

A Clinical Trial to Evaluate Efficacy of Dhatri Lauh in Management of Annadrava Shoola & Parinama Shoola w.s.r. to Peptic Ulcer

Dr. Khushboo Gupta

¹Assistant Professor, Department of Roga Nidana evam Vikriti Vigyan, R.K. Ayurvedic Medical College & Hospital, Kashipur, Surai, Azamgarh, U.P., India,

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. Disorders related to the digestive system are more on the rise due to the faulty diet and an example of 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 40% 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.

Key Words: Annadrava Shoola, Parinama Shoola, Peptic Ulcer.

Introduction:

Shoola is derived from the root of “shul” which means pain. In Uttarsthana of Sushruta Samhita shoola is defined as “a sharp piercing pain, as pierced by a sharp nail”. According to Acharya Yogaratnakar, as mentioned in his book in Shoola Nidan Adhyaya : Pain as pierced by trident “trishula sambhawan chainan shulamahu”. In Ashtanga-hrudaya Nidan-sthana 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-Asadhyta in a very descriptive manner.

Annadrava shoola and Parinama Shoola have direct relation with the process of food digestion and they are a pain dominant diseases with 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 text book of Acharya Chakradatta in the Shoola-Rogadhikar Adhyaya. It is an effective drug in vati form with easy preparation and it is use as a Annadrava shoola and Parinama shoola healing medication in Ayurvedic medicine.

Aims & Objectives:

This clinical trial has the prime objective to know the efficacy of **Dhatri Lauh** in management of Annadrava Shoola & Parinama Shoola (Peptic Ulcer). During the trial, 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:

This 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, U.P., India. 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 Ghrit 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 mentioned in Ayurvedic text books. It is being used in the case of Annadrava shoola and Parinama shoola since years. In this 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 (peptic ulcer). 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 nidanas for Annadrava Shoola and Parinama Shoola. Parinama shoola has not been mentioned in the classical Ayurvedic texts. But the following guidelines can be considered as the causative factors of Annadrava Shoola and Parinama Shoola.

According to the Classical Text

AHARAJA NIDANA	VIHARAJA NIDANA	MANASIKA NIDANA
Amladi Atisevan	Divasavpna	Atikrodha
Lavanadi Atisevan	Ratrijagarana	Atibhaya
Ksharadi Atisevan	Atibhaar vahan	Atishoka

Tikshanadi Atisevann	Atiagnitaap	Atichinta
Shushkadi Atisevan	Atichankraman	
Ushnadi Atisevan	Atimaithun	
Katuadi Atisevan	Vegadharan	
Sheetadi Atisevan		
Atibhojan		
Abhojanam		
Kashayadi Atisevan		
Virudhdha bhojana		
Adhyasana		
Asatmya sevan		
Vishamasana		

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)
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

1- Mild

2- Moderate

3- Severe

Objective Grading:

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

Data Related to clinical trial:

- 1- 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.
- 2- Distribution of patients based on Viharaja Nidana:** Among 40 patients, 39 patients i.e., (97.5%) had Divasvapna, 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 Atimaithuna, 40 patients (100%) had Vega-dharana.
- 3- 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.

- 4- 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.
- 5- 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.
- 6- 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 Hrillasa, 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.
- 7- 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.
- 8- 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.
- 9- 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, Hrillasa, 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 Hritkanthadaha, 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. The main aim of this trial 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 etc.

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 (*Embllica officinalis*), Yastimadhu (*Glycyrrhiza glabra*), Lauh Bhasma (Magnetic iron calx)

and Guduchi (*Tinospora cardifolia*) (as Bhavna dravya). Amalaki is a very popular drug and having wide range of actions, but in this regard, its ulcer healing, mucoprotective and enhancing the effect of Lauha are worth to be noted. Yastimadhu (Liquorice) is also an effective ingredient, which has several actions like Anticholinergic, cytoprotective, ulcer healing are 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 the clinical trial.

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), Hrilasa (nausea), Chardi (Vomiting), Hritkantha Daha (Burning Sensation in chest and throat), Praseka (Water-Brash), Amlodgar (Acid Regurgitation), Avipaka (Indigestion), Aruchi (Anorexia), Trushna (Excessive Thirst), Arati (Restlessness), Gaurva (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:

During the trial, 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 patients suffering from Annadrava shoola and Parinama shoola (peptic ulcer) and fulfill the criteria of selection of the trial 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.

Among the selected 40 patients, observations of the trial 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-Brush), 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.

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.

REFERENCES:

1. Charaka Samhita of Agnivesha, revised by Charaka and Supplemented by Dridhbala with Ayurveda Dipika commentary by Chakrapanidutta edited by Vaidya Yadavji Trikamaji Acharya, Chaukhambha Surbharati Prakashana, Varanasi, Reprint 2000.
2. Madhava Nidana with Madhukosha Commentary edited by Shri Sudarshan Shastri and Shri Yadunanadana Upadhayaya, Chaukhambha Sanskrit Sansthana, 26th edition 1976.
3. Sushruta Samhita edited with Ayurveda Tattva Sandipika hindi Commentary by Kaviraja Ambikadutta Shastri Part-2, Chaukhambha Sanskrit Sansthan, Varanasi 2015
4. Yogaratnakar, Vidyotini Hindi Commentary by Vaidya Lakshmi Patil Shastri, published by Chaukhambha Prakashana, Varanasi reprint in 2008.
5. The American journal of Gastroenterology, 2002
6. Bhavaprakasha edited by Pandit Sri Brahma Shankara Mishra, edition 2012, vol-2, Chaukhambha Sanskrit Bhawan, Varanasi
7. Chakradatta by Priyavrata Sharma, ed-2nd 1998, Chaukhambha Publishers.
8. Bhaisajya Ratnavali by Sri Kaviraja Ambikadatta Shastri Ayurvedacharya, Chaukhambha Sanskrit Sansthan, Varanasi.
9. Dravyaguna Vigyana by Prof. P.V. Sharma, vol-2, chaukhambha Bharati Academy.
10. Jorgensen. T.vergara peptic ulcer disease gastroenterology disease in India, 2006.