

AN ETIOPATHOLOGICAL STUDY OF ANNADRAVA SHOOLA AND PARINAMA SHOOLA W.S.R. TO PEPTIC ULCER AND ITS THERAPEUTIC STUDY (UPSHAYATMAK PARIKSHANA) WITH DHATRI LAUH**Dr. Khushboo Gupta^{1*}, Dr. Avadhesh Kumar² and Dr. Shailendra Kumar Singh³**¹M.D. Scholar, Department of Roga Nidan Evum Vikruti Vigyan, Government P.G. Ayurvedic College & Hospital, Varanasi.²Reader & H.O.D., Department of Roga Nidana Evum Vikruti Vigyan, Government P.G. Ayurvedic College & Hospital, Varanasi.³Reader & H.O.D., Department of Roga Nidana Evum Vikruti Vigyan, SLBSS, Government Ayurvedic College & Hospital, Handia, Prayagraj.***Corresponding Author: Dr. Khushboo Gupta**

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ABSTRACT

Annadrava Shoola and Parinama Shoola can be compared to Gastric Ulcer and Duodenal Ulcer as explained in modern medical science respectively. Annadrava Shoola shows the characteristic features of Pain before, during the digestion and after the digestion, while Parinama Shoola shows feature of pain during the digestion of food. The present era is an era of new inventions and the modern medical science has stuck the mind of all by its day-to-day development. Disorders related to the digestive system are more on the rise due to the faulty diet and one such condition is peptic ulcer. Peptic ulcer disease is an ulcer (mucosal erosion) of the gastro-intestinal tract that is usually acidic and thus extremely painful. Peptic ulcer is a worldwide problem and its prevalence in India is quite high. Recent studies suggest approximately 10% of adults at some times of their lives get affected by peptic ulcer. It is true that modern medical science has grown up considerably, still it has to face a big question mark in so far as some miserable problems are concerned. The problem selected for this work is one among them. Considering the solemnity and incidence of the disease, the present study is aimed to observe Efficacy of Trial Drug Dhatri Lauh in clinically Diagnosed cases of Annadrava Shoola and Parinama Shoola.

KEYWORDS: Annadrava Shoola, Parinama Shoola, Peptic Ulcer, G.I.T.**INTRODUCTION**

Shoola is derived from the root of “shul” which means pain. In Uttarsthan of Sushruta Samhita shoola is defined as: a sharp piercing pain, as pierced by a sharp nail. According to Yogaratnakar, as mentioned in his Shoola nidana adhyaya: Pain as pierced by trident “trishula sambhawan chainan shulamahu”. In Ashtanga-hrudaya Nidana-sthan this Shoola is described as pierced by needle where the patient feel difficulty in breathing due to the pain. According to all Acharyas in all type of Shoola, Vata Dosha plays a predominant role. In case of Annadrava Shoola and Parinama Shoola there is no any description found in any text book of Brihatrayi like Charak Samhita, Sushruta Samhita and Astanga Sangraha. Acharya Madhavakar was the first author who has described Annadrava Shoola and Parinama Shoola as a separate disease entity. After acharya Madhavakar, many other Acharyas followed him and mentioned about both the diseases along with their features, treatment, Sadhya-sadhyta in a very descriptive manner.

Annadrava shoola and Parinama Shoola have direct relation with the process of food digestion and a pain dominant diseases-wide distribution of age with peak incidence in middle age. Annadrava shoola and Parinama shoola both are the diseases of Annavaha Srotas but among the diseases of Annavaha srotas, Annadrava shoola and Parinama shoola predominantly disturb the daily life. The study and use of crude drugs are one of the oldest of medical sciences. Crude drugs have always constituted more than half of the remedial agents in use at any time (**FAERGUSON 1958**). Various drugs are also described in Ayurvedic texts, for management of Annadrava shoola and Parinama shoola, which are being commonly used by Ayurvedic clinicians, since long time. When considering about the treatment for Annadrava shoola and Parinama shoola, trial drug Dhatri Lauh (herbo-mineral compound) is mentioned in Chakradatta in Shoola-rogadhikar adhyaya. It is an effective drug in vati form with easy preparation and for the justification of its use as a Annadrava shoola and Parinama shoola healing medication in Ayurvedic medicine.

Need of This Research Work

The present time is the era of fast food, irregularities in daily meal-time, sedentary life-style and mental stress. All these factors ultimately disturb the digestive system resulting in the manifestation of various disease, among them are Annadrava Shoola and Parinama Shoola. Every year over three lacks people around the world have ulcer related surgeries, because of the persistent symptoms or complications. All the operations for Peptic Ulcer have achieved their aim to some extent but with varying degree of morbidity, mortality and post-operative side-effects. Because of this condition, the person always remains in the state of discomfort. The treatment which has been advocated for this condition is usually symptomatic and has its own limitations. Dietary modifications in such patients have proved to be successful, however they are of limited value in the chronic progressive nature of the disease. Various drugs have been used for the treatment of Peptic Ulcer in Ayurvedic system, however, till date no remedy is available to make a permanent long-lasting therapy. The present study was planned with holy aim to find out a beneficial, safe and cost-effective drug in the management of Annadrava Shoola and Parinama Shoola.

AIMS AND OBJECTIVES

The present study has the prime objectives to know the efficacy of **Dhatri Lauh** in management of Annadrava Shoola & Parinama Shoola (Peptic Ulcer). During the study, the available literature in the Ancient & Modern medical books with regard to Annadrava Shoola & Parinama Shoola & Peptic Ulcer has been compiled & critically analyzed. This enables one to understand the physio-pathology of the disease & pharmacodynamics of the procedure in a better way. Taking these factors into consideration, the various objectives of the study can be enumerated as follows,

- 1- To review & analyze available literature of Annadrava Shoola & Parinama Shoola in Ayurvedic texts.
- 2- To review & analyze Peptic Ulcer in Modern Medical Science.
- 3- To evaluate the efficacy of **Dhatri Lauh** in Annadrava shoola & Parinama Shoola.

MATERIAL AND METHODS

The present clinical trial was studied in uncomplicated cases of Annadrava shoola and Parinama shoola. Selection of patients were done randomly from O.P.D. and I.P.D. of Roga Nidan and Kaya Chikitsa, Government P.G. Ayurveda College and Hospital, Varanasi. Patients for this clinical study were selected from 17th Dec 2020 to 10th May 2021.

The detailed symptomatic case history, demographic profile was recorded according to proforma prepared. After clinical examination, they were subjected to necessary modern laboratory examination, then diagnosis was confirmed and trial drug Dhatri Lauh was given.

In this clinical study total number of 40 patients were taken and all of them were given trial drug Dhatri Lauh 500mg BD with unequal amount of Ghrith and Honey for 30 days. Follow-up was done on each 7th day of period of study.

Inclusion Criteria

- Patients with clinical features of Annadrava Shoola and Parinama Shoola as per Ayurvedic Texts as well as Modern System of Medicine.
- Both sexes irrespective of Religion.
- Age of >16years and <60 years.

Exclusion Criteria

- Patients with features of malignant ulcer were excluded.
- Patients with complications of ulcer were excluded.
- Patients with uncontrolled diabetes.
- Patients with uncontrolled Hypertension (SBP \geq 140 mmHg or DBP \geq 90 mmHg)
- Patients having congenital deformity were excluded.
- Patients having immune-compromised diseases.
- Age <16 years
- Age >60 years
- Patients associated with uncontrolled systemic diseases were excluded.

Clinical Profile

The symptoms and sign were graded on a 0,1,2,3 scale for statistical valuation as follows.

0-Absent, 1- mild, 2-moderate, 3-severe

Grading of common symptomatology was done in above manners.

Drug

Trial Drug Dhatri Lauh is very effective and popular herbo-mineral compound. It is being used in the case of Annadrava shoola and Parinama shoola since years. In this present clinical trial, this Herbo-mineral compound drug is taken to see the efficacy of this drug in the patients of Annadrava shoola and parinama shoola. The drug was prepared in Ayurvedic pharmacy, Government P.G. Ayurveda College and Hospital, Varanasi. Its active constituents are.

- ❖ Amalaki churna (4 part)
- ❖ Yashtimadhu churna (1part)
- ❖ Lauha Bhasma (2 part)
- ❖ Guduchi (as Bhawna Dravya)

The dose of drug was given in this clinical study 1000 mg (1 gm) in two divided doses per day with unequal amount of ghrith and honey. The duration was kept 4 weeks.

Assessment Criteria

Assessment was done by considering the base line of data of Subjective parameters and objective parameters to before and after medication and was compared for

assessment of result. All the results were analyzed statistically for p-value using un-paired t-test.

1- On the basis of Etiological factors

The specific nidana for Annadrava Shoola and Parinama Shoola Parinama shoola has not been mentioned in the

classical texts. But the following guidelines can be considered as the causative factors of Annadrava Shoola and Parinama Shoola.

According to the Classical Text

Aharaj nidan

Amladi Atisevan
Lavanadi Atisevan
Ksharadi Atisevan
Tikshanadi Atisevan
Shushkadi Atisevan
Ushnadi Atisevan
Katuadi Atisevan
Sheetadi Atisevan
Atibhojan
Abhojanam
kashayadi
Virudhha bhojana
Adhyasana
Asatmya sevan
Vishamasana

Vihaaraj nidan

Divasvapna
Ratrijagaran
Atibhaar vahan
Atiagnitaap
Atichankraman
Atimaithun
Vegadharan

Mansika Nidan

Atikrodh
Atibhaya
Atishoka
Atichinta

According to Contemporary Medical Science

❖ Increase production of Gastric Acid due to excessive intake of-

Cereals
Poultry/Meats
Spicy foods
NSAIDs
Alcohol
Smoking:
Fatty food/Fast foods
Tea (empty stomach)

Irregular Dietary Habit

- ❖ **Prolonged fasting**
- ❖ **Excess Tension**
- ❖ **H. Pylori Infection**
- ❖ **Sleep Pattern** - regular/irregular
- ❖ **Sleep quality** - sound/disturbed
- ❖ **Trauma / Injury**
- ❖ **Other Causes**

2- Subjective Criteria

On the basis of Symptoms as given follow.

Gradation Parameter.

S.N.	Symptoms	Grade	Observation
1-	Udarshoola (Epigastric pain)	0	No pain
		1	Mild pain
		2	Moderate pain
		3	Severe pain
2-	Hrillasa (Nausea)	0	No nausea
		1	Mild nausea occasionally
		2	Persistent moderate nausea
		3	Persistent severe nausea
3-	Hritkantha daha (Burning Sensation)	0	No heart burn
		1	Occasional retrosternal burning
		2	Retrosternal burning 1-2 times, relived by antacids
		3	Frequent retro-sternal burning
4-	Adhaman (Flatulence)	0	Absent feeling of gaseous distension
		1	Sometime mild gaseous distension
		2	Moderate persistent gaseous distension
		3	Severe persistent gaseous distension
5-	praseka (Water-brash)	0	No complaint of water brash
		1	Occasional feeling of water
		2	Frequent complaint of watery mouth
		3	Regular complaint of watery mouth

6-	Amlodgar (Acid Regurgitation)	0	No acid regurgitation
		1	Occasional feeling of sour and bitter regurgitation
		2	2-3 complaints of acid regurgitation per day
		3	Frequent complaint of acid regurgitation
7-	Chardi (Vomiting)	0	No vomiting
		1	2-3 vomiting/week
		2	4-5 times vomiting/week
		3	5 or more than 5 times vomiting week

S.N.	Symptoms
8-	Avipaka (Indigestion)
9-	Aruchi (Anorexia)
10-	Trishna (Thirst)
11	Arati (Discomfort)
12-	Rakta Vamana (Haematemesis)
13-	Krishna varna-mala (Malena)
14-	Gaurav (Heavyness)
15-	Mala Apravriti (Constipation)
16-	Swedadhikya (perspiration)

Gradation:**0- Absent****2- Moderate****1- Mild****3- Severe****Objective Grading.**

S.N.	Laboratory Test	Grade	Observation
1-	*H. Pylori Rapid Test via Immunochromatographic Assay	0	Non-reactive
		1	Reactive

*The Immunochromatographic Assay test was performed at Laboratory of Government P.G. Ayurveda College and Hospital, Varanasi using a commercial kit, H. Pylori Rapid test kit by Standard Diagnostics bio-line^R following the manufacturer's instruction. Antibodies in the test samples, if present, formed antibody-antigen complexes with immobilized H. Pylori antigen on the membrane of the kit. The bound antibody-antigen complexes were subsequently detected by anti-human IgG conjugated to colloidal gold resulting in the appearance of the pink colored bands.

Investigations

For diagnostic purpose.

- Blood group,
- Hb%,
- R.B.S.
- L.F.T.
- USG Abdomen (to exclude other diseases) (if found necessary)

Data Collection: patients were thoroughly examined subjectively. Detailed history pertaining to the mode of onset, previous ailment, previous treatment history, family history, habits, routine investigations, USG Abdomen and radiological features are also investigated when needed to exclude other pathologies.

OBSERVATION AND RESULTS

Total 40 patients of Annadrava Shoola and Parinama Shoola (Peptic Ulcer) fulfilling the criteria for diagnosis were treated along with validation of disease state.

Demographic Data

- 1- Distribution of Patients as per Age:** Among 40 patients, 10 patients i.e., (25%) were of 16-30 age group, 16 patients i.e., (40%) were of 31-45 age group, 14 patients i.e., (35%) were of 46-60 age group.
- 2- Distribution of Patients as per Sex:** Among 40 patients, 30 patients i.e., (75%) were males and females were 10 patients i.e., (25%).
- 3- Distribution of Patients as per Religion:** Among 40 patients, 37 patients i.e., (92.5%) were Hindus, 03 patients, i.e., (7.5%) were Muslims.
- 4- Distribution of Patients as per Occupation:** Among 40 patients, 05 patients i.e., (12.5%) were from Agriculture, 06 patients i.e., (15%) were Labor, 10 patients i.e., (25%) were House-wives, 07 patients i.e., (17.5%) were Businessmen, 07 patients i.e., (17.5%) Servicemen, 05 patients i.e., (12.5%) were Students.
- 5- Distribution of patients as per Socio-economic Status:** Among 40 patients, 11 patients i.e., (27.5%) were lower class, 25 patients i.e., (62.5%) were middle class, 04 patients i.e., (10%) were upper class.
- 6- Distribution of patients as per Marital Status:** Among 40 patients, 34 patients i.e., (85%) were

married while 06 patients i.e., (15%) were unmarried.

- 7- Distribution of patients as per Educational Status:** Among 40 patients, 32 patients i.e., (80%) were educated while 08 patients i.e., (20%) were uneducated.
- 8- Distribution of patients as per Habitat:** Among 40 patients, 22 patients i.e., (55%) were from Rural area while 18 patients i.e., (45%) were from Urban area.

Data Related to Personal Status

- 9- Distribution of patients based on Deha Prakruti:** Among 40 patients, 07 patients i.e., (17.5%) were Vataja Prakruti, 04 patients i.e., (10%) were Pitta Prakruti, 09 patients i.e., (22.5%) were Kapha Prakruti, 04 patients i.e., (10%) were Vata-Pitta Prakruti, 09 patients i.e. (22.5%) were Pitta-Kapha Prakruti, 07 patients i.e., (17.5%) were Kapha-Vata Prakruti.
- 10- Distribution of patients based on Manas Prakruti:** Among 40 patients, 10 patients i.e. (25%) were Satva manas Prakruti, 18 patients i.e. (45%) were Raja Manas Prakruti and 12 patients i.e. (30%) were Tama Manas Prakruti.
- 11- Distribution of patients based on Diet:** Among 40 patients, 14 patients i.e. (35%) were vegetarian and 26 patients i.e. (65%) were of mixed diet.
- 12- Distribution of patients based on Addiction:** Among 40 patients, 38 patients i.e. (95%) had the habit of Tea/Coffee, 13 patients i.e. (32.5%) had the habit of Alcohol, 09 patients i.e. (22.5%) had the habit of Smoking, 12 patients i.e. (30%) had the habit of Tobacco/ Betel/ Pan, 02 patients i.e. (5%) had no any kind of addiction.
- 13- Distribution of patients based on Sleep pattern:** Among 40 patients, 03 patients i.e. (7.5%) had regular sleep while 37 patients i.e. (92.5%) had irregular sleep pattern.
- 14- Distribution of patients based on Sleep Quality:** Among 40 patients, 19 patients i.e. (47.5%) had sound sleep while 21 patients i.e. (52.5%) had disturbed sleep.
- 15- Distribution of 40 patients based on Mental Status:** Among 40 patients, 12 patients i.e., (30%) were Normal, 18 patients i.e., (45%) were aggressive, 10 patients i.e. (25%) were in depression while 40 patients i.e., (100%) were in Anxiety.
- 16- Distribution of 40 patients based on Agni:** Among 40 patients, 16 patients i.e., (40%) had Vishama Agni, 19 patients i.e., (47.5%) had Mandagni, 06 patients i.e., (15%) had Tikshna Agni.
- 17- Distribution of 40 patients based on Nature of Bowel:** Among 40 patients, 05 patients i.e. (12.5%) had normal bowel, 18 patients i.e. (45%) had hard bowel and 17 patients i.e. (42.5%) had sticky bowel.
- 18- Distribution of patients based on Koshtha:** Among 40 patients, 08 patients i.e., (20%) were of Mrudu Koshtha, 22 patients i.e., (55%) were of Madhyam Koshtha, 10 patients i.e., (25%) were of Krura Koshtha.

19- Distribution of patients based on Sara: Among 40 patients, 03 patients i.e., (7.5%) were of Pravara Sara, 31 patients i.e., (77.5%) were of Madhyam Sara while 06 patients i.e., (15%) were of Avara Sara.

20- Distribution of patients based on Samhanana: Among 40 patients, 02 patients i.e., (5%) were of Pravara Samhanana, 29 patients i.e., (72.5%) were of Madhyama Samhanana while 09 patients i.e. (22.5%) were of Avara Samhanana.

21- Distribution of patients based on Pramana: Among 40 patients, 02 patients i.e., (5%) were of Pravara Pramana, 34 patients i.e., (85%) were of Madhyam Pramana while 04 patients i.e., (10%) were of Avara Pramana.

22- Distribution of patients based on Satmya: Among 40 patients, 04 patients i.e., (10%) were of Pravara Satmya, 21 patients i.e., (52.5%) were of Madhyam Satmya and 15 patients i.e., (37.5%) were of Avara Satmya.

23- Distribution of patients based on Satva: Among 40 patients, 08 patients i.e., (20%) were of Pravara Satva, 20 patients i.e., (50%) were of Madhyam Satva and 12 patients i.e., (30%) were of Avara Satva.

24- Distribution of patients based on Abhyavaharana Shakti: Among 40 patients, 07 patients i.e., (17.5%) were of Pravara Abhyavaharana Shakti, 19 patients i.e., (47.5%) were of Madhyam Abhyavaharana Shakti and 14 patients i.e., (35%) were of Avara Abhyavaharana Shakti.

25- Distribution of patients based on Jarana Shakti: Among 40 patients, 04 patients i.e., (10%) were of Pravara Jarana Shakti, 16 patients i.e., (40%) were of Madhyam Jarana Shakti and 20 patients i.e., (50%) were of Avara Jarana Shakti.

26- Distribution of patients based on Vyayama Shakti: Among 40 patients, 02 patients i.e., (5%) were of Pravara Vyayama Shakti, 31 patients i.e., (77.5%) were of Madhyama Vyayama Shakti, 07 patients i.e., (17.5%) were of Avara Vyayama Shakti.

27- Distribution of patients based on Aharaja Nidana: Among 40 patients, 40 patients i.e., (100%) had Amladi Atisevana, 36 patients i.e., (90%) had Lavanadi Atisevana, 27 patients i.e., (67.5%) had Ksharadi Atisevana, 30 patients i.e., (75%) had Tikshanadi Atisevana, 25 patients i.e., (62.5%) had Shushkadi Atisevana, 35 patients i.e., (87.5%) had Ushnadi Atisevana, 24 patients i.e., (60%) had Katuadi Atisevana, 23 patients i.e., (57.5%) had Sheetadi Atisevan, 27 patients i.e., (67.5%) had Atibhojana, 40 patients i.e. (100%) had Abhojana, 28 patients i.e., (70%) had Kashayadi Atisevana, 40 patients i.e., (100%) had Viruddha Bhojana, 33 patients i.e., (82.5%) had Adhyasana, 32 patients i.e., (80%) had Asatmya Sevan, 39 patients i.e., (97.5%) had Vishamasana.

28- Distribution of patients based on Viharaja Nidana: Among 40 patients, 39 patients i.e.,

(97.5%) had Divaswapna, 40 patients i.e., (100%) had Ratrijagarana, 15 patients i.e., (37.5%) had Atibharvahana, 31 patients i.e., (77.5%) had Atiagnitaap, 34 patients i.e., (85%) had Atichankramana, 17 patients i.e., (42.5%) had Atimaitihuna, 40 patients (100%) had Vega-dharana.

29- Distribution of patients based on Manasika Nidana: Among 40 patients, 18 patients i.e., (45%) had Atikrodha, 21 patients i.e., (52.5%) had Atibhaya, 25 patients i.e., (62.5%) had Atishoka and 40 patients i.e., (100%) had Atichinta.

30- Distribution of patients based on Etiological Factors: Among 40 patients, 40 patients i.e., (100%) had excessive intake of Cereals, 26 patients i.e., (65%) had excessive intake of Poultry/Meats, 38 patients i.e., (95%) had excessive intake of Spicy foods, 19 patients i.e., (47.5%) had excessive intake of NSAIDs, 13 patients i.e., (32.5%) had excessive intake of Alcohol, 09 patients i.e., (22.5%) had excessive smoking, 28 patients i.e., (70%) had excessive intake of Fast foods, 38 patients i.e., (95%) had Tea (empty stomach), 40 patients i.e., (100%) had irregular dietary habits, 40 patients i.e., (100%) had prolonged fasting, 38 patients i.e., (95%) had excessive tension and 03 patients i.e., (7.5%) had Trauma/Injury.

31- Distribution of patients based on Chronicity of Illness: Among 40 patients, 11 patients i.e., (27.5%) had <1yr of illness, 23 patients i.e., (57.5%) had 1-5yr of illness, 04 patients i.e., (10%) had 6-10yr of illness and 02 patients i.e., (5%) had >10yr of illness.

32- Distribution of patients based on Symptoms as per Ayurveda: Among 40 patients, 40 patients i.e., (100%) had Udarshoola, 39 patients i.e., (97.5%) had Hrillassa, 40 patients i.e., (100%) had Hritkantha Daha, 40 patients i.e., (100%) had Adhamana, 40 patients i.e., (100%) had Praseka, 40 patients i.e., (100%) had Amlodgar, 20 patients i.e., (50%) had Chardi, 40 patients i.e., (100%) had Avipaka, 26

patients i.e., (65%) had Aruchi, 24 patients i.e., (60%) had Trushna, 40 patients i.e., (100%) had Arati, no any patient i.e., (0%) had Rakta Vamana and Krushna-varna mala, 39 patients i.e., (97.5%) had Gaurav, 21 patients i.e., (52.5%) had Mala-Apravruti and 25 patients i.e. (62.5%) had Swedadhikya.

33- Distribution of patients based on Symptoms as per Modern Science: Among 40 patients, 40 patients i.e., (100%) had Pain in Abdomen, 40 patients i.e., (100%) had Acid Regurgitation, 39 patients i.e. (97.5%) had Nausea, 20 patients i.e., (50%) had Vomiting, 26 patients i.e., (65%) had Anorexia, 40 patients i.e., (100%) had Flatulence, 21 patients i.e., (52.5%) had constipation, 40 patients i.e., (100%) had Indigestion, 40 patients i.e., (100%) had Heart-Burn, 40 patients i.e., (100%) had Water-brash, no any patient i.e. (0%) had Malena and Hematemesis, 39 patients i.e., (97.5%) had Heaviness and 25 patients i.e., (62.5%) had Excessive perspiration.

34- Distribution of patients based on incidence of H. Pylori: Among 40 patients, 21 patients i.e., (52.5%) were H. Pylori positive, 19 patients i.e., (47.5%) were H. Pylori negative.

35- Distribution of patients based on Blood Group: Among 40 patients, 05 patients i.e., (12.5%) were of A+ Blood Group, 17 patients i.e., (42.5%) were of B+ Blood Group, 03 patients i.e., (7.5%) had AB+ Blood Group and 15 patients i.e., (37.5%) were of O+ Blood Group.

RESULT

Effect of therapy on different parameter such as Udar shoola, Hrillassa, Hritkantha daha, Adhaman, Praseka, Amlodgar, Chardi, A vipaka, Aruchi, Trishna, Arati, Rakta vamana, Krishna varna-mala, Gaurav, Mala apravruti, Swdadhikya, were examined and recorded before and after the treatment and subjected to statistical analysis as follows.

Showing effect of therapy on Subjective & Objective Criteria

Complain		N	Mean	Std. Dev.	S.E.	't' value	df	p-value	Remark
Udarshoola	B.T.	40	2.10	0.44	0.07	29.33	39	<0.001	HS
	A.T.	40	0.23	0.42	0.07				
Hrillasa	B.T.	40	1.23	0.53	0.08	15.06	39	<0.001	HS
	A.T.	40	0.04	0.27	0.04				
Hritkantha Daha	B.T.	40	2.25	0.49	0.08	21.16	39	<0.001	HS
	A.T.	40	0.48	0.51	0.08				
Adhamana	B.T.	40	1.28	0.45	0.07	21.00	39	<0.001	HS
	A.T.	40	0.23	0.42	0.07				
Praseka	B.T.	40	2.15	0.58	0.09	24.13	39	<0.001	HS
	A.T.	40	0.43	0.50	0.08				
Amlodgara	B.T.	40	2.25	0.59	0.09	24.13	39	<0.001	HS
	A.T.	40	0.38	0.49	0.08				
Chhardi	B.T.	40	0.60	0.67	0.11	5.65	39	<0.001	HS
	A.T.	40	0.00	0.00	0.00				
Avipaka	B.T.	40	1.43	0.50	0.08	17.72	39	<0.001	HS

	A.T.	40	0.13	0.33	0.05				
Aruchi	B.T.	40	0.90	0.78	0.12	7.33	39	<0.001	HS
	A.T.	40	0.08	0.27	0.04				
Trushna	B.T.	40	0.68	0.62	0.10	6.30	39	<0.001	HS
	A.T.	40	0.13	0.33	0.05				
Arati	B.T.	40	2.08	0.42	0.07	21.60	39	<0.001	HS
	A.T.	40	0.43	0.50	0.08				
Gaurav	B.T.	40	1.33	0.53	0.08	15.76	39	<0.001	HS
	A.T.	40	0.23	0.42	0.07				
Mala Apravruti	B.T.	40	0.88	0.94	0.15	5.60	39	<0.001	HS
	A.T.	40	0.18	0.38	0.06				
Swdadhikya	B.T.	40	0.75	0.67	0.11	6.90	39	<0.001	HS
	A.T.	40	0.20	0.41	0.06				
H. Pylori infection	B.T.	40	0.53	0.51	0.08	4.33	39	<0.001	HS
	A.T.	40	0.20	0.41	0.06				

Showing effect of therapy on different subjective parameters (In Percentage)

Parameters	B.T.	A.T.	%	Improvement
Udarshoola	2.10	0.23	89.29%	Marked improvement
Hrillasa	1.23	0.08	93.88%	Marked improvement
Hritkantha Daha	2.25	0.48	78.89%	Marked improvement
Adhaman	1.28	0.23	82.35%	Marked improvement
Praseka	2.15	0.43	80.23%	Marked improvement
Amlodgar	2.25	0.38	83.33%	Marked improvement
Chardi	0.60	0.00	100.00%	Marked improvement
Avipaka	1.43	0.13	91.23%	Marked improvement
Aruchi	0.90	0.08	91.67%	Marked improvement
Trishna	0.68	0.13	81.48%	Marked improvement
Arati	2.08	0.43	79.52%	Marked improvement
Rakta vama	0.00	0.00	0.00%	
Krishna varna mala	0.00	0.00	0.00%	
Gaurav	1.33	0.23	83.02%	Marked improvement
Mala-apravruti	0.88	0.18	80.00%	Marked improvement
Swedadhikya	0.75	0.20	73.33%	Moderate improvement

A maximum percentage i.e., 100% improvement was observed in parameter chardi, 93.88% improvement was observed in Hrillasa, 91.67% improvement was observed in Aruchi, 89.29% improvement was observed in Udarshoola, 83.33% improvement was observed in Amlodgar, 83.02% improvement was observed in Gaurav, 82.35% improvement was observed in

Adhaman, 81.48% improvement was observed in Trishna, 80.23% improvement was observed in Praseka, 80.00% improvement was observed in Mala-apravruti, 79.52% improvement was observed in Arati, 78.89% improvement was observed in Hritkantha-daha, and 73.33% improvement was observed in Swedadhikya parameter.

Showing effect of therapy on Objective parameter (In Percentage)

Parameter	B.T.	A.T.	Percentage	Improvement
H. Pylori Infection	0.53	0.20	61.90	Moderate improvement

61.91% improvement was observed in case of H. Pylori infection.

Overall effect of therapy

Overall effect of treatment was 83.30 % which is a marked improvement.

DISCUSSION

At the completion of clinical study, the observational and results have to be interpreted and critically discussed to arrive at logical conclusions. This thesis is entitled "An Etiopathological Study of Annadrava Shoola and

Parinama Shoola w.s.r. to Peptic Ulcer and its Therapeutic study (Upshayatmak Parikshana) with Dhatri Lauh". The main aim of this study is to evaluate the therapeutic effect of Dhatri Lauh in the management of Annadrava Shoola and Parinama Shoola i.e., Peptic Ulcer.

By considering the efficacy of Dhatri-Lauh, it was decided to perform a clinical study based on scientific parameters and evaluate the efficacy of the trial drug in management of Annadrava Shoola and Parinama Shoola as it has been already said that clinical description of

annadrava shoola and parinama shoola was gradually evolved in texts first of all, by Madhavakar and further scientific input was added by Acharya Vijay Rakshit, Bhava Prakash & Yogaratnakar.

Hundreds of therapeutic therapies are described in Ayurvedic classics for management of Annadrava Shoola and Parinama Shoola, Dhatri Lauh is among such a formula and contains 4 important ingredients i.e., Amalaki, Yastimadhu, Lauh Bhasma and Guduchi (as Bhavna dravya). Amalaki is a very popular drug and having wide range of actions, but in this regard, its ulcer healing, mucoprotective and enhance the effect of Lauha are worth to be noted. Yastimadhu (Licorice) is also an effective ingredient, which has several actions, Anticholinergic, cytoprotective, ulcer healing is important to quote, Lauha Bhasma has quality of Rasayana and also having pacifying effect of Pitta and Kapha. Dhatri Lauh is such a unique compound which possess all such ingredients, by realizing all these unique qualities. Because of these unique ingredients Dhatri lauh was taken for clinical evaluation under present study.

Regarding the various observations, incidence of Age was most common in middle age group. This can be due to predominance of Pitta Dosha in this age group. Observation of Sex incidence, Peptic ulcer is more common in males than females. Observations regarding dietary habits showed that people who used to take mixed diet, fast foods, spicy diet, tea in empty stomach, Alcohol, Smoking were more prone to develop this disease than those patients who were taking ordinary diet, thus suggesting Pitta prakopaka ahara (aggravating diet) aggravates the disease, indicating that Annadrava Shoola and Parinama Shoola are a pitta dominant disease.

Response of treatment was assessed in terms of clinical and investigational improvement. Both, improvement was calculated statistically and by reduction of mean difference of symptoms score.

Highly significant improvement ($p < 0.001$) was found in symptoms like Udarshoola (pain in abdomen), Hrillasa (nausea), Chardi (Vomiting), Hritkantha Daha (Burning Sensation in chest and throat), Praseka (Water-Brush), Amlodgar (Acid Regurgitation), Avipaka (Indigestion), Aruchi (Anorexia), Trushna (Excessive Thirst), Arati (Restlessness), Gaurava (Heavyness), Mala Apravruti (Constipation), Swedadhikya (Excessive Perspiration). This trial drug also found Highly significant against H. Pylori infection ($p < 0.001$).

It is found that trial drug (Dhatri Lauh) showed excellent response in all of the symptoms of peptic ulcer. Total clinical response was also calculated in each patient and then percentage of reduction was calculated.

Investigational (H. Pylori Rapid Test Kit) improvement was also assessed in positive cases of peptic ulcer by repeat examination which is moderated improvement, it may be due to that, it requires long term treatment and further study.

PROBABLE MODE OF ACTION OF DHATRI LAUH

1- AYURVedic ASPECT

- ❖ Since, Vata Dosha is considered as the most prominent and most potent factor in initiating and maintaining the pathogenesis of Annadrava Shoola and Parinama Shoola, so Vata-anulomana property of Yastimadhu, Guduchi, Lauh Bhasma might probably helped in disease regression.
- ❖ Pitta dosha is considered as the predominant Dosha in Annadrava Shoola and Parinama Shoola, so we can say the Pitta-sarak Property of Amalaki, Mulethi, Yastimadhu might helped in removing the Saam-Pitta.
- ❖ Annadrava Shoola and Parinama Shoola are Rasaja Vyadhi and according to our Ayurvedic literature Langhan is considered as the one of the best treatments of Rasaja Vyadhi. Use of Pachaka Ausadhi lies under the process of Langhan. Guduchi, Lauh Bhasma and Amalaki might helped in proper digestion and removing the Ama dosha.
- ❖ Dipan activity of Guduchi, Lauh Bhasma might helped in stimulating the appetite.
- ❖ Shoola might be reduced due to Udarshoola Shamak property of Amalaki, Yastimadhu and Lauh bhasma.
- ❖ Daha-prashamana property of Amalaki, Yastimadhu might helped in reducing the burning sensation in GIT.

MODERN ASPECT

- ❖ Ulcer regression might be because of Anti-ulcer activity of Yastimadhu, Amalaki and Guduchi.
- ❖ Since, there is a strong causal relation between H. Pylori infection and Peptic ulcer, hence anti H. Pylori activity of Amalaki, Yastimadhu and Guduchi probably stopped the disease progression.
- ❖ There is an anti-spasmodic property in Amalaki, Lauh bhasma, yastimadhu, which helped in reducing or pulverizing the abdominal pain.
- ❖ Anti-inflammatory activity of Guduchi, Amalaki, Yastimadhu and lauh bhasma probably helped in checking the process of the disease.
- ❖ There is a strong relationship between ulcer and stress, so anti stress activity of Guduchi, amalaka might helped in alleviating stress.
- ❖ Infection with H. Pylori is associated with generation of free radicals which leads to oxidative stress in the gastric mucosa, so anti-oxidative therapy stimulates the healing of peptic ulcer. Anti-oxidative property of Amalaki, Yastimadhu and Guduchi probably helped in checking the progression of the disease, like Licorice has such flavonoids like- Glabrin and Glabridin.

SUMMARY

The entire work is summarized in this section. Present clinical study entitled as “An Etiopathological Study of Annadrava Shoola and Parinama Shoola w.s.r. to Peptic Ulcer and its Therapeutic Study (Upshayatmaka Parikshana) with Dhatri Lauh” was completed with a clinical trial. This dissertation has mainly 3 parts.

Part 1 includes Introduction, Objectives of the study, Literary review. During the study, the available literature in the ancient and modern medical books with regard to Annadrava Shoola and Parinama Shoola along with Peptic ulcer (gastric ulcer and duodenal ulcer) were completed and critically analyzed. This has enabled to understand the physiopathology of the Annadrava Shoola and Parinama Shoola and mode of action of the therapeutics in a better way. The essential drug required for the study along with their properties is described under the section of material and methods.

Part 2 deals with methodology. Method of preparation of the medicines along with study design is mentioned is mentioned under the heading of methodology. The patients suffering from Annadrava shoola and Parinama shoola (peptic ulcer) and fulfill the criteria of selection of the present study were randomly selected. The patients were subjected for detail clinical examination as per the specially designed proforma. Investigations which include Blood typing with Rh, H. Pylori rapid test and L.F.T. were done. H. Pylori rapid test was done before and after the treatment to analyze the effectiveness of clinical trial drug Dhatri lauh on eradication of H. Pylori bacteria. The present clinical study comprises of 40 patients, then they were divided into two categories i.e., Annadrava shoola and Parinama shoola according to their Sign and Symptoms and both the diseases were given clinical trial drug Dhatri Lauh.

Part 3 deals with observations, Results, Discussion, Conclusion and Summary. Among the selected 40 patients, observations of present study reveals that the incidence of Annadrava shoola and Parinama Shoola (Peptic Ulcer) is more among the middle age group, in males, middle class, married people, persons having Mandagni, Mixed diet, having addictions like tea/coffee, alcohol, drinking, having irregular and disturbed sleep, having Mental stress, having excessive indulgence in mentioned Aharaja, Viharaja and Mansika Nidana.

Response of treatment was assessed in terms of clinical and investigational improvement. Both, improvement was calculated statistically and by reduction of mean difference of symptoms score.

Highly significant improvement ($p < 0.001$) was found in symptoms like Udarshoola (pain in abdomen), Hrilasa (nausea), Chardi (Vomiting), Hritkantha Daha (Burning Sensation in chest and throat), Praseka (Water-Brash), Amlodgar (Acid Regurgitation), Avipak (Indigestion), Aruchi (Anorexia), Trushna (Excessive Thirst), Arati

(Restlessness), Gaurav (Heavyness), Mala Apravruti (Constipation), Swedadhikya (Excessive Perspiration). This trial drug also found Highly significant against H. Pylori infection ($p < 0.001$).

It is found that trial drug (Dhatri Lauh) showed excellent response in all of the symptoms of peptic ulcer. Total clinical response was also calculated in each patient and then percentage of reduction was calculated.

Investigational (H. Pylori Rapid Test Kit) improvement was also assessed in positive cases of peptic ulcer by repeat examination which is moderated improvement, it may be due to that, it requires long term treatment and further study.

After the observations when results were statistically analyzed, the overall effect of therapy reveals that in this clinical study 83.30 % i.e., marked improvement was found.

CONCLUSIONS

It can be concluded that, the present study proved the efficacy of Dhatri-Lauh in management of Annadrava Shoola and Parinama Shoola (Peptic Ulcer). The mode of its action may be Cytoprotective, Antisecretory, increases the mucosal resistance and prokinetic action etc.

The following conclusions can be drawn from the observations of the present study.

- 1- According to the present knowledge the normal functioning of the Agni, Pachaka pitta means the secreto-enzymatic functioning of GIT which is deranged in this disease.
- 2- The etiological factors mentioned in context of this disease according to Ayurveda are to be applied to the present-day food habits for pin pointing the causative factors. The irresistible stress and strain of this present era are related with the pathogenesis of this disease. Present lifestyle that has disturbed the food habits gives rise to Agnimandya, Ajirna and finally leads to Annadrava Shoola and Parinama Shoola.
- 3- From this study it can be concluded that non-compliance of code of healthy diet selection and eating habits play a major role in causation of the disease. Hence, we can say that code and conduct of healthy eating is important to achieve early and better result of the treatment as Nidana Parvarjana.
- 4- The clinical trial drug Dhatri Lauh was effective in alleviating the symptoms of Annadrava Shoola and Parinama Shoola, it may be due to its Deepan, Pachana, Pitta-sarak, Udarshoola Nashak, Vata-anulomana, Anti-inflammatory, Anti-ulcer, Anti-oxidant, Anti-stress, Anti-spasmodic and Rasayana properties.
- 5- On the basis of above-mentioned facts, thoughts, data and results, it can be concluded that Dhatri Lauh is definitely effective in the management of

Annadrava Shoola and Parinama Shoola, most importantly with life-style and dietary modifications. The study was conducted for a limited period and in a limited number of patients, hence it is suggested that to reveal more about efficacy of the trial drug and its satisfactory therapeutic response, the trial must be taken in a large number of heterogenous population, so that more reliable statistical data can be obtained.

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