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ORIGINAL ARTICLE

OPEN LABEL SINGLE CENTRIC CLINICAL EXPLORATORY OF EFFICACY STUDY ON FRUIT FIBER CAPSULE, AN AYURVEDIC PROPRIETARY FORMULATION

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ABSTRACT

Background of the study: Gastrointestinal disorders such as Amlapittha (GERD), Ajeerana (indigestion), Agnimandya (loss of appetite), Gulma (peptic ulcer), and Kroorakoshta (bowel disturbances) are prevalent health concerns. Traditional Ayurvedic medicine offers natural therapeutic solutions for digestive health. The present study clinically validates the efficacy of Fruit Fiber Capsule, a proprietary Ayurvedic formulation, in managing these conditions. The primary objective of this Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was to evaluate the effectiveness of Fruit Fiber Capsule in relieving gastrointestinal symptoms and improving digestive health. **Methods:** A total of 20 patients suffering from digestive disorders were enrolled in this study following ethical clearance. Patients were administered 1-2 capsules twice daily with lukewarm water for 30 days. Clinical investigations and laboratory assessments were conducted on Day 1 (Baseline) and Day 30 (End of Trial) by qualified AYUSH practitioners. Patients' symptoms, including epigastric pain, halitosis, bloating, fatigue, and abdominal discomfort, were monitored throughout the trial. **Results:** After 30 days of treatment, 75% (15 patients) showed very good improvement, 15% (3 patients) exhibited moderate improvement, 5% (1 patient) had mild improvement, and 5% (1 patient) reported no significant relief. One participant dropped out. The results indicate that Fruit Fiber Capsule significantly alleviated digestive disorders and enhanced overall gastrointestinal health. **Conclusion:** The study confirms that Fruit Fiber Capsule is an effective Ayurvedic intervention for digestive disorders, showing promising outcomes in GERD, indigestion, and bowel disturbances. Further large-scale studies are recommended for broader validation.

Keywords: Gastrointestinal disorders, Amlapittha, Ajeerana, Agnimandya

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INTRODUCTION

Digestive health is a crucial aspect of overall well-being, influencing nutrient absorption, immune function, and metabolic balance. Gastrointestinal disorders such as Amlapittha (Gastroesophageal Reflux Disease – GERD), Ajeerana (Indigestion), Agnimandya (Loss of Appetite), Gulma (Peptic Ulcer), and Kroorakoshta (Bowel Disturbances) affect millions worldwide, leading to significant discomfort and reduced quality of life[1].

Conventional treatment approaches for these disorders include proton pump inhibitors (PPIs), antacids, and prokinetics; however, prolonged usage of these medications is often associated with adverse effects, including nutrient malabsorption, dependency, and gut microbiota imbalance[2]. Consequently, the need for safer, natural, and effective alternatives has directed scientific interest toward Ayurvedic medicine, which has been traditionally used for centuries to manage digestive ailments[3].

Ayurveda, an ancient system of medicine, classifies digestive disorders based on the concept of **Agni (digestive fire), Doshas (biological energies – Vata, Pitta, Kapha), and Ama (toxins)**[4]. According to Ayurvedic principles, Amlapittha (GERD) results from aggravated Pitta dosha, leading to excessive acid secretion and inflammation in the stomach and esophagus[5]. Ajeerana (indigestion) and Agnimandya (loss of appetite) occur due to weakened digestive fire, leading to improper food breakdown and absorption[6]. Gulma (peptic ulcers) are caused by imbalances in the digestive system, often leading to chronic gastritis and ulcer formation, while Kroorakoshta (irregular bowel movements) results from an imbalanced Vata dosha, affecting intestinal motility and bowel regulation[7].

Modern scientific research has validated the efficacy of various Ayurvedic herbal formulations in treating gastrointestinal disorders[8]. Among these, Fruit Fiber Capsule, a proprietary Ayurvedic formulation, has been developed as a natural remedy to enhance digestive health. This formulation contains a blend of herbal extracts that possess carminative, anti-inflammatory, gastro-protective, and digestive stimulant properties. Herbal ingredients used in Ayurvedic medicine, such as Terminalia chebula (Haritaki), Emblica officinalis (Amla), Terminalia bellirica (Bibhitaki), Plantago ovata (Psyllium husk), and Foeniculum vulgare (Fennel), have demonstrated significant therapeutic benefits in digestive health[9].

Scientific studies highlight the role of dietary fiber and phytoactive compounds in improving gut motility, reducing acid reflux, and promoting beneficial gut microbiota[10]. Terminalia chebula (Haritaki), a key ingredient in the Fruit Fiber Capsule, has been traditionally used for its laxative, antimicrobial, and digestive-enhancing properties[11].

Clinical studies have shown that Haritaki modulates intestinal function, reduces bloating, and alleviates constipation through its mild purgative effects[12]. Similarly, Emblica officinalis (Amla) is a potent antioxidant and gastroprotective agent, known to improve digestion, strengthen gut mucosa, and reduce hyperacidity[13].

One of the major challenges in treating digestive disorders is maintaining gut

microbiome balance. Prebiotics and fiber-rich formulations play a vital role in promoting the growth of beneficial gut bacteria, thereby enhancing nutrient absorption and overall gut health[14]. The presence of Plantago ovata (Psyllium husk) in Fruit Fiber Capsule aids in softening stool consistency, regulating bowel movements, and preventing constipation, making it a valuable ingredient in Ayurvedic treatment for gut health[15].

Another major concern in gastrointestinal health is chronic inflammation, which contributes to conditions like **ulcers, gastritis, and irritable bowel syndrome (IBS)**[16]. Traditional Ayurvedic formulations target these issues through anti-inflammatory and mucosal-protective herbs such as Foeniculum vulgare (Fennel), which acts as an antispasmodic and relieves abdominal discomfort[17]. These herbs collectively work to restore digestive equilibrium, enhance enzymatic activity, and regulate intestinal motility[18].

The clinical validation of Fruit Fiber Capsule is of paramount importance to bridge the gap between traditional Ayurvedic knowledge and modern scientific evidence[19]. The present study aims to evaluate the efficacy and safety of this proprietary Ayurvedic formulation through a Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial conducted under stringent regulatory guidelines[20]. The study focuses on assessing symptomatic relief in GERD, indigestion, bowel disturbances, and peptic ulcers over a 30-day treatment period.

Previous research on Ayurvedic gastro-protective formulations has demonstrated promising results, suggesting that herbal interventions can serve as effective alternatives to conventional medications while minimizing side effects[21]. The incorporation of plant-based bioactive compounds in treatment strategies aligns with the global shift toward natural and holistic healthcare[22].

Given the increasing prevalence of gastrointestinal disorders and the limitations of conventional treatment approaches, this study seeks to provide scientific validation for the effectiveness of Fruit Fiber Capsule in improving digestive health. By conducting systematic clinical investigations and laboratory assessments, this research will contribute to the growing body of evidence supporting the role of Ayurvedic medicine in modern healthcare[23].

METHOD AND MATERIALS

Description of the population to be studied:

The population of Salem city is more than 10,00,000, and the estimated prevalence rates of patients with “Amlapittha (GERD), Ajeerana (Indigestion), Agnimandya (Loss of appetite), Gulma (Peptic Ulcer) and Kroorakoshta (Bowel disturbances) along with symptoms like Epigastric pain, halitosis (Bad breath), Pain in the abdomen, fatigue, bloating of abdomen” etc. shall be more than 10% in the area. To recruit the participants, we had advertised in the Social media (friend's groups, Local groups, Private Siddha/Ayurveda doctor groups, and on the Facebook pages of Siddha/Ayurveda hospitals and creating awareness in public exhibitions.

Responsibility of potential risks and benefits, if any, to human subjects.

As per Siddha/Ayurveda textual references found in First schedule (section 3a) of Drugs and cosmetic act 1940, and scientific research studies done anywhere regarding the herbal ingredients found in the formula supplied by the manufacturing unit, an Undertaking has been obtained from the Manufacturer of the product that the Sample supplied for clinical trials contains only the herbal ingredients mentioned in the references found in first schedule Siddha/Ayurveda classical texts.

The Clinical research center has recruited the patients willing for the study after obtaining their written consent and provided the medicine in the prescribed dosage indicated in the package under the supervision of qualified Siddha/Ayurveda physician.

It has been clarified to the manufacturer that any Metals if included in the formula should conduct Toxicity studies and Pre-clinical animal studies before conducting clinical trials, and it was also clarified that the Manufacturer of the product is solely responsible for potential risk - if any, to human subjects undergoing this clinical study.

Quality control and quality assurance: The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word “For Clinical studies only”.

Description of and justification for, the route of administration, dosage, dosage regimen, and treatment period.

Route of Administration Dosage - Oral usage

Dosage - 1-2 capsules bds with 100 ml lukewarm water.

Dosage regimen - Morning and night, after food. Treatment period - 30 days.

Trial Study Center: The centre of study is, Outpatient department. CRO - Ashram Siddha research institute, Swarnapuri, Salem city, Salem district.

IEC clearance: The prospective Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is duly approved by the INSTITUTIONAL ETHICAL COMMITTEE FOR CLINICAL RESEARCH OF THECRO, Ashram Siddha Research Institute, constituted under Rule-7 and registered under Rule-8 of The Central Drugs Standard Control Organization \CDSCO) under Directorate General of Health Services, Ministry of Health and Family welfare, Govt. of India as per Ethical guidelines for Biomedical Research on Human subjects 2006 issued by AYUSH-ICMR guidelines. All patients were obtained with written informed consent.

Sample size and Period of study
Enrollment : 20 patients
Study Start Date: 29.11.2024
Study Completion Date: 31.12.2024

Screening Of Patients for Study: In the present study, patients suffering from symptoms like “Amlapittha (GERD), Ajeerana (Indigestion), Agnimandya (Loss of appetite), Gulma (Peptic Ulcer) and Kroorakoshta (Bowel disturbances) along with symptoms like Epigastric pain, halitosis (Bad breath), Pain in the abdomen, fatigue, bloating of abdomen” etc. was taken for study. The Inclusion and exclusion were made by recording their past history and through clinical examination. After recruitment, all follow-up visits were performed at the same hospital by qualified

Siddha/Ayurveda graduate investigators in keeping with the protocol.

Obtaining patient consent: Whenever a patient is included in the study a consent form in his mother tongue (enclosed) detailing the procedures with side effects if any, benefits from the treatment, was explained and details of the follow up visit was also explained. The procedure for referral clause, withdrawal, and adverse effects was explained thoroughly.

Criteria for Inclusion: Patients above 20 years and below 60 years, suffering from clinical symptoms like "Amlapittha (GERD), Ajeerana (Indigestion), Agnimandya (Loss of appetite), Gulma (Peptic Ulcer) and Kroorakoshta (Bowel disturbances) along with symptoms like Epigastric pain; halitosis (Bad breath), Pain in the abdomen, fatigue, bloating of abdomen" etc. was taken for study.

Criteria for Exclusion: Participants will be excluded if they are above 60 years, experiencing or have a history of the following: Osteo arthritis, history of drug/alcohol abuse, night/shift-work employment, Diabetic complications, Psoriatic arthritis and any endocrine disorders.

Criteria for withdrawal: During the course of the trial, if any serious conditions develop (or) the symptoms aggravate which requires urgent treatment, such subjects may be withdrawn from the trial.

Outcome measure: Routine Examination and assessment as per Indian Medicine Physiology

The complete History and physical examination of the patients along with Envagaithaervu, tridoshanaadi, saptha dhatu thaervu etc. were recorded in a case sheet on first day. The second Clinical assessment were done on 30th day of treatment.

Blood test: Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

Intervention: The patients were provided with Proprietary Ayurvedic Medicine — FRUIT FIBRE CAPSULE, and advised to take 1-2 capsules, Morning and evening.As Lifestyle management with diet and exercise can improve the condition and patient self- management life style changes were advised.

Success indicators: Reduction of minimum 10 percent in symptoms at baseline and at the completion of treatment in the words of the patient, and measured as per the physician's conscience, can be taken as Success indicator.

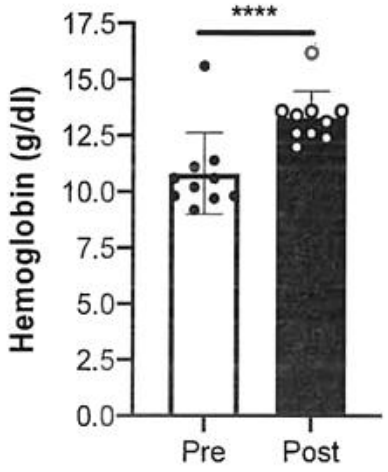
Laboratory Investigations and discussion:

Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

SPECIMEN	TEST NAME	METHOD	VALUE	UNITS	REF.RANGE
HAEMATOLOGY					
Blood	Hemoglobin	Sysmex XS 8ooi	..	g/dl	13.0-17.0
Blood	RBC count	Sysmex XS 8ooi	..	mil/cu.P	4.5-6.5
Blood	Haematocrit (PCV)	Sysmex XS 8ooi	..	%	40-54
Blood	MCV	Sysmex XS 8ooi	..	fl	75-95
Blood	MCH	Sysmex XS 8ooi	..	picogram	27-32
Blood	MCHC	Sysmex XS 8ooi	..	g/dl	32-36
Blood	Red cell width	Sysmex XS 8ooi	..	%	11-16
Blood	Platelet counts	Sysmex XS 8ooi	..	lakhs/cumm	1.5-4.0
Blood	Total WBC count	Sysmex XS 8ooi	..	cells/cumm	4000-11000
Blood	Differential count (DC)	VESMATIC ESAY			
	Neutrophils		..	%	40-80
	Lymphocytes		..	%	20-40
	Eosinophils		..	%	01-06
	ESR		..	mm/hr	0-10
CLINICAL PATHOLOGY URINE COMPLETE					
Urine	Protein	Combur UX strip (ROCHE)		..	
Urine	Ketone			..	
Urine	Pus cells			..	/Hpf
Urine	Epithelial cells			..	/Hpf

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



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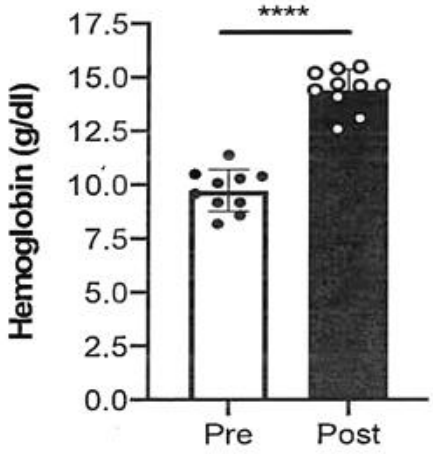

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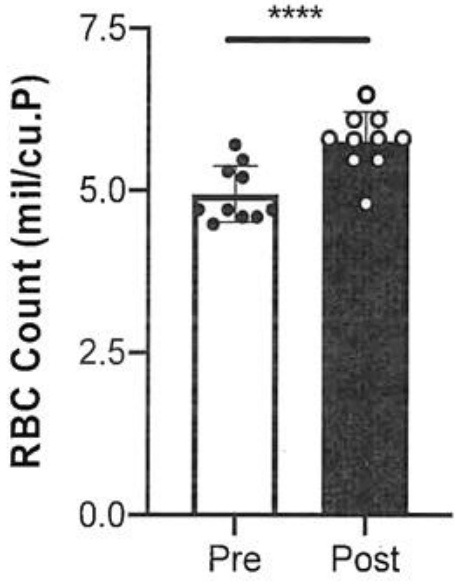

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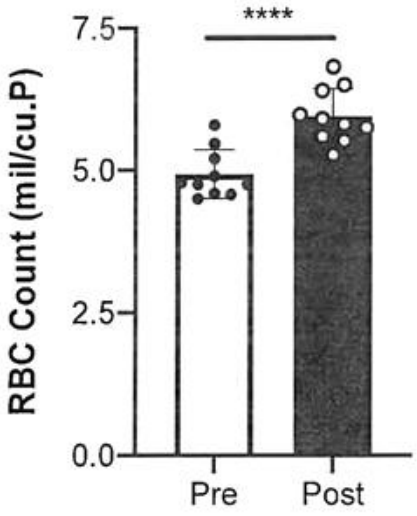

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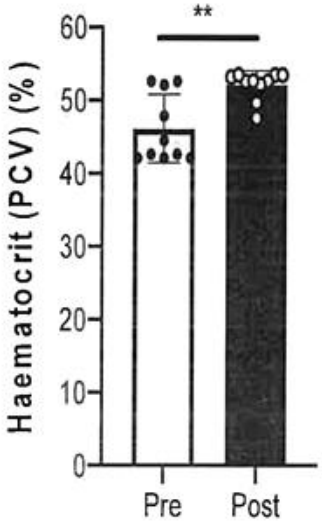

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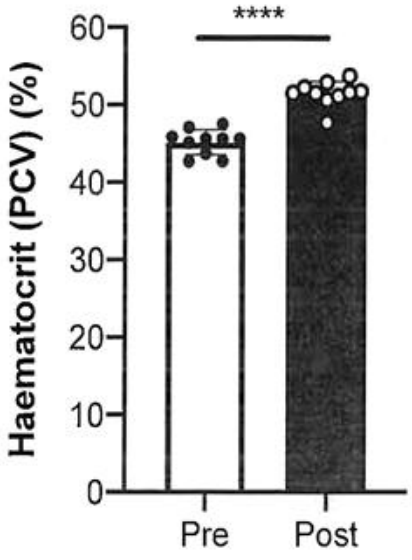

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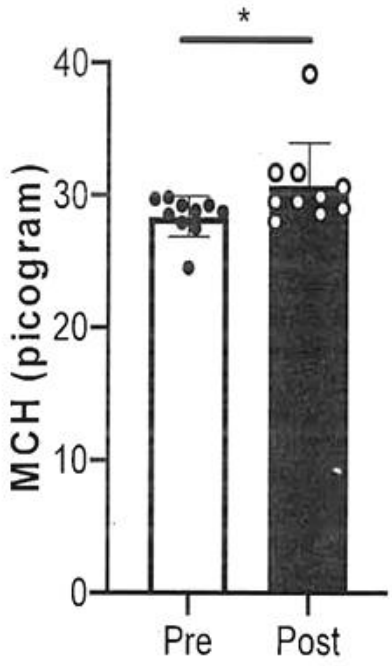

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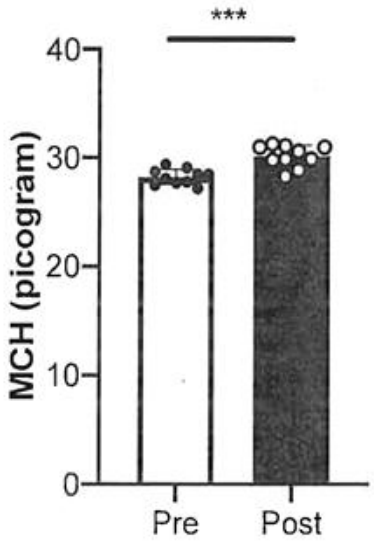

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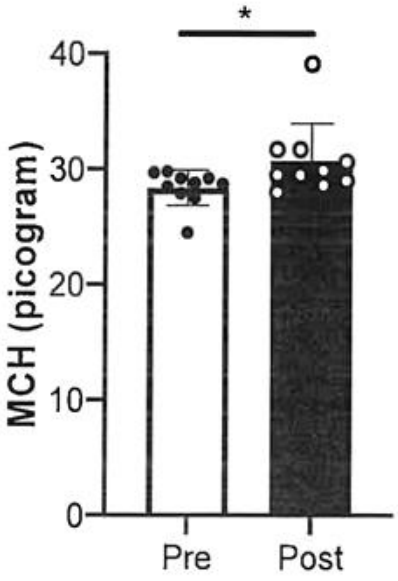

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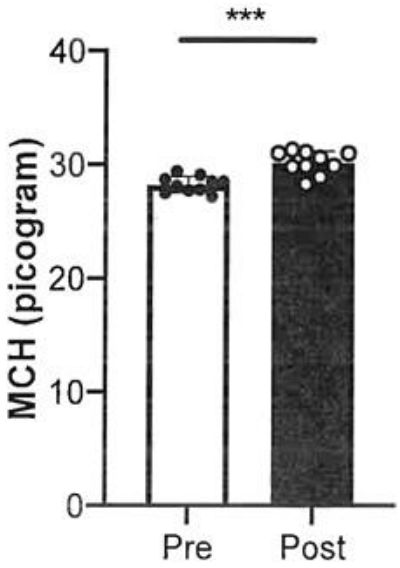

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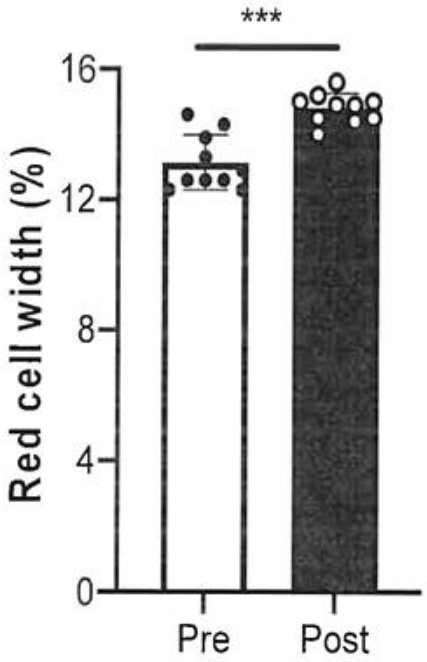

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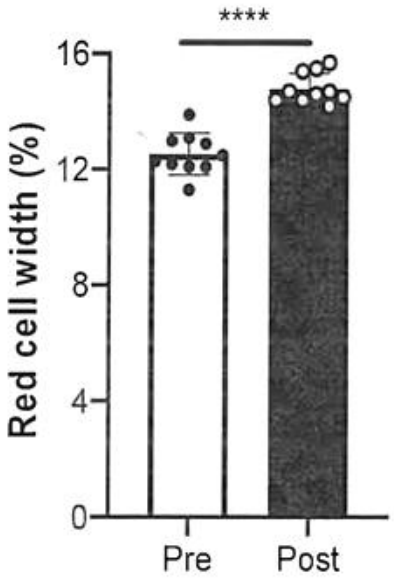

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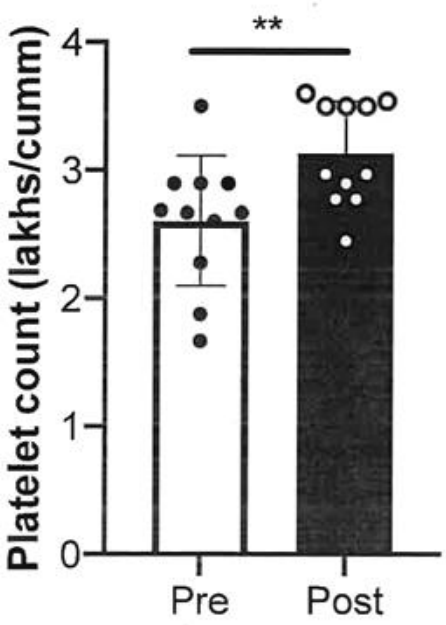

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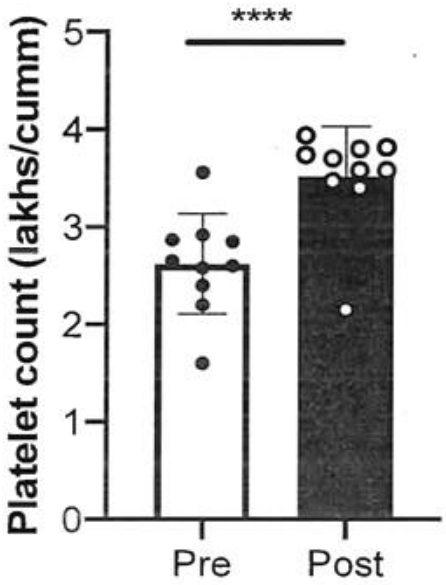

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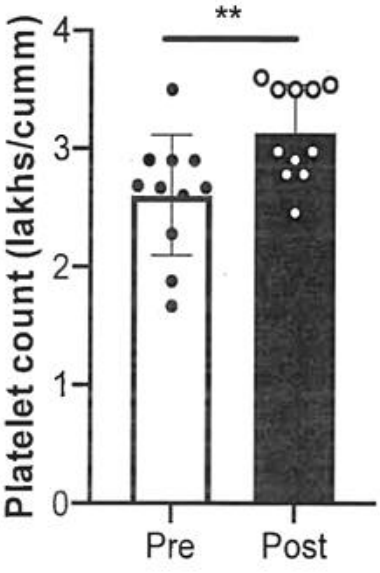

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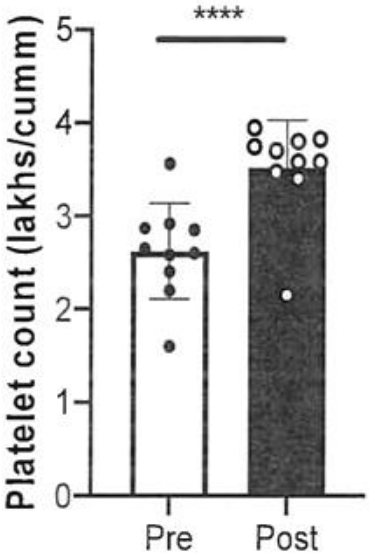

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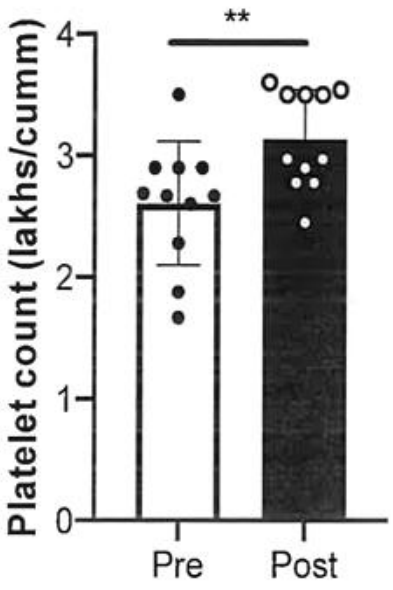

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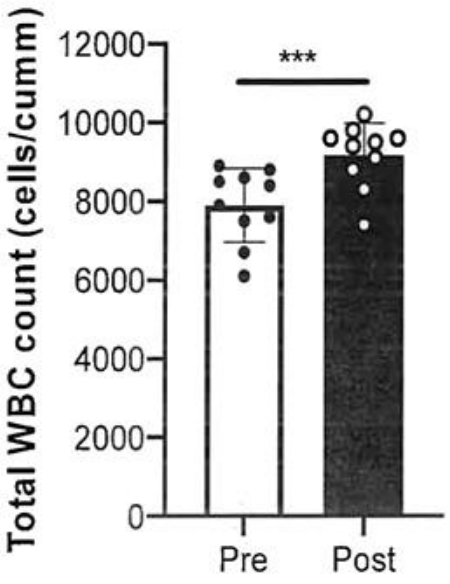

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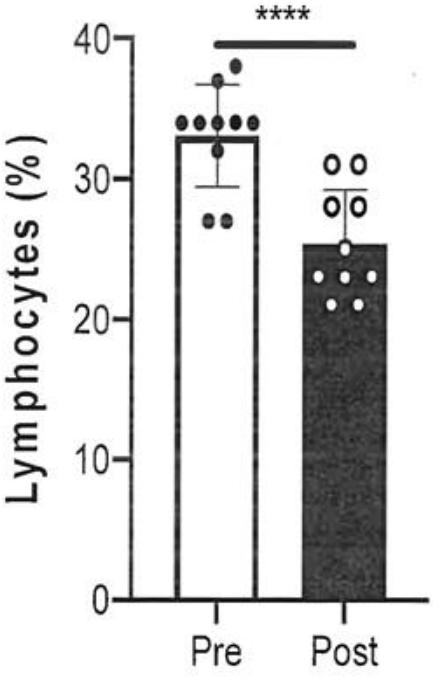

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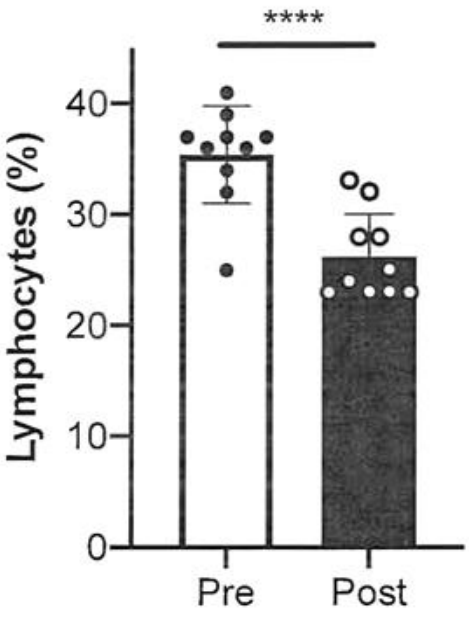

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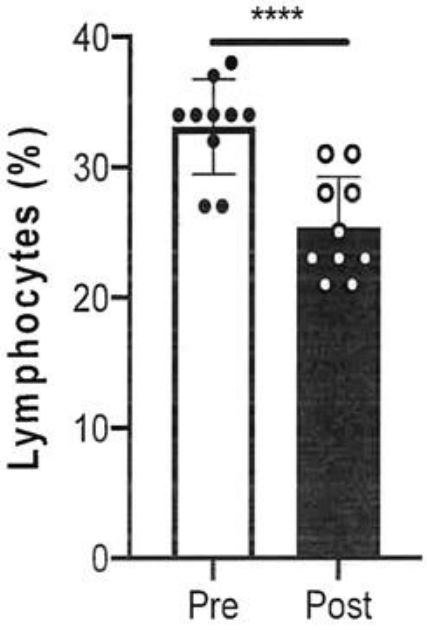

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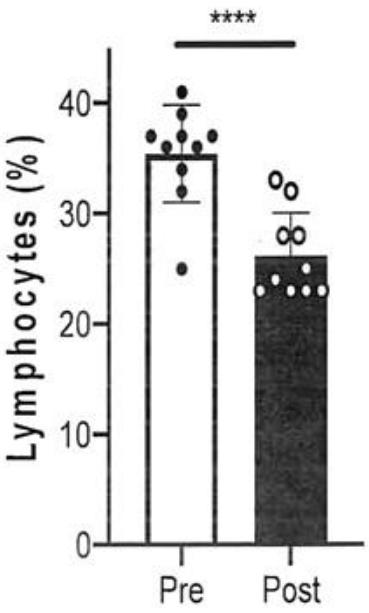

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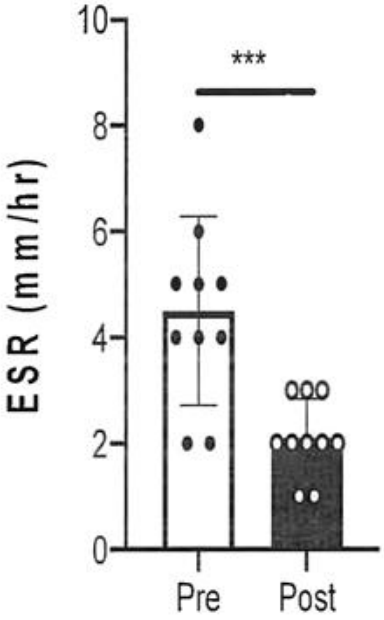

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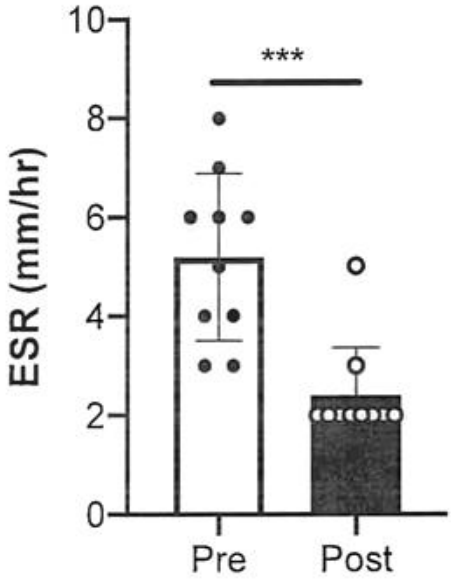
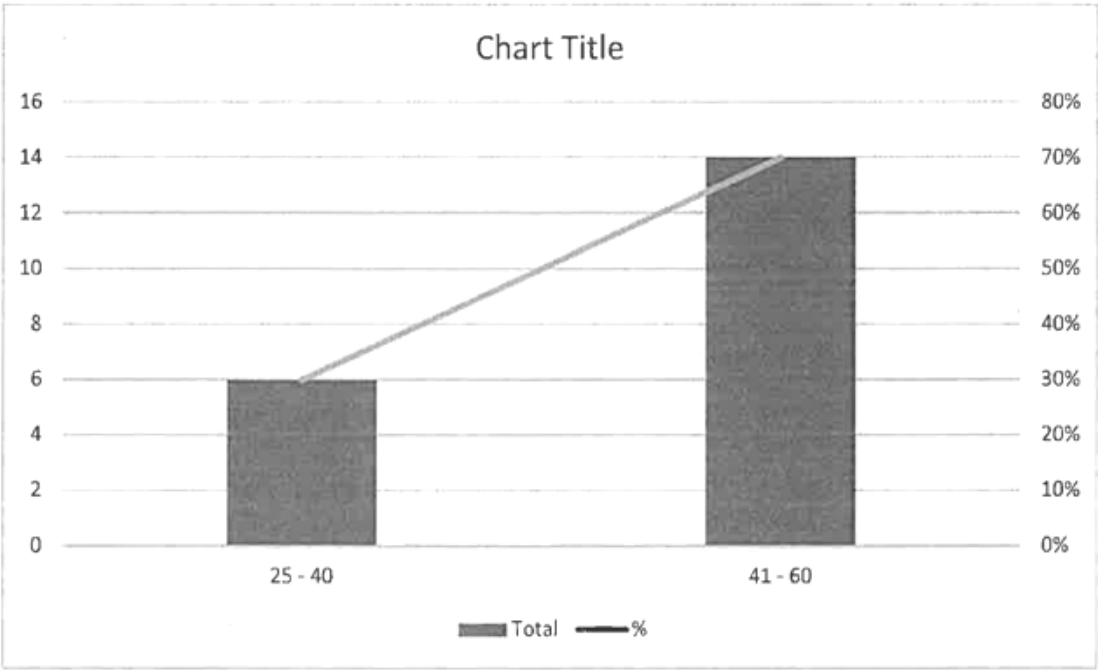


Cohort B

Discussion and Statistical analysis of the Results Obtained

TABLE -1.1 ; Age group of Patients (20)

Age group	Total	%
25 - 40	06	30%
41 - 60	14	70%

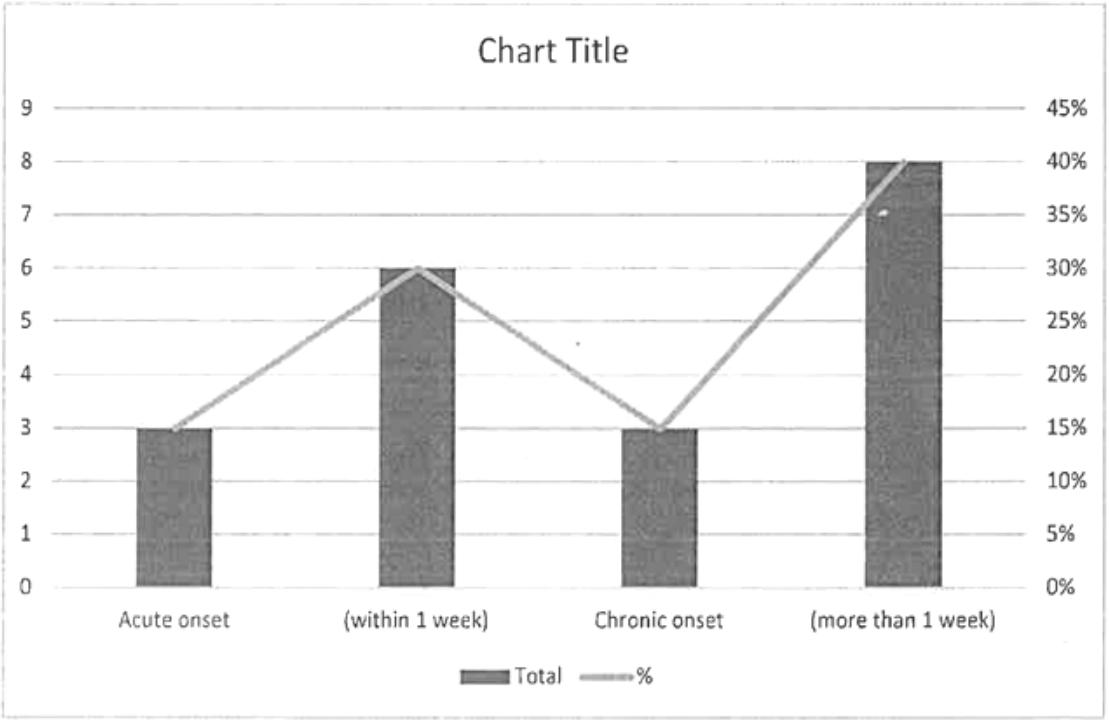


Interpretation

In total, 6 patients belonging to age group 25-40 years and 14 patients belonging to age group 41-60 years respectively had been taken for study.

TABLE – 1.2; Chronicity of the Disease (20)

Onset		Total	%
Acute onset (within 1 week)	21-30 years	3	15%
	31-40 years	6	30%
Chronic onset (more than 1 week)	21-30 years	3	15%
	31-40 years	8	40%

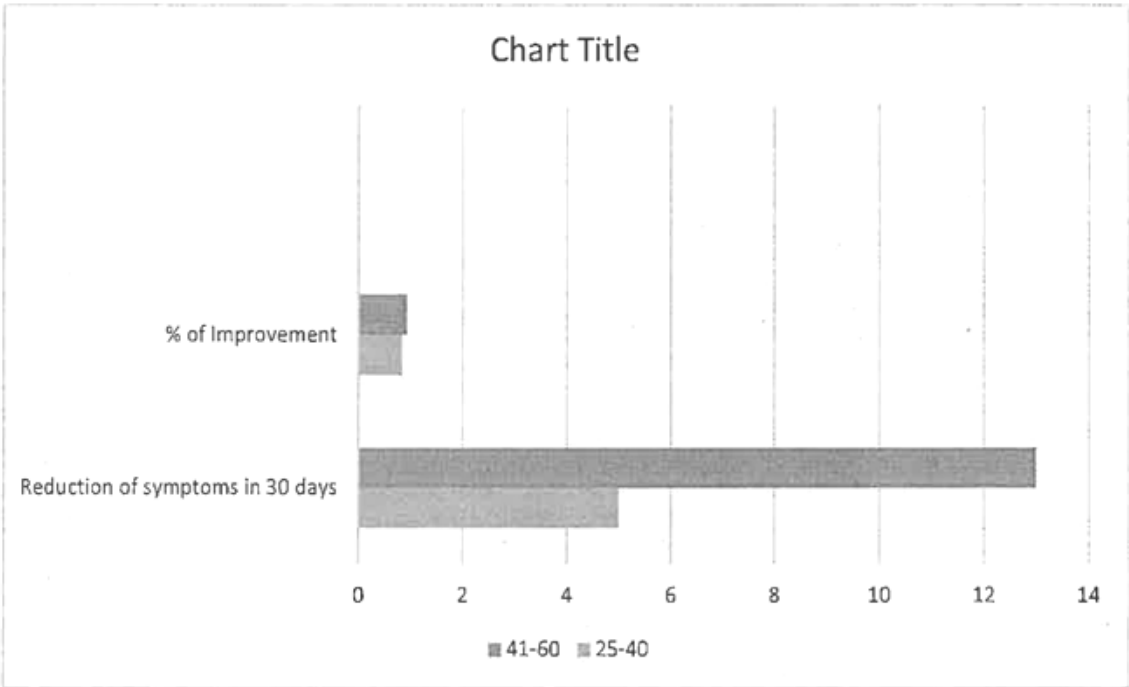


Interpretation

In total, 6 patients belonging to age group 25-40 years and 14 patients belonging to age group 41-60 years respectively who had been taken for study had the symptoms from within one week and more than one week.

TABLE – 1.3; Reduction of Amlapittha clinically- in One month (20)

Age group	Reduction of symptoms in 30 days	% of Improvement
25-40	5	83.3%
41-60	13	92.8 %

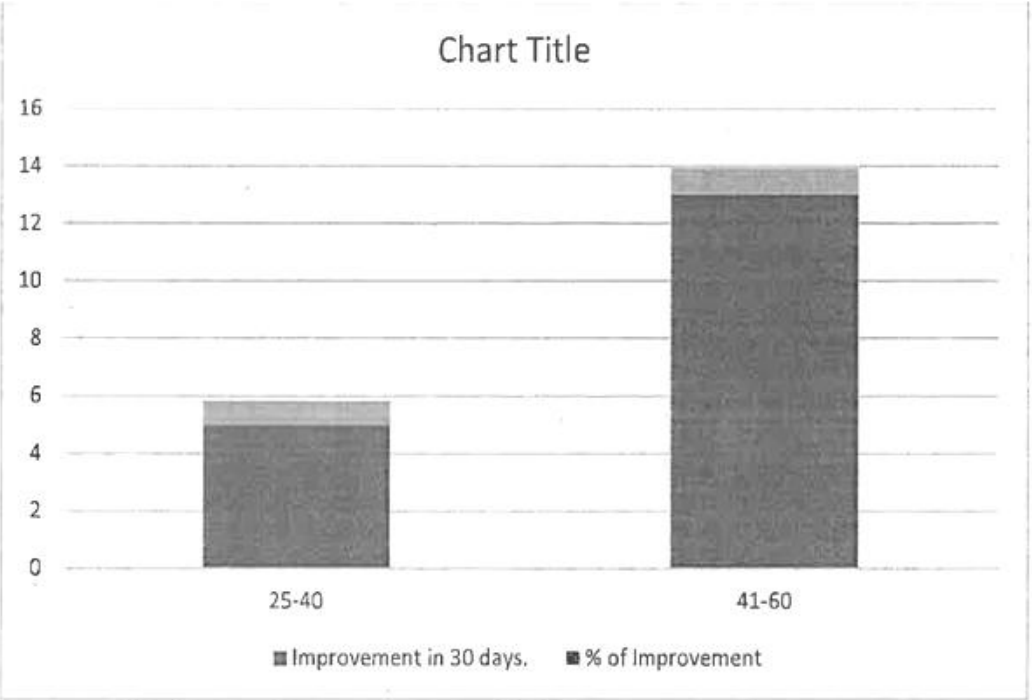


Interpretation

After the treatment of 30 days, 83% belonging to age group 25-40 years and 93% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

TABLE – 1.4; Improvement of agnimandya in One month (20)

Age group	Improvement in 30 days.	% of Improvement
25-40	5	83.3%
41-60	13	92.8 %

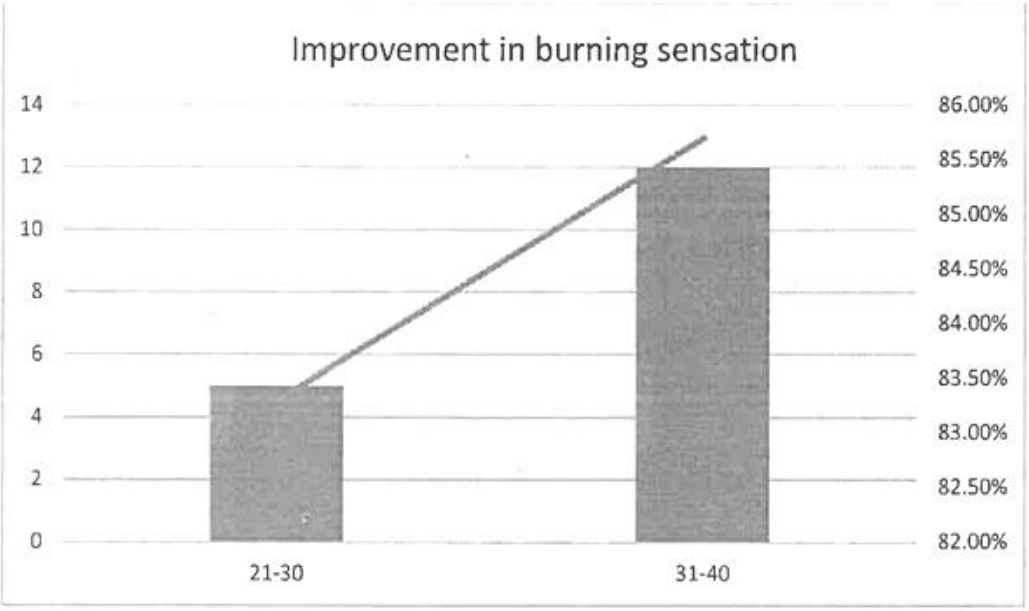


Interpretation

After the treatment of 30 days, 83% belonging to age group 25-40 years and 93% belonging to age group 41-60 years respectively had significant improvement of symptoms.

TABLE – 1.5; Improvement of Burning sensation in One month (20)

Age group	Improvement of *Burning sensation* in 30 days.	% of Improvement
25-40	5	83.3 %
41-60	12	85.7 %

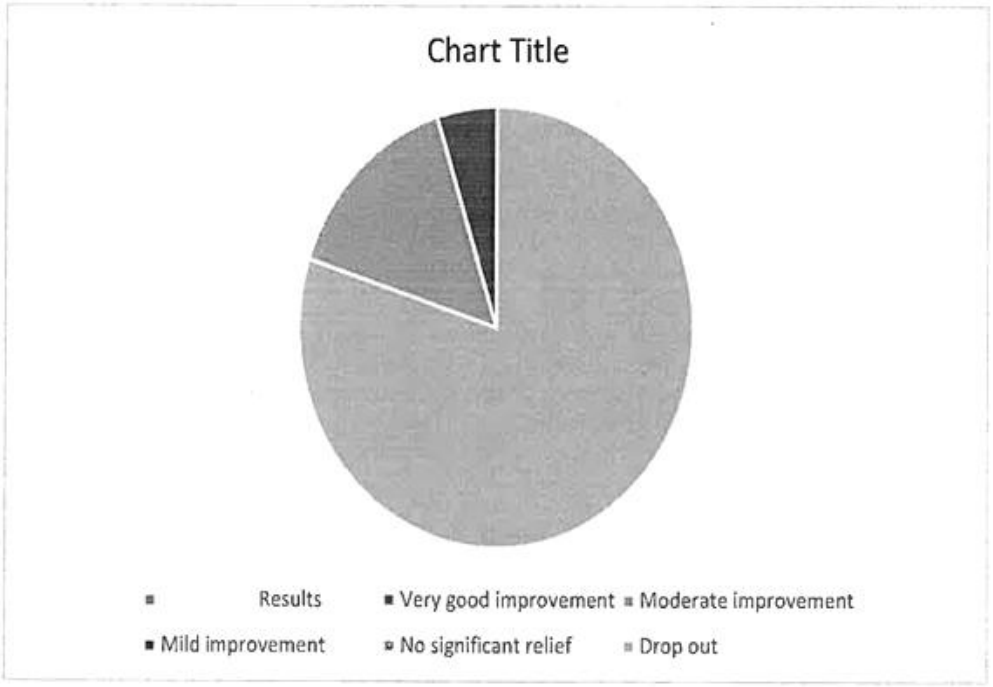


Interpretation

After the treatment of 30 days, 83% belonging to age group 25-40 years and 86% belonging to age group 41-60 years respectively had significant improvement of Burning sensation due to gulma.

Table – 1.6; **Overall results of Treatment in reduction of Clinical symptoms and Laboratory investigations in patients treated (Total 20 patients)**

Results	No. of patients	Percentage
Very good improvement	15	75 %
Moderate improvement	02	10 %
Mild improvement	01	5 %
No significant relief	01	5 %
Drop out	01	5 %

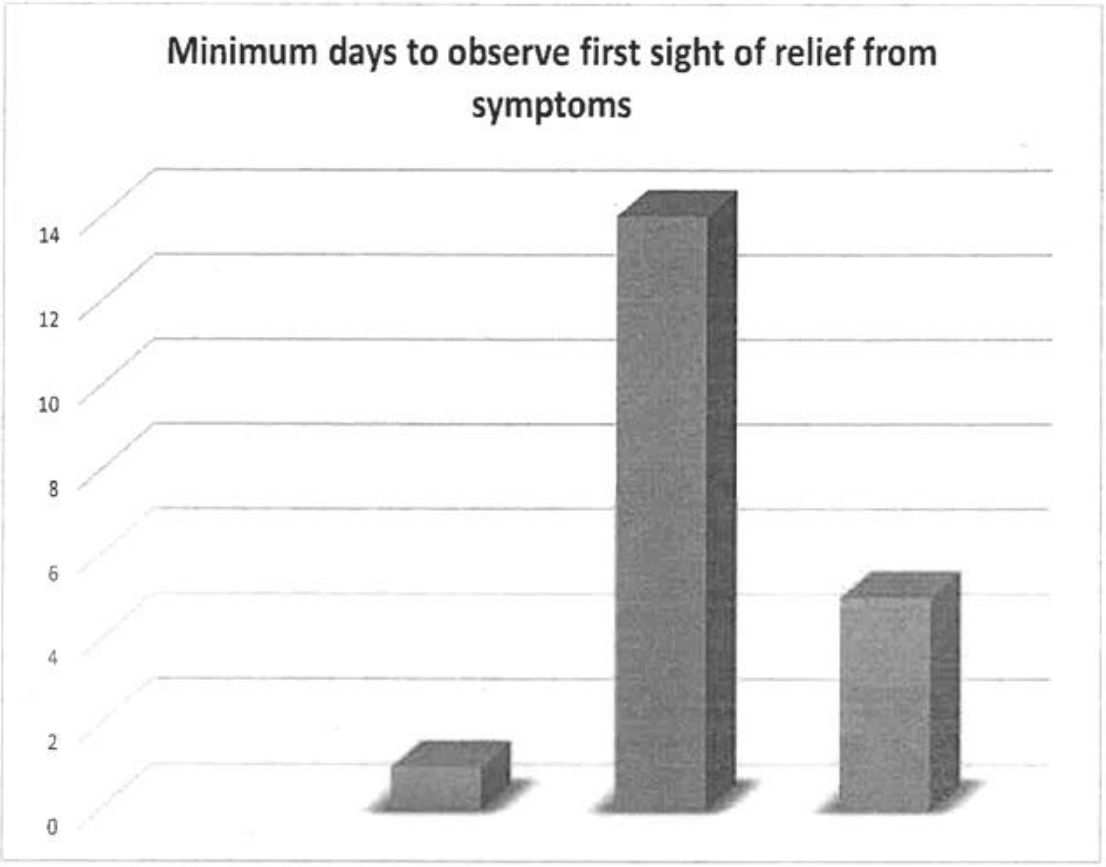


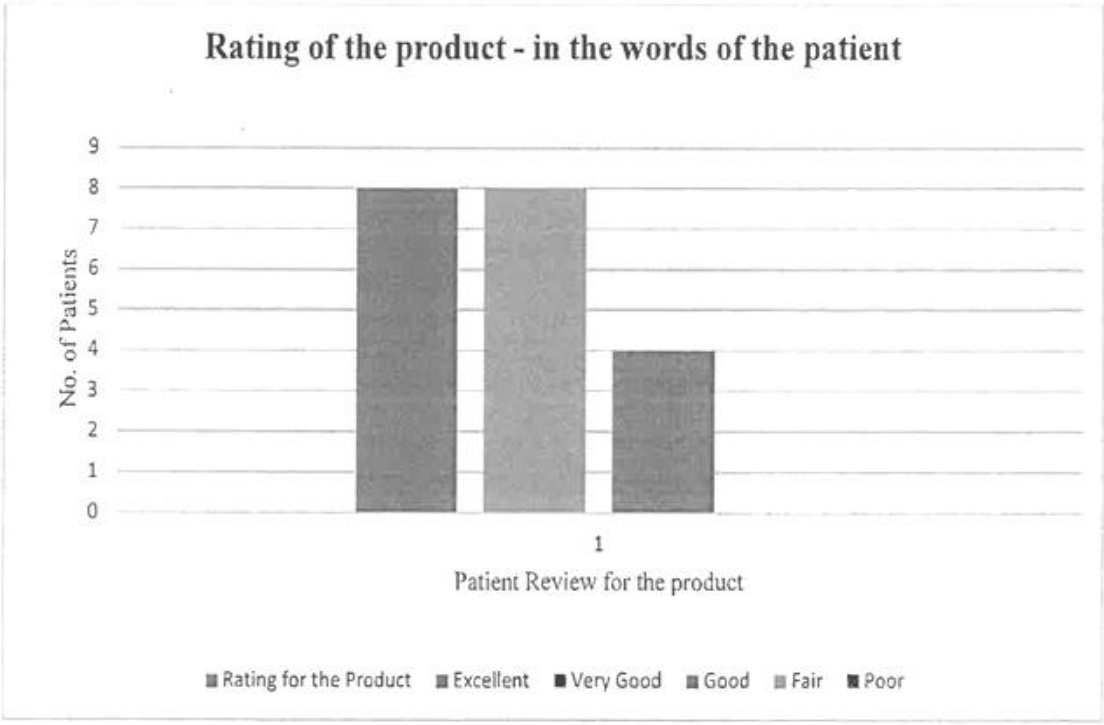
Interpretation

After the treatment of 30 days, 15 patients (75%) had very good improvement of symptoms, 3 patients (15%) had moderate improvement, one (05%) patient had mild improvement, No significant relief (05%) and one dropout (05%) from the study.

Table-1. Minimum days to observe first sight of relief from GERD, Gastritis and Gastric ulcer

S. no	Unique.ID	Age/sex	Date of issue of medicine	Date of first sight of relief observed	Number of days required for first sight of relief
1	1023	30/M	05.12.24	12.12.24	7
2.	1325	26/F	05.12.24	13.12.24	8
3.	1494	30/M	05.12.24	10.12.24	5
4.	1904	41/M	05.12.24	13.12.24	8
5.	2320	31/F	05.12.24	12.12.24	7
6.	2496	26/F	05.12.24	11.12.24	6
7.	2517	29/M	06.12.24	13.12.24	7
8.	2592	47/M	06.12.24	12.12.24	6
9.	2731	23/F	06.12.24	15.12.24	9
10.	2959	44/F	06.12.24	13.12.24	7
11.	3085	41/F	06.12.24	11.12.24	5
12.	3567	57/M	06.12.24	16.12.24	10
13.	3770	29/F	07.12.24	11.12.24	4
14.	3835	36/M	07.12.24	13.12.24	6
15.	3943	30/F	07.12.24	12.12.24	5
16.	4112	53/M	07.12.24	16.12.24	9
17.	4550	28/F	07.12.24	12.12.24	5
18.	4709	32/F	08.12.24	14.12.24	6
19.	4753	53/M	08.12.24	18.12.24	10
20.	4810	50/M	08.12.24	17.12.24	9


Minimum days to observe first sight of relief from symptoms
14
12
10
8
6
4
2
0


Rating of the product - in the words of the patient
No. of Patients
9
8
7
6
5
4
3
2
1
0
1
Patient Review for the product
Rating for the Product
Excellent
Very Good
Good
Fair
Poor

Direct access to source data/documents

We hereby agree that the investigator(s)/institution will permit trial-related monitoring, audits, institutional review board/independent ethics committee review, and regulatory inspection(s), by the Research Council/Department of AYUSH providing direct access to source data/documents.

Quality control and quality assurance

The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The lable should necessarily contain the word "For Clinical studies only".

Compensation to the Participant

As per GCP guidelines the subjects were compensated for the inconvenience and time present in connection with their participation in this clinical trial,by signing a Voucher after payment of compensation.

Participant protections and ethics

To protect human participants, the protocol was written according to general ethical guidelines, such as the Declaration of Helsinki and Good Clinical Practice and was approved by the institutional ethical committee of the organization. The study participant consent process includes information about potential risks, benefits, alternatives, and responsibilities during the trial.

Before participants agree to participate in this trial, researchers will explain this information in detail in person.

Data and safety monitoring

Regular monitoring that will be clarified in a standard operating procedure will be conducted to ensure good data quality. Monitors from IEC will evaluate whether the case report forms are properly written and whether the recruiting and treatment procedures are adequately performed according to the protocol. Investigators will be contacted to discuss whether it is necessary to revise the study protocol or inclusion criteria and other important issues. The investigators and independent researchers will assess the progress of the clinical trial and severeadverse events and determine whether they are acceptable and whether it will be necessary for the trial to be modified or stopped.

Case Sheets prepared for each patient and all the records and vouchers will be retained with the treatment centre for Three years.

CONCLUSION

The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is designed to evaluate the efficacy of Proprietary Ayurvedic Medicine - FRUIT FIBRE CAPSULE, Manufactured by VIJAYANI NUTRACEUTICALS PVT LTD, No.2B/1,2B/2, 6th street, 3rd Main Road, Ambattur Industrial estate South, Ambattur, Chennai-600058. Tamil Nadu. Onpatients suffering from clinical symptoms of Amlapittha (GERD), Ajeerana(Indigestion), Agnimandya (Loss of appetite), Gulma (Peptic Ulcer) and Kroorakoshta (Bowel disturbances).

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine - FRUIT FIBRE CAPSULE is highly effective in controlling Clinical symptoms o/ "Amlapittha (GERD), Ajeerana (Indigestion), Agnimandya (Loss of appetite), Gulma (Peptic Ulcer) and Kroorakoshta (Bowel disturbances) along with symptoms like Epigastric pain, halitosis (Bad breath), Pain in the abdomen, fatigue, bloating of abdomen" etc. It also contributed for their

Digestive health at baseline and at the completion of treatment, in the recruited patients.

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