JANUARY - FEBRUARY-2017

VOLUME 1 ISSUE 3

ISSN-2456-4354

PIJAR

PARYESHANA

INTERNATIONAL JOURNAL OF AYURVEDIC RESEARCH

www.pijar.org

ISSN-2456-4354

A Clinical Study and Management of Peptic Ulcer by Tiktadya Ghrita and Kaparda Bhasma.

Dr. N. B. Mashetti[1], Dr. Santoshi G. Sakharani.[2]

[1]Professor and HOD, Dept. of Post Graduate Studies in Shalya Tantra, BLDEA'S, AVS, Ayurveda Mahavidyalaya, Vijayapur, [2]Post Graduate Scholar, Dept. of Post Graduate Studies in Shalya Tantra, Ayurvedic Medical College and P. G. Centre, Davanagere.

Abstract:

Background: Peptic ulcer is a very common disease of GI tract. Now a days due to irregular food habits, drugs, sedentary life style and socio economic status etc., has become most prevalent disorder. **Objective:** A comparative clinical study to evaluate the efficacy of *Tiktadyaghrita* with and without *Kapardabhasma* in Peptic ulcer. **Methods:** Patients presenting with classical signs and symptoms of peptic ulcer with confirmed endoscopy were selected randomly and were distributed into two groups. Scoring of symptoms and relief of signs and symptoms were done arbitrarily. Group-A was given *Tiktadyaghrita* 15g tds. with *Sukhoshnajala* for one month. The cases in Group-B were subjected to *Tiktadyaghrita* and *Kaparda Bhasma* – 80mg tds before meals for period of one month. **Results:** Group-A cases shows better improvement. Out of 20, 16 patients had got complete remission. While in Group-B, 18 patients were completely cured. In Group-A, 14 patients showed good improvement and 2 patient got excellent improvement while in Group-B, 18 patients showed excellent improvement. **Discussion:** The overall effect of the two groups was assessed, it was observed that in Tiktadyaghrita 75% had moderate remission and in the Tiktadyaghrita and Kapardabhasma group 80% had moderate remission and 20% had average remission.

Key words: Parinamashula, Peptic ulcer, Tiktadyaghrita, Kapardabhasma

Introduction:

From Stone-Age to space age food pattern of people has undergone innumerable changes. The changes of course have been always for the better aspect of life, yet most of the diseases are firmly rooted in poor dietary habits and life style[1]. None of the existing system of medicine is the complete answer for all the health problems as all these aim at symptomatic relief rather than a total cure.

Peptic ulcer is very common disease of GI tract. Now a days due to irregular food habits, drugs, sedentary life style and socioeconomic status etc., has become most prevalent disorder. It affects the areas of mucosa exposed to acidic gastric contents; the main pathology is between acid pepsin system and mucosal ability to resist digestion. Ulceration can occur in number of sites, oesophagus, stomach, duodenum, jejunum. Now it is recognized that H-pyloric infection is causative factor and even usage of NSAIDS and smoking etc. It occurs more commonly in men with male and female ratio of 5:1 in duodenal ulcers, 2:1 in gastric ulcers.[2]

However acid peptic disease remains a major source of morbidity and mortality that every surgeon can expect to encounter on many occasions.[3],[4] The above facts uphold the necessity for approaches that provide a potential cost saving therapy associated with use of simple treatment technologies. At this instance, Ayurveda with its holistic philosophy could make a hopeful attempt in solving the devastating problem.

Parinamashula as the name itself suggests is a pain predominant disease related to the Annavahasrotas. This srotas is the basis for the vary subsistence of life. It has been also described in Mahagada could this be due to the fact that it was an Abhyantaravyadhi and hence not visualized earlier. If that is the case, then the latest advances in gastrointestinal examination like Barium meal and endoscopy should relate this short coming and thus aid is confirmatory diagnosis and treatment at the earliest.

This disease is frequently correlated to duodenal ulcer alone or can similar symptomatology also be elicited in other disease pertaining to the prime site of digestion that is grahani. The present study is an endeavor to ascertain the disease *Parinamashula* conceptually and practically. The efficacy of *Tiktadyaghrita*[5] and *Kapardabhasma*[6] which are having *Shodhaka*, *Ropaka* and *Shulahara* properties are been selected.

In clinical study, 20 patients diagnosed as peptic ulcer i.e, *Parinamashula* have been taken incidentally and an endoscopic evaluation has also been carried out to reduce the modern correlate of this disease. The patients were divided into two groups randomly and treated with the above mentioned drugs. The pre-test and post-test data are observed and analyzed statistically. The selected compounds provided significant relief in nearly all the parameters. It is hoped that this study will add to the existing knowledge and result in better and efficient management of the disease, Peptic ulcer.

Study objective:

A comparative clinical study to evaluate the efficacy of Tiktadya Ghrita with and without Kaparda Bhasma in Peptic ulcer with special reference to *Parinamashula*.

Materials and Methods:

Patient selection and study design:

The study is carried on the patients attending the OPD and IPD of Ayurvedic Medical College and Hospital, Davangere. The patients diagnosed of peptic ulcer and which have undergone endoscopy was considered for the study.

The sample was selected randomly from the population, consisting of irrespective of sex, age, economic status and occupation with features satisfying the inclusion criteria. Informed consent was taken from the patient before including them in the trial.

Patient selection

Patients complaining of *Udarashula* (abdominal pain) and having *Pratyatma Lakshana* of *Parinamashula* attended the OPD and IPD of Ayurvedic Medical Hospital Davangere were selected for the present study. 40 patients were registered for the study; the complete details of the patients were recorded as per a detailed proforma consisting of all the relevant data.

Inclusive criteria:

1. Patients presenting the signs and symptoms of peptic ulcer were selected for the study.
2. Acute and chronic gastric and duodenal ulcers were also selected.
3. Patients confirmed of having peptic ulcer through endoscopy were selected.

Exclusive criteria:

1. Patients having complications like perforations, bleeding ulcers, etc. are excluded.

2. Patients having malignancy and HIV etc. are excluded.

Investigations:

Patients were subjected to the following investigations as per requirement.

1. Routine hematological and urine investigations.
2. Endoscopy was performed as endoscopic visualization of the gastric mucosa not only permits the recognition of lesions such as ulcers, erosions,mucosal irregularities, and polyps but also provides additional information such as color, texture and degree of vascularity of mucosa.
3. Stool for occult blood.

Study design:

A randomized clinical comparative study with a pre-test and post-test design was conducted where in, 20 patients of either sex were assigned, randomly in each groups viz., Group-A and Group-B and regular follow up after 7 days, after 1 month treatment till 6^{th} week.

Intervention:

The patients were treated in following manner. **Group-A:** Patients in this group were administered with Tiktadya Ghrita for a period of 1 month.

- **Contents of *Tiktadyaghruta (Ref- Bh. Ra. 47/63)* are as follows.**

a. *Tiktamoola* 1 Part
b. *Nishamoola* 1 Part
c. *Yashtimoola* 1 Part
d. *Naktapatra* 1 Part
e. *Patolapatra* 1 Part
f. *Maltipatra* 1 Part
g. *Nimbapatra* 1 Part
h. *Ghruta* 32Part

- **Method of preparation**: above mentioned drugs were made into kalka form and mixed with 32 parts of ghruta, 128 parts of jala in a snehapatra and according to snehapakavidhi,ghruta was prepared over mandagni till Ghruta attains proper paka.
- **Dose** - 15gms tds
- **Anupana** - Sukoshnajala
- **Duration** - 1 month

Group-B: Patients in this group were administered with *Tiktadya Ghrita* and *Kaparda Bhasma.*

- **Varathika / Kapardabhasma (Ref. Ayurveda Rasayana)**

Varahtika which are Peetavarna with spots are considered as best are selected. Selected Varahtika are kept on teevragni till its color is changed to white, then bhavana of kumara swarasa is given because, after the shuddikarana,varathika becomes more kshariya, after the bhavana of swarasa. 2-3 times bhavana of jala is given later, by this it becomes mrudu.

- **Dose -** 15gms tds (Tiktadyaghrita) and 80mg tds before meals (Kapardabhasma)
- **Anupana -** Sukoshnajala
- **Duration -** 1 month

Criteria for Assessment:

The improvement or otherwise in the disease status was evaluated by adopting gastrointestinal symptoms rating scale. Other symptoms were graded arbitrarily.

Parameters:

Parameter	Finding	Points
Abdominal pain	No or transient pain	0
	Occasional aches and pains interfering with some social activities	1
	Prolonged and troublesome aches and pains causing requests for relief and interfering with many social activities	2
	Severe or crimping pains with impact on all social activities	3
Burning sensation	No or transient	0
	Occasional discomfort of short duration	1
	Frequent episodes of prolonged discomfort; requests for relief	2
	Continuous discomfort with only transient relief by antacids	3
Acid regurgitation	No or transient regurgitation	0
	Occasional troublesome regurgitation	1
	Regurgitation once or twice a day; requests relief	2
	Regurgitation several times a day; only transient and insignificant relief from antacids	3
Sucking sensation in the epigastrium	No or transient sucking sensation	0
	Occasional discomfort of short duration; no requests for food or antacids between meals	1
	Frequent episodes of prolonged discomfort; requests for food and antacids between meals	2
	Continuous discomfort; frequent requests for food or antacids	3
Nausea and vomiting	No nausea	0
	Occasional episodes of brief duration	1
	Frequent and prolonged nausea; no vomiting	2
	Continuous nausea; frequent vomiting	3
Borborygmus	No or transient borborygmus	0

	Occasional troublesome borborygmus of short duration	1
	Frequent and prolonged episodes which can be measuredby moving without impairing social performance	2
	Continuous borborygmus severely interfering with social performance	3
Abdominal distension	Occasional or transient distension	0
	Occasional discomfort of short duration	1
	Frequent and prolonged episodes which can be measured by adjusting the clothing	2
	Continuous discomfort severely interfering with social performance	3
Eructation	No or transient eructation	0
	Occasional troublesome eructation	1
	Frequent episodes interfering with some social activities	2
	Frequent episodes severely interfering with social performance	3
Loose stools	Normal consistency	0
	Somewhat loose	1
	Runny	2
	watery	3
Hard stools	Normal consistancy	0
	Somewhat hard	1
	Hard	2
	Hard and fragmented; sometimes in combination with diarrhea	3
Feeling of incomplete evacuation	Feeling of complete evacuation without straining	0
	Defecation somewhat difficult; occasional Feeling of incomplete evacuation	1
	Defecation definitely difficult; often feeling of incomplete evacuation	2
	Defecation extremely difficult; regular feelings of incomplete evacuation	3
Aruchi	Absent	0
	Mild	1
	Moderate	2
	Severe	3
Trushna	Absent	0
	Mild	1
	Moderate	2
	Severe	3
Arati	Absent	0
	Mild	1
	Moderate	2

	Severe	3
Vepana	Absent	0
	Mild	1
	Moderate	2
	Severe	3
Sammoha	Absent	0
	Present	1

Duration of treatment:

To see the efficacy of the drug the present study incorporates a minimum 1 month medication.

Diet: Patients were kept under normal diet. Spicy diet was restricted.

Follow-up:

To confirm the result and to check for recurrence, patients were followed-up with observation once in 7 days up to 28 days, after the end of 1 month medication.

Statistical analysis:

The obtained data was analyzed statistically and presented as mean ± SEM (Standard Error of Mean). The data generated during the study were subjected to student's "Unpaired 't' Test" test for unpaired data to assess the statistical significance between the two groups. The change in sign and symptom scores was analyzed by "Paired 't' test". The values were considered significant at the levels of $p < 0.05$, $p < 0.01$ and $p < 0.001$.

Observations and Results:

A total of 40 patients fulfilling the inclusion criteria were enrolled in the study. 20 patients in each, Group-A and Group-B respectively were registered.

There were 22 male and 18 female. 32.5 % 0f patients were in the age group of 20-30, 25 % of patients were in the age group of 30-40, 22.5 % 0f patients were in 40-50, 15% were in 50-60, 5% were in 60-70 years of age group.(Fig. 2), 45% (18) of Patients were females and 55% (22) were males. 45% (18) of patients were heavy worker, 5% (2) did moderate work and 50% (20) had sedentary occupation. 57.5% (57.5) of patients were vegetarian, while 42.5% (17) consumed mixed diet. 17.5% (7) of patients were addicted to smoking, 12.5% (5) were alcoholic, 57.5% (23) gave history of regular consumption of tea/coffee. 7.5% (3) of patients had history of Adhyashana, 25% (10) had Samashana habit, 47.5% (19) gave history of Vishamashana, 7.5% (3) gave history of Viruddhashana, 12.5% (5) were having habit of Pramitashana. 60% (24) of patients complained of disturbed sleep while 40% (16) had no such complaint. Amongst the patient 65% (26) of patients were of Vata Pitta Prakruti, 27.5% (11) were of Pitta Kaphaja, 7.5% (3) were of Vata Kaphaja Prakruti. 45% (18) of the patients were suffering from Vishamagni, 55% (22) were suffering from Mandagni. 7.5% (3) patients had Madhura Rasa Satmya, 22.5% (9) were Amla Rasa Satmya and 50% (20) had Katu Rasa Satmya. The most important feature was Shula and was seen in allthe patients in both the groups. 45% had Kukshi Shula, 40% had Jathara Parshvashula, 60% had Nabhi Shula, 47.5% had Sthanantra Sula, 50% had Bhuktamatri Prashamati, 30% had complained of Vante Prashamati, 60% had both Jirna Anne Prasamyati and Odanena Vivardhati. (figure 3)

Results

Effect on Shula

The mean value of Shula of Group A and B was 2.850 before treatment and P ≤ 0.001, it was statistically significant, the comparision between groups was also statistically significant

Group	BT-AT	Unpaired 't' test			
		Diff	SD	't'	'p'
A	2.850	0.459	0.366	0.000	= 1.000
B	2.850		0.366		

Effect on Daha

The mean value of Daha for Group A was 2.750 and B was 2.700 before treatment and P ≤ 0.001, and both the group were statistically significant, the comparision between groups was also statistically significant.

Group	BT-AT	Unpaired 't' test			
		Diff	SD	't'	'p'
A	2.750	0.510	0.444	0.438	0.666
B	2.700		0.470		

Effect on Atopa

The mean value of Atopa for Group A was 2.300 and B was 2.350 before treatment and P ≤ 0.001, and both the group were statistically significant, the comparision between groups was also statistically significant.

Group	BT-AT	Unpaired 't' test			
		Diff	SD	't'	'p'
A	2.300	0.826	0.923	-0.271	0.789
B	2.350		0.745		

Effect on Chardi and Hrullasa

The mean value of Chardi - Hrullasa for Group A was 1.150 and B was 2.350 before treatment and P ≤ 0.001, and both the group were statistically significant, the comparision between groups was also statistically significant.

Group	BT-AT	Unpaired 't' test			
		Diff	SD	't'	'p'
A	1.150	1.473	1.473	-3.644	=0.002
B	2.350		0.745		

Effect on Udgara

The mean value of Udgara for Group A was 1.842 and B was 1.500 before treatment and P ≤ 0.001, and both the group were statistically significant, the comparision between groups was also statistically significant.

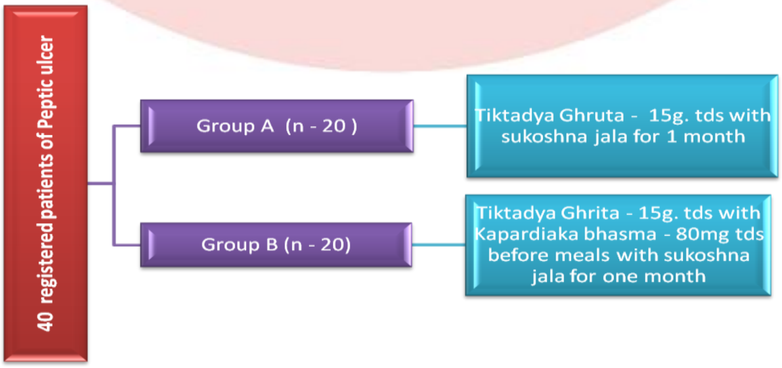
Group	BT-AT	Unpaired 't' test			
		Diff	SD	't'	'p'
A	1.842	1.558	1.344	0.736	=0.471
B	1.500		1.318		

Effect on Aruchi

The mean value of Aruchi for Group A was 1.500 and B was 1.250 before treatment and P ≤ 0.001, and both the group were statistically significant, the comparision between groups was also statistically significant.

Group	BT-AT	Unpaired 't' test			
		Diff	SD	't'	'p'
A	1.500	1.446	1.192	0.773	=0.449
B	1.250		1.070		

Figure 1 – Trial profile of 40 patients of Peptic ulcer



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ISSN-2456-4354

Figure 2 - Age wise distribution of 40 Patients of Peptic ulcer

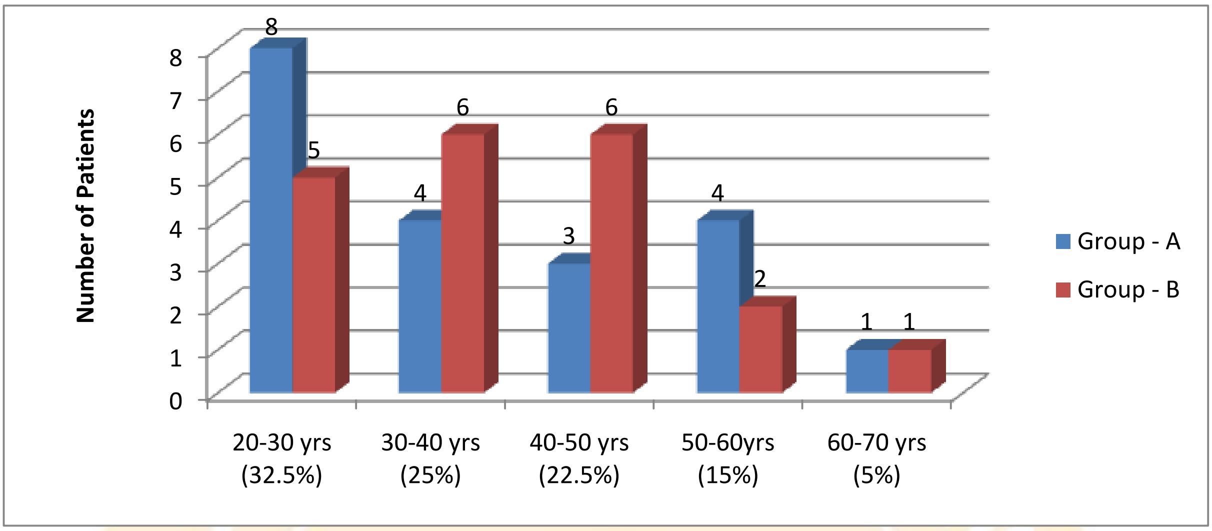
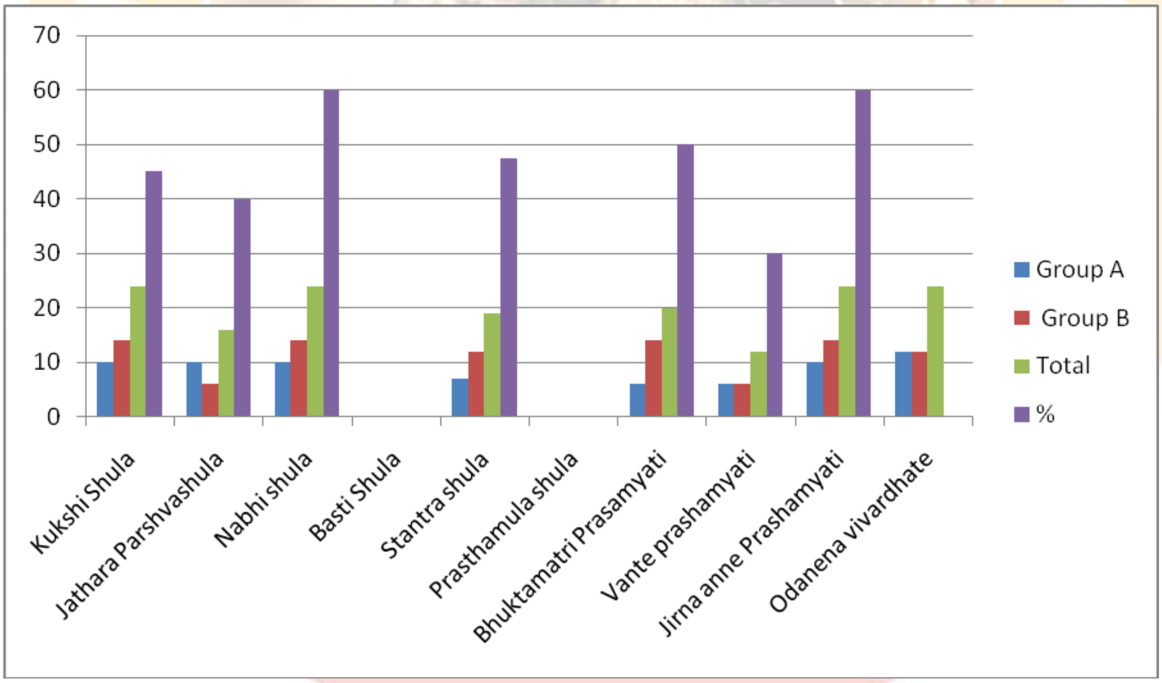


Figure 3 – Incidence of Laxana wise distribution of 40 Patients of Peptic ulcer



Discussion:

The present study aimed to look for an effective, safe and affordable alternative treatment of *Parinamashula (peptic ulcer)* resulted from faulty diet and life style. 32.5% of patients were in age group of 20-30 yrs, 25% were in age group of 30-40yrs, while 22.5% were in 40-50yrs of age group, 15% were in 50-60 yrs of age and 5% were in 60-70 yrs of age group. 95% were in age group of 20-60 years which comes under Madhyamavaya where Pittajavyadhi are more common.

Peptic ulcer are more frequent in this age group. In this study 55% were male and 45% were female. Its due to high degree of saririka and manasika stress are seen in males. Male : Female ratio in D. ulcer is 4:1 and in G. ulcer is 3.5:1. 70% patients were married while 30% were single. Graduate comprised 40%, high school were 35%, while 25% were uneducated. People armed with higher degree are occupied in work. So may be one of cause. 40% of patients belonged to lower middle class; 47.5% were of middle class and 12.5% belonged to upper middle class. The ignorance and heavy work may be reason for less representation from upper middle class. 45% had heavy degree of work, 5% had moderate degree of work and 50% were sedentary. All most all patients were subjected to either physical or mental stress. 57.5% of patients were strict vegetarian and 42.5% were of mixed diet; non vegetarian food being guru paki by nature, leads to agnimandya and also suklata of aahara which cause chronic peptic ulcer. Excess consumption of tea/coffee were seen in 57.5% of patients, 17.5% gave H/o smoking, 12.5% gave H/o alcohol. These factors provoke formation of peptic ulcer. 7.5% of patients gave H/o Adhyashana, 25% gave H/o samsama, 47.5% gave H/o Vishamashana, 7.5% gave H/o viruddhashana, 12.5% gave H/o pramitashana. All above are known to cause agnimandya and aama and thus predispose to parinamashula. 60% of patients complained of disturbed sleep, 4% had no complain, loss of sleep was due to pain in some patients while others due to some family problem. Patients who complained of pain stated the time around mid night which is time for pitta prakopa, which is feature of D. ulcers. 35% of patients gave H/o mental stress while 65% did not have the complaint manasikakarana are known to lead to ajirna and doshaprakopa, stress enhances the secretion of Hcl acid and thus cause inflammatory reaction.

Among the patients 65% were Vatapittaprakruti and 27.5% were of Pitta-kaphaja, 7.5% of Vata-kaphaja. So 65% were pitta predominance that predisposed for occurrence of pitta pradhanavyadis. 45% of patients were suffering from vishamagni and 55% were from mandagni. This corroborates the fact that jatharagnidushti causes parinamashula. 27.5% of patients were of pravarasamhanana, 60% were madhyama and 12.5% were avarasamhanana. 7.5% of patients gave H/o taking madhura rasa, 22.5% for amla rasa, 20% liked lavana rasa and 50% liked katu rasa. This may indicate pitta prakopa caused by katu rasa; madhura rasa being guru paaki causes agnimandya and kaphaprakopa. All the 3 types of nidana such as aaharaja, viharaja and manasika were observed in the patients. Among the rasa katu, amla, madhura rasa was elicited; vishamashana, virudhashana, pramitashana and adhyashana were common in the patients. Manasika Karana could also be elicited.

All the patients gave the history of Kukshishula (pain abdomen) during digestion. The site of pain however varied with 60% localizing the pain around the nabhi (peri-umbelical area), 47.5% pointed towards stanantara (amashayapradesha, epigastric area), and 40% felt pain jatharaparshwa (Rt. hypochondrium). These sites also correlate with those mentioned for ch.Gastriris and peptic ulcers.

All the patients said that pain was relieved following digestion. The time of occurrence of pain in the patients varied between 45min, 2hours after consumption of food. The type of pain was burning in most, dull aching and nonspecific discomfort in few. All the patients have observed aggravation in the pain following consumption of specific foods like meat, fried foods etc.

The endoscopy finding were predominantly of chronic atrophic gastritis(27.5%), deudinal ulcers were 27.5%; 20% were gastric ulcers, chronic superficial gastritis, chronic atrophic gastritis with hyperplasia was found in 10% each. Duodenitis were seen in 7.5% endoscopy couldn't be performed in 2 patients due to their financial constraints. Chronic atrophic gastritis was Type B predominantly, i.e in 17.5% and Type AB in 10%. 1 patient had coexisting gastric and duodenal ulcer. All of these diseases however, presented with Parinamashula Laxana.

Probable Classical mode of action of drugs in peptic ulcers.

The drugs in this Ghruta contains properties which are, *Vrunashodhana*, *Ropana* and *Krumihara*, *Pittahara* etc., the drugs pocess *Vatapitta Shamana* property. As the disease taken for the study is Vata Pitta predominant *Ghruta* is the medium of combination of drugs as it has Vruna Shodhana and Ropana properties and is Vata Pitta Shamaka. Therefore, the action of drug is enhanced by Ghruta. It also reduce the Rukshata of Vayu.

Conclusion:

The Tiktadya Ghruta and Kaparda Bhasma which is used classically showed good results which was analysed by statistical method. The efficiency of Tiktadya Ghruta and Kaparda Bhasma in comparision with Tiktadya Ghruta showed more significant result in cases of peptic ulcer. This work can be studied better in single or double combination with Tiktadya Ghruta to analyze further better result. No complications were observed in any patients during the study period.

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Corresponding Author
Dr. N. B. Mashetti.
Professor and HOD,
Dept. of Post Graduate Studies in Shalya Tantra, BLDEA'S, AVS, Ayurveda Mahavidyalaya, Vijayapur,
Email: drnbmashetti@gmail.com

Source of Support: NIL
Conflict of Interest : None declared