

A RANDOMIZED SINGLE BLIND CLINICAL STUDY IN THE MANAGEMENT OF PEPTIC ULCER DISEASE BY POLY HERBOMINERAL COMBINATION

Dr. Srinivas K Bannigol¹, Dr. Mahesh D Desai²

¹Professor and HOD, ².Asso. Prof, Department of Post Graduate Studies in Shalya Tantra, Ayurveda Mahavidyalaya, Hubli-580024.

Abstract

Disorders related to the digestive system are on the rise due to the faulty diet and habits. One such condition is Peptic ulcer. Peptic ulcer is an worldwide problem and its prevalence in India particularly south India is quite high, Recent studies suggests approximately 10% of adults at some times of their lives get affected by peptic ulcer. The cardinal feature of Peptic Ulcer Disease is pain during digestion of food which torments the person at every meal time and is a source of constant discomfort. Peptic ulcer can be correlated to Parinama Shoola. Parinama Shoola is also a disease of Annavaha srotas. Parinama Shoola that is Tridosaja is Asadhya. Parinama Shoola associated with Upadrava is Asadhya. The present study is undertaken to assess the efficacy of Leela Vilas Ras and Yashtimadhu gritha in Peptic ulcer disease. The combination of Leela Vilas Ras and Yashtimadhu Gritha is the ideal line of treatment in Peptic ulcer disease.

Key words: Parinama Shoola, Pitta, Peptic Ulcers, Peptic Ulcer Disease, Leela Vilas Ras, Yashtimadhu Gritha

Introduction

Ayurveda advocates the principle that Prevention is better than cure. Many theories have been explained to maintain health. The chief amongst them is Traya Upastambha (Three pillars of life) i.e. Ahara, Nidra and Brahmacharya¹. These three are

responsible for healthy and longevity of life. Amongst these three prime importance has been given to Ahara. Various rules are mentioned under the heading Ahara vidhi. Strict adherent to these rules of Ahara keeps the body away not only from metabolic diseases but also from other diseases. So the

principles of Aharavidhi mentioned in Ayurveda are relevant in present era.

The present era is an era of new inventions and the Modern Medical science has struck the minds of all by its day to day developments. It is true that the Modern Medical science has progressed considerably; still it has to face a big challenge in so far as some miserable problems are concerned.

Disorders related to the digestive system are on the rise due to the faulty diet and habits. One such condition is Peptic ulcer. It is also known as *ulcus pepticum*. Peptic ulcer disease is an ulcer (mucosal erosions) of an area of the gastrointestinal tract that is usually acidic and thus extremely painful. Though lot of work has been done on the etiology of this condition, one specific etiological agent cannot be incriminated in the causation of this particular disease especially in our country. However, the available information supports the central role of H.pylori and a necessary role of acid and pepsin. As much as 80% of ulcers are associated with Helicobacter pylori, a spiral-shaped bacterium that lives in the acidic

environment of the stomach. Ulcers can also be caused or worsened by drugs such as aspirin, other NSAIDs and glucocorticoids. Since Stress forms the most important single feature in causing peptic ulcer and today's modern life is full of stress and strain, hence this condition is on the increase. Peptic ulcer is an worldwide problem and its prevalence in India particularly south India is quite high, Recent studies suggests approximately 10% of adults at some times of their lives get affected by peptic ulcer².

Modes of treatment for this disease have been changing time to time. The disease is recognized as medico-surgical entity. Earlier Surgery was the ultimate treatment in this disease. The results after surgery were also not completely satisfactory, as early and delayed complications were associated along with recurrence. Off late surgery in this condition has been avoided except in managing complications of this condition. In consequence many new drugs have come up in modern era with promising ulcer healing effect. But none of these are labeled as ideal since their failure to give permanent cure besides some

other side effects. Triple therapy is currently regarded as the reference of anti-*Helicobacter pylori* treatment³. However, antibiotic-associated gastrointestinal side effects like Bloating, diarrhea and taste disturbances are among the major pitfalls of such regimens⁴. Moreover antibiotic resistant strains of *H.pylori* are on rise worldwide. The ideal treatment is the one that cures the original disease and also does not lead to another. The quest for such a medicine is always a challenge for all the Medical sciences including Ayurveda.

Shula is the presenting and the most troublesome symptom in all the disease of Annavaha srotas. Hence in the field of Gastroenterology Diagnosis and Management of Shoola plays a vital role. Parinama Shoola is a disease of Annavaha srotas. This condition has not been mentioned in any of the Brhatrayis. But the diseases Gulma, Shoola and Grahani may be taken as a guideline to understand this disease. Later Acharyas of Laghutrayis have explained Parinama Shoola as a separate entity. Pratyatma lakshana of this disease is pain during digestion of

food which torments the person after every meal time and is a source of constant discomfort. Yogaratnakara have mentioned Parinama Shoola as Durvijneyam and Mahagada i.e. difficult to identify and cure due to the serious nature of this disease.

The disease Parinama Shoola can be compared to peptic ulcer as explained in modern medical science. Considering the gravity of the condition, increasing incidence of the disease and non-availability of ideal treatment the present study is under taken. In the present study two formulations namely **Leela Vilas Ras**⁵ and **Yashtimadhu Gritha**⁶ are taken to find their efficacy in Parinama Shoola (Peptic ulcer) and an attempt also has been made to compare the efficacy of these formulations.

The patients suffering from Parinama Shoola (Peptic ulcer) who fulfills the criteria of selection of the present study were selected. The patients were subjected for detail clinical examination and investigations as per the specially designed proforma. The present clinical study comprises of 120 patients. They were divided into three groups as Group-A,

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Group-B and Group C each having 40 patients. All the Group patients were advised to undergo upper GI endoscopy before and after treatment.

Materials & Methods

Source of Data:

- Patients attending the OPD and IPD of Ayurveda Mahavidyalaya Hospital, Hubli.

Method of Collection of Data:

- Patients attending the Shalya Tantra OPD and IPD of Ayurveda Mahavidyalaya, Hubli, diagnosed as Parinama shoola (peptic ulcer) and fulfilling the inclusion criteria were selected.
- Patients were registered and recorded as per the specially designed clinical proforma.
- Reviews of literature was collected from Post Graduate Library, Department of Shalya Tantra, Ayurveda Mahavidyalaya, Hubli, and from Authentic Research Journals, Websites, and Digital Publications etc. The important books and journals required for the study will be procured from reputed international sellers.
- Required Medicines were prepared in the Department of Rasa Shastra and

Bhaisajya Kalpana, Ayurveda Mahavidyalaya Hubli.

- The raw materials and the medicines prepared were subjected to Chemical analysis study.

Inclusion Criteria:

- Patients with clinical features of Parinama shoola (Peptic ulcer).
- Presence of ulcer/erosions diagnosed by upper gastrointestinal endoscopy were selected.
- Patients of both sexes between 20 to 60 years age were included in the study.

Exclusion Criteria:

- Patients with features of malignant ulcer were excluded.
- Patients with acute features and with complication were excluded.
- Patients associated with uncontrolled systemic diseases were excluded.

1. Leela Vilas Rasa:

2. Yashti Madhu Ghrita:

Parameters of Study:

Following subjective and objective parameters were considered for the study.

Subjective:

1. Pain
2. Nausea
3. Vomiting

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4. Haematemesis

Anupana : Sukoshna Jala

Objective:

Duration : 3 months.

1. Malaena.

Follow Up : 1 month

2. Presence of ulcers/erosions assessed by Upper gastrointestinal Endoscopic study.

Group C:

Sample size: Minimum of 40 patients

Procedure : Internally

Study Design:

Drug : Leela Vilas Ras and
Yashtimadhu Grita

Present study is a Randomized single blind comparative clinical study.

Dosage : 125mg + 20ml twice
daily in empty stomach

Sample Size:

Minimum of 120 patients were selected randomly and categorized into three Groups as Group A, Group B and Group C.

Anupana : Sukoshna Jala

Duration : 3 months.

Follow Up : 1 month

Group A:

Observations & Results:

The subjects who were registered for the study were assessed according to a standard proforma. The details recorded are being put forth here. Totally 40 subjects completed the study in each group. The details are as follows:

Sample size:

Minimum of 40 patients

Procedure : Internally

Drug : Leela Vilas Ras

Dose : 125mg twice daily in
empty stomach

Anupana : Amalaki Choorna

➤ Maximum patients belonged to the age group of 41 to 50 years with 38.33%.

Duration : 3 months.

Follow Up : 1 month

Group B

Sample size: Minimum of 40
patients

➤ Maximum patients were males with 66.66%.

Procedure : Internally

➤ Maximum patients were married with 89.16%

Drug : Yashtimadhu Gritha

➤ Maximum patients had primary education with 22.50%

Dosage : 20ml. Twice daily
in empty stomach

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- Maximum patients belonged to Hindu religion with 89.16%
- Maximum patients had No habits with 49.16%
- Maximum patients belonged to middle income group with 57.50%
- Maximum patients had good quality of sleep with 50%
- Maximum patients had active occupation with 41.66%
- Maximum patients belong to O+ blood group with 37.50%
- Maximum patients had mixed diet with 60.83%
- Maximum patients had Vata Pitta prakruti with 28.33%

RESULTS

Effect of therapy on different parameters such as Udara Shoola(Epigastric Pain), Hrrlasa(Nausea), Vami(Vomitting), Hrit Daha(Heart Burn),Melena were examined and recorded before and after the treatment and subjected to statistical analysis as follows:

Summary Of Statistics With Regards To Pain In Peptic Ulcer Disease in all Three Groups:

ANNOVA: Single Factor						
Parameters	Group A		Group B		Group C	
Count	40		40		40	
Sum	39		51		71	
Mean	0.975		1.275		1.775	
SD	0.589		0.512		0.486	
ANOVA						
	Sum of Squares	Df	Mean Square	F Value	P Value	F Critical
Between Groups	13.06667	2	6.533333	12.34396	0.000014	3.073763
Within the Groups	61.925	117	0.529274			
Total	74.99167	119				

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The f value of all three groups is 12.34 which is higher than the f critical value of 3.07 which is statistically significant ($p = 0.000014$) with regards to pain treated in all the groups. There is a difference in all groups in reduction of pain.

**TABLE SHOWING THE COMPARISON BETWEEN THE GROUPS USING POST HOC TESTS WITH
BONFERRONI CORRECTION**

Parameters	Group A v/s Group B		Group B v/s Group C		Group C v/s Group A	
Mean	0.975	1.275	1.275	1.775	1.775	0.975
SD	0.589103	0.512179	0.512179	0.486538	0.486538	0.589103
Pooled Variance	0.550641		0.499359		0.537821	
P Value	0.074459		0.002217		0.000006	
Remarks	FALSE		TRUE		TRUE	
	Insignificant		Significant		Significant	

The comparison between Group A and Group B is statistically insignificant which signifies that Group A and Group B are equally effective in reduction of Pain. The comparison between Group B and Group C is statistically Significant which signifies that Group B is effective in reduction of Pain when compared to Group C. The comparison between Group C and Group A is statistically Significant which signifies that Group B is effective in reduction of Pain when compared to Group A.

**SUMMARY OF STATISTICS WITH REGARDS TO NAUSEA IN PEPTIC ULCER DISEASE IN ALL
THREE GROUPS**

ANNOVA: Single Factor						
Parameters	Group A	Group B	Group C			
Count	40	40	40			
Sum	42	55	61			
Mean	1.05	1.375	1.525			
SD	0.305	0.291	0.255			
ANOVA						
	Sum of Squares	Df	Mean Square	F Value	P Value	F Critical
Between Groups	4.716667	2	2.358333	8.298496	0.000426	3.073763
Within the Groups	33.25	117	0.284188			
Total	37.96667	119				

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The f value of all three groups is 8.29 which is higher than the f critical value of 3.07 which is statistically significant ($p = 0.000426$) with regards to Nausea treated in all the groups. There is a difference in all groups in reduction of Nausea.

**TABLE SHOWING THE COMPARISON BETWEEN THE GROUPS USING POST HOC TESTS WITH
BONFERRONI CORRECTION**

Parameters	Group A v/s Group B		Group B v/s Group C		Group C v/s Group A	
Mean	1.05	1.375	1.375	1.525	1.525	1.05
SD	0.305	0.291	0.291	0.255	0.255	0.305
Pooled Variance	0.298		0.273		0.280	
P Value	0.0094		0.203		0.00013	
Remarks	TRUE		FALSE		TRUE	
	Significant		Insignificant		Significant	

The comparison between Group A and Group B is statistically Significant which signifies that Group A is more effective in reduction of Nausea than Group B. The comparison between Group B and Group C is statistically Insignificant which signifies that Group B and Group C are equally effective in reduction of Nausea. The comparison between Group C and Group A is statistically Significant which signifies that Group C is effective in reduction of Nausea when compared to Group A.

**SUMMARY OF STATISTICS WITH REGARDS TO VOMITING IN PEPTIC ULCER DISEASE IN ALL
THREE GROUPS**

ANNOVA: Single Factor						
Parameters	Group A		Group B		Group C	
Count	40		40		40	
Sum	15		15		15	
Mean	0.375		0.375		0.375	
SD	0.240		0.240		0.240	
ANOVA						
	Sum of Squares	Df	Mean Square	F Value	P Value	F Critical
Between Groups	0	2	0	0	1.00	3.073763
Within the Groups	28.125	117	0.240385			
Total	28.125	119				

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The f value of all three groups is 0 which is lower than the f critical value of 3.07 which is statistically Insignificant ($p = 1.00$) with regards to Vomiting treated in all the groups. There is no difference in all groups in reduction of Vomiting.

TABLE SHOWING THE COMPARISON BETWEEN THE GROUPS USING POST HOC TESTS WITH BONFERRONI CORRECTION

Parameters	Group A v/s Group B		Group B v/s Group C		Group C v/s Group A	
Mean	0.375	0.375	0.375	0.375	0.375	0.375
SD	0.240	0.240	0.240	0.240	0.240	0.240
Pooled Variance	0.240		0.240		0.240	
P Value	1		1		1	
Remarks	FALSE		FALSE		FALSE	
	Insignificant		Insignificant		Insignificant	

The comparison between Group A and Group B is statistically Insignificant which signifies that Group A and Group B are equally effective in reduction of Vomiting. The comparison between Group B and Group C is statistically insignificant which signifies that Group B and Group C are equally effective in reduction of Vomiting. The comparison between Group C and Group A is statistically insignificant which signifies that Group C and Group A are equally effective in reduction of Vomiting.

SUMMARY OF STATISTICS WITH REGARDS TO HAEMETEMESIS IN PEPTIC ULCER DISEASE IN ALL THREE GROUPS:

ANNOVA: Single Factor						
Parameters	Group A		Group B		Group C	
Count	40		40		40	
Sum	2		3		4	
Mean	0.05		0.075		0.1	
SD	0.048		0.071		0.092	
ANOVA						
	Sum of Squares	Df	Mean Square	F Value	P Value	F Critical
Between Groups	0.05	2	0.025	0.353474	0.702991	3.073763
Within the Groups	8.275	117	0.070726			
Total	8.325	119				

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The f value of all three groups is 0.353 which is lower than the f critical value of 3.07 which is statistically Insignificant (p = 0.702) with regards to Haemetemesis treated in all the groups. There is no difference in all groups in reduction of Haemetemesis.

**TABLE SHOWING THE COMPARISON BETWEEN THE GROUPS USING POST HOC TESTS WITH
BONFERRONI CORRECTION**

Parameters	Group A v/s Group B		Group B v/s Group C		Group C v/s Group A	
Mean	0.05	0.075	0.075	0.1	0.1	0.05
SD	0.048	0.071	0.071	0.092	0.092	0.048
Pooled Variance	0.059		0.081		0.070	
P Value	0.649		0.696		0.402	
Remarks	FALSE		FALSE		FALSE	
	Insignificant		Insignificant		Insignificant	

The comparison between Group A and Group B is statistically Insignificant which signifies that Group A and Group B are equally effective in reduction of Haemetemesis. The comparison between Group B and Group C is statistically insignificant which signifies that Group B and Group C are equally effective in reduction of Haemetemesis. The comparison between Group C and Group A is statistically insignificant which signifies that Group C and Group A are equally effective in reduction of Haemetemesis.

**SUMMARY OF STATISTICS WITH REGARDS TO MALENA IN PEPTIC ULCER DISEASE IN ALL
THREE GROUPS**

ANNOVA: Single Factor						
Parameters	Group A		Group B		Group C	
Count	40		40		40	
Sum	6		7		8	
Mean	0.15		0.175		0.2	
SD	0.130		0.148		0.164	
ANOVA						
	Sum of Squares	Df	Mean Square	F Value	P Value	F Critical
Between Groups	0.05	2	0.025	0.16932	0.844445	3.073763
Within the Groups	17.275	117	0.14765			
Total	17.325	119				

A RANDOMIZED SINGLE BLIND CLINICAL STUDY IN THE MANAGEMENT OF PEPTIC ULCER DISEASE BY POLY HERBOMINERAL COMBINATION

The f value of all three groups is 0.169 which is lower than the f critical value of 3.07 which is statistically Insignificant (p = 0.844) with regards to Malena treated in all the groups. There is no difference in all groups in reduction of Malena.

TABLE SHOWING THE COMPARISON BETWEEN THE GROUPS USING POST HOC TESTS WITH BONFERRONI CORRECTION

Parameters	Group A v/s Group B		Group B v/s Group C		Group C v/s Group A	
Mean	0.15	0.175	0.175	0.2	0.2	0.15
SD	0.130	0.148	0.148	0.164	0.164	0.130
Pooled Variance	0.139		0.156		0.147	
P Value	0.765		0.777		0.562	
Remarks	FALSE		FALSE		FALSE	
	Insignificant		Insignificant		Insignificant	

The comparison between Group A and Group B is statistically Insignificant which signifies that Group A and Group B are equally effective in reduction of Malena. The comparison between Group B and Group C is statistically insignificant which signifies that Group B and Group C are equally effective in reduction of Malena. The comparison between Group C and Group A is statistically insignificant which signifies that Group C and Group A are equally effective in reduction of Malena.

SUMMARY OF STATISTICS WITH REGARDS TO ENDOSCOPY FINDINGS IN PEPTIC ULCER DISEASE IN ALL THREE GROUPS

ANNOVA: Single Factor						
Parameters	Group A		Group B		Group C	
Count	40		40		40	
Sum	47		50		64	
Mean	1.175		1.25		1.6	
SD	1.019		0.858		0.912	
ANOVA						
	Sum of Squares	Df	Mean Square	F Value	P Value	F Critical
Between Groups	4.116667	2	2.058333	2.21194	0.114047	3.073763
Within the Groups	108.875	117	0.930556			
Total	112.9917	119				

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The f value of all three groups is 2.211 which is lower than the f critical value of 3.07 which is statistically Insignificant ($p = 0.114$) with regards to Endoscopic findings treated in all the groups. There is no difference in all groups in healing of the Ulcers.

TABLE SHOWING THE COMPARISON BETWEEN THE GROUPS USING POST HOC TESTS WITH BONFERRONI CORRECTION

Parameters	Group A v/s Group B		Group B v/s Group C		Group C v/s Group A	
Mean	1.175	1.25	1.25	1.6	1.6	1.175
SD	1.01	0.85	0.858	0.912	0.912	1.01
Pooled Variance	0.939		0.885		0.966	
P Value	0.730		0.100		0.056	
Remarks	FALSE		FALSE		FALSE	
	Insignificant		Insignificant		Insignificant	

The comparison between Group A and Group B is statistically Insignificant which signifies that Group A and Group B are equally effective in healing of the Ulcers. The comparison between Group B and Group C is statistically insignificant which signifies that Group B and Group C are equally effective in reduction of healing of the Ulcers. The comparison between Group C and Group A is statistically insignificant which signifies that Group C and Group A are equally effective in healing of the Ulcers.

Discussion

The fast paced stressful lifestyle coupled with inappropriate dietary habits have made man susceptible to a variety of disorders. Parinama shoola, one such disorder, was selected for the present study.

Parinama shoola is not mentioned in any of the Brhatrayi. Acharya Charaka has elaborated two diseases, Grahani and Gulma. These two chapters may be taken as

guidelines for understanding diseases of Annavaha srotas. Even in case of Parinama shoola, the basic principles related to nidana pancaka may be applied from the above chapters itself. Acharya Sushruta however has identified Shoola as an independent disease. Acharya Vagbhata has also followed Acharya Charaka descriptions itself. The later generations of scholars have identified Parinama shoola as a separate disease entity and have also

elaborated diverse chikitsa for the same.

The nidana for Parinama shoola are not mentioned in any of the texts. Samanya shoola nidana applies in the case of Parinama shoola too. In addition to this, as Parinama shoola is a sannipataja vyadhi, the vishista shoola nidana pertaining to the tridosha were also included. This vyadhi being an Agnidustijanya vikara and an Annavaha srotovyadhi, the Annavaha Sroto dusti nidana also apply here. The Roopa told in parinama shoola "Sastika sali vrihinam odanena vivardhate" can also be regarded as nidana. This is evident from the fact that Duodenal ulcer is known to be more common in the rice-eating areas of India than in the wheat-eating areas⁹⁶. This difference is attributed to the increased mastication required by the unrefined wheat diet, which is associated with an increase in saliva, lower stomach acidity and reduced bile output. So it is not only what we eat but even more how we eat it that is relevant in peptic ulcer disease.

In recent days the use of NSAID's, Aspirin, Steroid Drugs also

becoming a major nidana for Parinama Shoola. Amlapitta is also a nidana for Parinama Shoola. Contemporary science also says Gastritis and Peptic ulcer are known to occur secondary to each other.

Psychological stress has a major role to play in causing gastritis and ulcers. This acts by an intense vagal stimulation that initiates a cholinergic activity. It stimulates gastrin secretion, reduces parietal cell threshold level for response to gastrin, stimulates histamine secretion that in turn triggers acid secretion and also stimulates pepsin secretion.

H-pylori infection is implicated with the causation of Peptic ulcers. H-pylori infection is present in virtually all patients with duodenal ulcers and about 70% of those with gastric ulcers. But only 10-20% of individuals worldwide infected with H.pylori actually develop peptic ulcers⁹⁷. Other events that may act alone or in connection with H.pylori to promote peptic ulceration include dietary factors, genetic factors, psychological factors etc. In Ayurveda also reference about the presence of krimi(Antrada,Udarada etc) in

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Amashaya is there. Although none of the ayurvedic classics have described the involvement of krimi in parinama shoola.

Another thing which should be noted here is it not merely the presence of H.pylori which causes peptic ulcer, the reaction of stomach tissue to particular bacteria causes it. Also it's worthy to remind of "beeja-kshetra nyaya" here. Modern medicine believes that removing the causative organism by giving some visha will kill the organism (beeja) and thereby curing the disease (Drug-Bug theory). Ayurveda however believes in making the land infertile (kshetra) thereby preventing the growth of Beeja(Organism) and get rid of disease. In case of peptic ulcer Modern medicine is aiming at the eradication of H.pylori while Ayurveda aims at improving the protective mechanism of the mucosal layer of Stomach and duodenum.

The f value of all three groups is 12.34 which is higher than the f critical value of 3.07 which is statistically significant ($p = 0.000014$) with regards to pain treated in all the

groups. There is a difference in all groups in reduction of pain.

The f value of all three groups is 8.29 which is higher than the f critical value of 3.07 which is statistically significant ($p = 0.000426$) with regards to Nausea treated in all the groups. There is a difference in all groups in reduction of Nausea.

The f value of all three groups is 0 which is lower than the f critical value of 3.07 which is statistically Insignificant ($p = 1.00$) with regards to Vomiting treated in all the groups. There is no difference in all groups in reduction of Vomiting.

The f value of all three groups is 0.353 which is lower than the f critical value of 3.07 which is statistically Insignificant ($p = 0.702$) with regards to Haemetemesis treated in all the groups. There is no difference in all groups in reduction of Haemetemesis.

The f value of all three groups is 0.169 which is lower than the f critical value of 3.07 which is statistically Insignificant ($p = 0.844$) with regards to Malena treated in all the groups. There is no difference in all groups in reduction of Malena.

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Conclusions

- From this study it can be concluded that non compliance of code of healthy diet selection and eating plays a major role in causation of this disease.
- Vata Pradana Tridoshas, Agnimandhya, Sangam and Avaranam plays role in pathogenesis.
- Parinama Shoola is mentioned as Mahagada due to the Chronic nature of the disease.
- Parinama Shoola and Peptic ulcer disorder have Striking Similarity.
- Endoscopy plays a significant role in making precise Diagnosis of this condition.
- Present study reveals that the incidence of Parinama shoola (Peptic ulcer) is more among the age group of 41-50 years, males, middle class, Married and Persons having Mandagni.
- The incidence of Parinama shoola (Peptic ulcer) is more in Persons

having habits of Smoking, excessive tea/coffee intake and in persons with Mental stress.

- Both the trial drugs used in this study possessed Agnidipana, Amapacana, Tridosasamana, Sulaprasamana, Vranaropana and Rasayana property which can effectively break the samprapti of Parinama Shoola.
- Both Leela Vilas Ras and Yashtimadhu Gritha are equally effective in Peptic Ulcer Disease.
- But the combination of both Leela Vilas Ras and Yashtimadhu Gritha are more effective in Peptic Ulcer Disease

Bibliography:

1. Yogaratnakara, With Vidyotini Hindi Commentary By Vaidya Lakshmipati Shastri, Edited By Bhisagratna Brahmasankar Shastri, fifth edition, Varanasi, Chaukhambha Orientalia Publishers; 1993;Pp504, Pg No 11,12, (YR, Uttarardha shula chikitsa)
2. Hussien MA, Ibrahim HK, Ghorab DM. Sterile Lyophilized Pantoprazole sesquihydrate: Formulation and Manufacturing Economics. www.scopemed.org/?mno=17167 [Access: July 26, 2013].
3. Bailey and love's, short practice of surgery, 22nd Edition, Edited by

**A RANDOMIZED SINGLE BLIND CLINICAL STUDY IN THE MANAGEMENT OF PEPTIC
ULCER DISEASE BY POLY HERBOMINERAL COMBINATION**

- Charles v, Mann, Chapman and Hall Publishers, ELBS London, 1995, Pp1041, Pg no 676-692
4. CCRW Edwards, Davidson's principle and practice of medicine, 19th edition, Churchill living stone, 2002, Pp 1274, Pg no 782-788
5. Indradev Tripathi, Yogaratnakara, Krishnadas academy, Varanasi, 1st edition, Amlapitta Nidana Chikitsa Prakarana, pg. no. 670, Pp. 894.
6. Hariprasad Tripathi, Harita Samhita, Choukambha Krishnadas Academy, 2nd edition, 74th chapter, pg no- 432, shloka- 84, Pp- 622.

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Corresponding author:

Dr. Srinivas K Bannigol

Professor and HOD, Department of Post Graduate Studies in Shalya Tantra, Ayurveda Mahavidyalaya, Hubli-580024

Email: drbannigol@yahoo.co.in