of 169 participants, respectively.

The mean Epigastric Pain Syndrome (EPS) score of 3.25 ± 1.24 at baseline visit significantly reduced to 0.09 ± 0.31 ($p<0.001$) at Visit 3 (Final Visit). Also, both the individual variables of EPS viz. Bothersome Epigastric Pain and Bothersome Epigastric Burning exhibited statistically significant ($p<0.001$) reduction at the final visit. All 204 participants reported ≥50% improvement in the mean EPS score at the final visit. At the final visit, 186 (91.18%) participants reported 100% improvement (Score 0). Score 0 (100% improvement) in Bothersome Epigastric Pain and Bothersome Epigastric Burning was reported by 83 (95.40%) out of 87 and 189 (92.65%) out of 204 participants, respectively.

It is important to note that Post Prandial Distress Syndrome (PPDS) variables viz. Bothersome Post Prandial Fullness and Bothersome Early Satiation resemble the two symptoms of Amlapitta viz. Guruta (abdominal heaviness) and Aruchi (loosely translated to anorexia), individually and combined. In our study, a statistically significant ($p<0.001$) reduction in scores of Bothersome Post Prandial Fullness, Bothersome Early Satiation, Guruta, and Aruchi at the final visit was reported as compared to baseline. Similarly, one of the variables of Epigastric Pain Syndrome (EPS), i.e., Bothersome Epigastric Burning, resembles the key Amlapitta symptom, i.e., Hrut Kantha Daha (burning sensation). Also, both the variables of EPS viz. Bothersome Epigastric Pain and Bothersome Epigastric Burning correlate to Hrut Kantha Daha (burning sensation). Our study reported a statistically significant ($p<0.001$) reduction in Bothersome Epigastric Pain, Bothersome Epigastric Burning, and Hrut Kantha Daha at the final visit compared to baseline. Thus, we can summarize that the symptom complex of Amlapitta closely resembles the clinical presentation of Gastritis and Functional Dyspepsia.

None of the participants reported adverse events and no Serious Adverse Events (SAEs) were reported throughout the study. All systemic examination parameters were found to be normal at all-time points of measurement. All the safety variables viz. Hb, CBC, ESR, AST, ALT, Serum Bilirubin, BUN, and Serum Creatinine were within the normal range at baseline visit and after completion of 14 days of treatment.

The primary and secondary endpoints of this study were achieved. Compared to the previous pilot study, another advantage of this study was the evaluation at two sites in different regions of India, which caters to a wide variety of populations, including different lifestyles and dietary habits. The findings of this study affirm the effectiveness and safety of Amlapitta Mishran Suspension in a wide variety of Indian populations. The compliance in taking study medication was well within the acceptable range (≥80%).

Based on the animal study using indomethacin as an gastric ulcer inducer by Vemula et al.[31], the possible mechanism of action of Amlapitta Mishran Suspension can be postulated to be preservation of gastroprotective prostaglandins and reduction in the secretion of hydrochloric acid. Furthermore, the structural integrity of gastric mucosa preserving capability of Amlapitta Mishran Suspension was confirmed by the data of a pilot clinical study published by Shetty et al.[8] The present study has reconfirmed the effectiveness of Amlapitta Mishran Suspension in clinical settings.

The fact that our study was single-arm meant that we couldn't make comparisons to the treatment options currently available. Furthermore, the open-label design may lead to bias from both participants and physicians when describing symptoms or conducting evaluations. In the future, we would like to plan a multi-center, double-blind, active-controlled clinical trial to evaluate the efficacy and safety of Amlapitta Mishran Suspension as an add-on to Proton Pump Inhibitors [PPI's] (Esomeprazole, Rabeprazole, etc.) as compared to the standard treatments like PPI's.

CONCLUSION

Amlapitta Mishran Suspension treatment for 14 days effectively and safely reduced the clinical symptoms of Amlapitta (symptomatic gastritis) assessed by Amlapitta Symptom Rating Scale (ASRS), Postprandial Distress Syndrome (PPDS) and Epigastric Pain Syndrome (EPS) scores.

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