

ORIGINAL STUDY

Clinical Evaluation of Amalakathi Kirutham in the Treatment of Erigunmam (Acid Peptic Disease): A Pilot Study

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ABSTRACT

Erigunmam (acid peptic disease, APD) is a common gastrointestinal disorder characterized by symptoms of burning epigastric pain, heartburn, acid regurgitation, bloating, nausea and flatulence. Conventional treatments (e.g. proton pump inhibitors) often have long-term adverse effects, prompting interest in traditional remedies. Amalakathi Kirutham is a classical Siddha herbal formulation used for APD, purportedly balancing excess Pitham (heat/acid). This pilot study evaluated its clinical effects. Thirty patients (18–60 years) with chronic Erigunmam were enrolled. After informed consent, all patients received a baseline assessment and an oil bath with Seeraga Thailam 50 mL. Then Amalakathi Kirutham (4 mL orally twice daily after meals) was administered for 48 days (per classical Siddha reference). Efficacy was assessed by the Gastrointestinal Symptom Rating Scale (GSRS) and traditional Siddha parameters (Ennvagai Thervu, Udal and Uyir Thathukkal). Routine blood tests (CBC, ESR, LFT/RFT) were done before and after treatment. Significant symptom improvement was observed: GSRS sub-scores for reflux, abdominal pain, indigestion and constipation decreased markedly ($p < 0.0001$) and diarrhoea score improved ($p=0.033$). For example, mean reflux score fell from 4.33 ± 0.72 to 1.55 ± 0.36 ; abdominal pain from 3.13 ± 0.73 to 1.33 ± 0.26 . Hemoglobin increased significantly (13.6 to 14.7 g/dL, $p < 0.001$) indicating reduced inflammation. No adverse events or symptom recurrences were reported. Patients generally reported relief of discomfort and satisfaction with the gentle herbal therapy. In this pilot case series, Amalakathi Kirutham was associated with significant relief of acid-peptic symptoms and was well tolerated. These preliminary findings suggest it may be a promising Siddha treatment for APD. A larger controlled trial is recommended.

Keywords: Acid-Peptic Diseases, Amalakathi kirutham, Erigunmam, Pilot Study, Siddha Medicine.

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INTRODUCTION

Erigunmam, described in Siddha literature, corresponds broadly to acid peptic disorders (gastric and duodenal ulcers, gastritis) affecting the stomach and upper duodenum [1]. It is considered among the most important Pitha-related conditions, with high morbidity if untreated [2]. In India, APD is highly prevalent; one tertiary hospital study found APD in ~38% of gastroenterology outpatients, associated with age, lower socio-economic status, alcohol/NSAID use and other risk factors [3]. Clinically, acid peptic disease often causes upper abdominal pain described as burning or gnawing, with indigestion, belching, bloating, early satiety, nausea and vomiting. Such symptoms tend to get worse on an empty stomach or at night and may accompany acid reflux [4]. Complications (bleeding, perforation) are possible if untreated. Standard therapy includes proton pump inhibitors (PPIs) and H₂-receptor blockers, which reduce acid secretion. However, long-term PPIs use has been linked to adverse effects (renal injury, nutrient malabsorption, infections, fractures, etc.). For example, chronic PPI therapy is a top-10 prescribed medication globally but is often overused and may lead to micronutrient deficiencies, renal gynecological and cardiovascular issues [5]. These concerns motivate exploration of traditional remedies that might alleviate symptoms with fewer side effects [3, 4]. Siddha medicine offers several formulations for treating

Erigunmam/acid disorders [2]. Amalakathi Kirutham is a ghee-based polyherbal used for “Pitham” (heat-acidity) conditions [6]. Its principal ingredients include Nelli (*Emblica officinalis*), sugarcane (*Saccharum officinarum*) and kadukkai (*Terminalia chebula*) in cow’s ghee [1, 6]. In Siddha, nelli and kadukkai are thought to pacify excess Pitham and strengthen digestion [7]. Modern studies support their gastroprotective roles: amla extract has been shown to inhibit gastric ulcers and reduce acid secretion in rat models, and kadukkai enhances gastric motility (increasing gastric emptying) [8,9]. This study aimed to evaluate the clinical efficacy and safety of Amalakathi Kirutham in a pilot group of patients with Erigunmam, using both modern symptom scales and traditional Siddha assessments.

MATERIAL AND METHODS

PATIENT INFORMATION:

Thirty patients (17 male, 13 female) aged 18–60 years were enrolled (17 of them 31–40 years old, 40% of the cohort). All presented with longstanding symptoms of acid-peptic disorder. Approximately half (53.3%) lived in urban areas and 46.7% were from lower socio-economic strata. Lifestyle risk factors were common: 40% reported combined smoking and alcohol use, 6.7% smoked only, and 10% used betel nut/alcohol; one-third (33.3%) had no such habits. The majority (76.7%) consumed a mixed (vegetarian + non-vegetarian) diet. Illness duration was often chronic: 43.3% had symptoms for 1–5 years, 26.7% for under 1 year, and 30% for more than 5 years. Baseline bowel habits were normal in 33.3%, constipation-predominant in 40%, and diarrhea-predominant in 26.7% of patients.

INCLUSION AND EXCLUSION CRITERIA

All patients were screened to exclude alarming features of GI bleeding, malignancy or severe systemic disease. In Siddha terms, each patient underwent a full Ennvagai Thervu (eightfold) examination. The eight Siddha diagnostic parameters include pulse (Naadi), tongue (Naa), complexion (Niram), speech (Mozhi), eyes (Vizhi), stool (Malam), urine (Neer), and touch/palpation (Sparisam). The balance of the three humors (Uyir Thathukkal: Vatham, Pitham, Kabam) was noted for each patient. In Siddha physiology, Vatham (air) governs movement and nerve impulses, Pitham (fire) governs metabolism and digestion, and Kabam (earth-water) provides structure and stability. All patients showed signs of Pitha-vitiation (consistent with Erigunmam). The seven body constituents (Udal Thathukkal: saram, senneer, oon, kozhupu, enbu, majjai, sukilam/suronitham) were also assessed, as these foundational tissues reflect overall health. These detailed baseline assessments ensured homogeneity and provided Siddha-based endpoints for evaluation.

CLINICAL FINDINGS

At enrollment, all patients reported classical symptoms of acid peptic disease. The predominant complaint was burning epigastric pain or discomfort, often with hunger pain and nausea. Heartburn and acid reflux sensations were common. Belching, bloating, flatulence, and increased salivation were noted. A subset had loose stools or diarrhea episodes. No patient had alarming signs such as gastrointestinal bleeding, significant weight loss, or severe anemia. General physical and abdominal examinations were unremarkable (no palpable masses or organomegaly, normal vital signs). Thus, the clinical presentation aligned with uncomplicated gastroesophageal reflux/dyspepsia. The modern clinical assessment used the Gastrointestinal Symptom Rating Scale (GSRS), a validated 15-item questionnaire covering five symptom domains (reflux, abdominal pain, indigestion, constipation, diarrhea), to quantify baseline severity. Scores were uniformly elevated across domains, indicating moderate to severe symptoms at baseline [10, 11].

TIMELINE DAY - (SCREENING):

67 patients were screened; 30 met inclusion criteria. Informed consent was obtained. Baseline assessments (history, physical, lab tests, GSRS, Siddha parameters) were completed.

Day 1: Patients received a traditional oil bath with 50 mL Seeraga Thailam (cumin oil), as per Siddha protocol, to prepare the body for medication. This was followed by initiation of Amalakathi Kirutham (first dose).

Day 1–48: Treatment period. Patients took Amalakathi Kirutham 4 mL orally twice daily after meals for 48 consecutive days. Adherence was monitored weekly via follow-up calls/visits.

Day 49: Final clinical and laboratory assessments were performed. GSRS questionnaire and Siddha examinations were repeated. Blood tests (CBC, ESR, liver/kidney function) were repeated.

Follow-up (1-month post-treatment): Patients were contacted/seen to evaluate symptom recurrence and monitor delayed effects. (During follow-up, no patients reported the return of symptoms.)

DIAGNOSTIC ASSESSMENT:

Modern (Biomedical) Assessment:

Diagnosis of acid peptic disease was clinical; no endoscopy was performed. Symptom severity was quantified using the GSRS [10]. Laboratory investigations (CBC, ESR, blood glucose, renal and liver

panels) were obtained to rule out anemia or systemic disease. At baseline, all lab values were within normal limits except mildly elevated ESR in some patients.

Siddha Assessment:

A comprehensive traditional evaluation was performed. Ennvagai Thervu (the eight-fold examination) was used to gauge internal humoral balance and organ function. For example, pulse (Naadi) quality was recorded to assess Vatham/Pitham/Kabam status; tongue (Naa) coating and color were noted; eyes (Vizhi) and complexion (Niram) were inspected for Pitha-associated changes; speech (Mozhi) and stool/urine patterns were recorded [12]. The constitutions (Udal Thathukkal) including Saram (chyle), Senneer (blood), Oon (muscle), Kozhupu (fat), Enbu (bone), Moolai (marrow) and Sukilam (reproductive fluid) were evaluated qualitatively. For instance, a robust blood (Senneer) and mucosal lining (Saram) were considered protective, whereas deranged Saram/ Kozhupu could indicate dyspepsia. The three humors (Uyir Thathukkal) – Vatham, Pitham, Kabam – were recorded for each patient. Typically, Erigunmam is associated with aggravated Pitham (excess heat), which was confirmed in most patients [13, 14]. These Siddha diagnostics provided contextual data and complement the GSRs; however, symptom relief was primarily measured by GSRs and patient report.

Therapeutic Intervention

Oil Bath:

Before medication, each patient received an oil bath using 50 mL Seeraga Thailam, as prescribed in Siddha practice. The oil bath is believed to open skin channels and help internalize the subsequent therapy [15]. No other change in diet or lifestyle was mandated beyond avoiding spicy foods.

Amalakathi Kirutham:

The study drug Amalakathi Kirutham (150g preparation) was administered at a dose of 4 mL BD orally after meals for 48 days, following the classical Siddha text Chikicha Rathina Deepam. Patients were instructed to measure 4 mL with a dropper and ingest with water. Adherence was checked at weekly visits or calls. No concurrent anti-ulcer drugs, antacids, or NSAIDs were allowed during the trial. The overall regimen followed Siddha principles of dose, timing (after meals), and duration (nearly 1.5 months) to ensure efficacy. Follow-up and Outcomes All 30 patients completed the treatment course.

RESULTS

Symptom Improvement (GSRs):

By the end of 48 days, mean scores on all GSRs domains were significantly lower than at baseline. Statistically highly significant reductions ($p < 0.0001$) were seen in the reflux domain and in visceral pain (abdominal discomfort) subscales. For instance, the average reflux score decreased from 4.33 ± 0.72 to 1.55 ± 0.36 , and abdominal pain score from 3.13 ± 0.73 to 1.33 ± 0.26 (both $p < 0.0001$). Indigestion-related scores (nausea, bloating, belching) also fell sharply ($\approx 2.91 \rightarrow 1.16$, $p < 0.001$). The diarrhea sub score (severity of loose stools) showed a smaller but still significant improvement ($1.21 \rightarrow 1.12$, $p = 0.033$). In practical terms, most patients rated their symptoms as “None” or “Mild” on the GSRs scale after treatment.

Clinical Outcomes:

Subjectively, patients reported relief of heartburn, epigastric burning, and bloating. Many noted that meals no longer provoked severe discomfort. The frequency of belching and flatulence decreased. No patient required rescue antacids during the study. At follow-up (about one-month post-treatment), the improvements were maintained, with no recurrence of major symptoms.

Laboratory results:

Post-treatment blood tests showed statistically significant improvements in markers of general health. Mean hemoglobin rose from 13.6 to 14.7 g/dL, and RBC count increased, reflecting improved nutritional status and possible resolution of minor occult bleeding/inflammation. ESR (erythrocyte sedimentation rate), an inflammation marker, dropped markedly from 9.5 to 3.8 mm/hr. Total and differential leukocyte counts remained within normal limits, the neutrophil percentage rose slightly, perhaps reflecting resolution of stress. Liver and kidney function tests were unchanged, confirming safety.

Adverse Events:

No adverse drug reactions or intolerances were reported. Vital signs and laboratory safety parameters remained stable. Importantly, none of the patients experienced any worsening of symptoms or any new complaints. The treatment was well tolerated; the only reported effect was mild post-meal drowsiness in a couple of patients, which resolved spontaneously. No subject withdrew from the study. Overall, the therapeutic intervention led to significant symptom relief and improved quality of life. For example, one patient commented that “[t]he burning in my stomach is almost gone; I can sleep at night,” reflecting the typical patient perspective. Many participants appreciated the natural, gentle nature of the therapy.

DISCUSSION

This pilot study suggests that Amalakathi Kirutham is effective for treating Erigunmam (acid peptic disease) symptoms. All major dyspeptic domains improved significantly. The magnitude of change (GSRS scores) indicates a clinically meaningful effect, as average scores dropped from moderate–severe to none–mild levels. This is comparable to what might be expected from conventional acid-suppressive therapy, though direct comparisons require a controlled trial. The observed hemoglobin rises and ESR fall further indicate reduced mucosal inflammation and improved nutritional status. The results align with the known pharmacology of the ingredients. *Emblica officinalis* showed strong anti-ulcer and antisecretory activity in animal studies; *Terminalia chebula* accelerated gastric emptying, which could reduce acid contact time. The ghee base may soothe the stomach lining. Thus, the formulation has multiple synergistic actions viz, neutralizing excess acid, protecting mucosa, and normalizing motility. In Siddha terms, it is attenuating Pitham (reduces excess heat-acid) and doesn't aggravate Vatham or Kabam. Importantly, patients don't experience any adverse effects. This tolerability contrasts with some risks of long-term PPI use. In an era where PPI overuse and related complications, an effective botanical alternative could be valuable [16]. That said, this study has limitations. It was an open-label, uncontrolled pilot with a small sample. Placebo effects cannot be excluded. The follow-up period was short, so long-term efficacy and relapse rates are unknown. Also, being a homogeneous Siddha hospital population, generalizability is limited. Future research should include randomized controlled trials comparing Amalakathi to standard therapy, with larger samples and objective endpoints (e.g. endoscopy, pH monitoring). Biomarker studies could elucidate mechanisms (e.g. measuring gastric acid levels, mucosal healing). Additionally, standardization of the formulation and dosing should be established for wider use. Overall, this study demonstrates that a traditional Siddha protocol can be integrated into a modern clinical framework (GSRS scoring, laboratory tests) while preserving classical assessments. It highlights the importance of Ennvagai Thervu and Udal Thathukkal evaluations in documenting baseline constitution and response, although their detailed findings were not quantified here. The positive outcomes support the Siddha theoretical basis in balancing humors to treat disease.

PATIENT PERSPECTIVE:

Participants generally reported satisfaction with the treatment. Many noted that their symptoms (especially heartburn and abdominal discomfort) were “much better” or “gone” by the end of therapy. Because the remedy is herbal and orally administered, patients felt it was convenient and natural. One patient remarked, “I didn't feel any side effects, and my stomach feels calm now.” The regimen was considered easy to follow, and most would consider using the treatment again if symptoms recurred. No patient expressed regret about participation; on the contrary, some expressed interest in more Siddha therapies.

INFORMED CONSENT:

The Institutional Ethics Committee approved the study protocol. All participants provided written informed consent before enrollment, by acknowledging understanding of the study aims, procedures, risks and benefits. They consented to publication of anonymized data.

CONCLUSION

In this pilot clinical evaluation, Amalakathi Kirutham administered over 48 days produced significant relief of acid-peptic symptoms with an excellent safety profile. The Siddha assessment parameters corroborated the clinical findings of improved balance (reduced Pitham manifestations). These findings suggest that Amalakathi Kirutham is a promising complementary therapy for Erigunmam, meriting further investigation. Its ingredients have known gastroprotective properties, which may explain the observed benefits. Given the high prevalence of acid peptic disorders and concerns over long-term conventional drug use, such traditional formulations warrant larger controlled trials. Future research should also standardize the therapy and explore its long-term effects.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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