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A Comparative clinical study to evaluate the effect of Indigenous compound drugs (*Shatavari mandoor* and *Pippali ghrita*) in *Parinama Shoola* Vis-à-vis Acid Peptic Disorders

Research Article

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Abstract

Background: : Acid peptic disease is the condition in which there is either excessive secretion of acid and pepsin or a weakened stomach mucosal defence, which is responsible for damage to the delicate mucosa and the lining of the stomach, oesophagus and duodenum resulting in ulceration.*Parinama shoola* in Ayurveda is comparable with Acid peptic disease.
Aim of study: The Aim of the study is to evaluate and compare the effect of indigenous compound drugs (*Shatavari mandoor* and *Pippali ghrita*) in uncomplicated cases of *Parinam shoola*.
Methods: This is a prospective, open labelled, randomised clinical trial. A total of 31 patients suggestive of features of *Parinama Shoola* (acid peptic disorder) were enrolled and were randomly divided in two groups- 12 patients were enrolled in group A and were given trial drug *Shatavari mandoor*,19 patients were enrolled in group B and were given trial drug *Pippali ghrita.* Duration of study was 3 months.
Results: Individually both groups showed statistically significant improvement in clinical symptoms i.e. pain in abdomen, epigastric burning, nausea, flatulence, loss of appetite and constipation ($p<0.01$), but the mean reduction in the symptoms of group A (*Shatavari mandoor* group) is more than group B (*Pippali ghrita* group).
Conclusion: Both trial drugs are effective in the treatment of *Parinama shoola*. *Shatavari mandoor* is more effective in the treatment of *Parinam shoola* in comparison to *Pippali ghrita.*

Keywords: Acid peptic disorder, epigastric pain, *Parinama shoola*, Peptic ulcer disease

Introduction:

An ulcer is defined as disruption of mucosal integrity of stomach and or duodenum leading to local defect or excavation due to active inflammation.

Peptic ulcers are estimated to occur in 6-15% of general population. The incidence of peptic ulcer declined steadily from 1960-1980 and then remained stable since then. (1)

The cardinal feature of peptic ulcer disease is epigastric pain which is characterised by gnawing or burning, may be ill defined, may be aggravated by meals or relieved few minutes after meals. Other associated symptoms include nausea, vomiting flatulence, abdominal distension, water brash etc.

In Ayurveda, *Parinama shoola* is a disease in which abdominal pain during digestion is observed. The aetiology, pathogenesis and clinical manifestation of *Parinama shoola* have got a striking similarity with acid peptic disorders in modern medicine.

The disease *Parinama shoola* was first mentioned by Madhavakara. In the aetio pathogenesis of *Parinama shoola* Madhavakar has given much importance to *vata* (2) in causing the disease, whereas Vijay rakshita in explaning the disease gave a specific and scientific pathogenesis of *Parinama shoola.* According to Vijay rakshita, *Parinama shoola* is a disease of *tridosha, pitta* predominance is present as the pain occurs during the period of digestion. (2)

In *Parinama shoola* abdominal pain occurs at the phase of digestion. ***'Bhukte Jeeryati yata Shoolam Tadeva Parinamajam'*** (3)

Three *dosas* i.e. *vata*, *pitta* and *kapha* are involved in the pathogenesis of *Parinama shoola.* In all types of *shoola* (pain), *vayu* is the predominant causative *dosha* which is correlated with sympathetic nervous mechanism of sensation of pain in the abdominal visceral organ. *Kapha* refers to the *kledaka kapha* which has parlance with mucus gel layer and mucin of modern medicine. So *kapha* is for defensive mechanism in the pathogenesis of *Parinama shoola.*Pitta is related with HCL and pepsin and it is for aggressive mechanism causative for *Parinama shoola.*

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Two trial drugs, *Shatavari mandoor* and *Pippali ghrita* were selected for the present study.

Many previous studies (clinical and experimental) regarding the antiulcer effect of *Shatavari mandoor* were done, which showed promising results in cases of acid peptic disorders. (4,5)

Pippali ghrita has been described in *Chakra dutta* in the context of *Parinama shoola*. According to Chakra dutta, *Pippali ghrita* has been able to treat complicated cases of *Parinama shoola.* (6) and thus it was assumed that *Pippali Ghrita* would be beneficial in patients of *Parinaana Shoola.*

This study revealed the effect of herbomineral drugs (*Shatavari mandoor* & *Pippali ghrita*) in the treatment of *Parinama shoola.*

Material & Methods

Study design: It is a prospective, randomised, open labelled, parallel designed, clinical study.

Inclusion criteria

Patients showing clinical signs and symptoms suggestive of *Parinama shoola* like pain in epigastric pain, heartburn, acid eructation, water brash etc.
Subjects above 20 years and below 60 years

Exclusion criteria

- Pregnant and lactating mothers
- Patients having gall bladder disease, worm infestation, cardiovascular and liver disorders.
- Malignant and complicated ulcers

Grouping of patients

Patients were randomly divided into two groups
Group A**:** 12 Patients were included in group A and were administered with trial drug *Shatavari mandoor.*
Group B: 19 Patients were included in group B and were administered with trial drug *Pippali ghrita.*

Criteria of assessment

Clinical signs and symptoms: *Udarasula* (pain in abdomen), *utklesa* (feeling of nausea and vomiting), *aruci* (loss of appetite), *hritkaṇṭhadaha* (heart burn) etc. were assessed before and after the treatment. Clinical assessment was made by grading as 0,1,2,3 on the basis of severity.

Grading pattern for signs and symptoms

Udar shoola (epigastric pain)
Grade-0: No Pain
Grade-1: Mild pain
Grade-2: Moderate pain
Grade-3: Severe pain

Hrikantha daha (burning in epigastric region)
Grade-0: No Heart burn
Grade-1: Occasional retrosternal burning
Grade-2: Retrosternal burning 1-2 times; relieved by food or antacids
Grade-3: Frequent retrosternal burning

Utklesh (nausea)
Grade-0: Absent nausea
Grade-1: Occasional desire to vomit
Grade-2: Frequent desire to vomit
Grade-3: Regular desire to vomit

Adhmaan (flatulence)
Grade-0: Absent feeling of gaseous distension
Grade-1: Occasional feeling of gaseous distension
Grade-2: Frequent feeling of gaseous Distension

Aruchi (loss of appetite)
Grade-0: Normal appetite
Grade-1: Mild loss of appetite
Grade-2: Moderate loss of appetite
Grade-3 Severe loss of appetite

Praseka (water brash)
Grade-0: No complaint of water brash
Grade-1: Occasional feeling of water
Grade-2: Frequent complaint of watery mouth
Grade-3: Regular complaint of watery mouth

Treatment Protocol

Trial Drugs

Table 1: Ingredients of trial drugs (all the parts of ingredients were taken by weight)

***Shatavari Mandoor* (7)**

Shatavari swarasa	2 parts
Mandur churna	2 parts
Godugdha	2 parts
Godadhi	1 parts
Go Ghrita	1 parts

***Pippali Ghrita* (6)**

Pippali Kawatha	4 parts
Pippali Kalka	1 part
Go Ghrita	1 part

Method of preparation of trial drugs

Method of preparation of *Shatavari mandoor*

Two parts of *Mandoor bhasma*, two parts of fresh juice of *Shatavari swaras*, two parts of cow's curd and milk and one part of cow's ghee were mixed and heated at low temp till the water content is evaporated and whole material becomes dry.
Dose: 1.5 gm. Bid
Mode of administration: Patients were advised to take the drug twice daily along with the meal. Drug is divided approximately into three parts, which should be taken in

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the first, middle and last bolus of the food.

Method of preparation of *Pippali ghrita*

Four parts of *Pippali kawatha*, one part of *Pippali kalka* and one part of *Go ghrita* are mixed together and heated till *ghrita* is prepared

Dose: 5 gm. Bid

Anupana : *Sukoshana dugdha* (Luke warm milk)

Follow up:

Total duration of treatment was 3 months. The symptoms and signs of patients were recorded in detail once in a month before and during the treatment.

Statistical analysis

The data obtained in clinical studies before and after treatment was expressed in terms of mean, standard deviation. Appropriate t' test was applied to test the significance of comparative mean values of before and after treatment.

Observation and results

The study of demographic profile displayed that *Parinama shoola* was more prevalent among males (60%), between the age group of 20-50 years, most of the patients belong to rural areas (63.3%), having spicy dietary habit (37%) and *vata-pitta deha prakriti (*43.6%), the *sharad ritu* (33.3%) and *rajasika manas prakriti* (66.6%), 20% of the patients were having anxiety and 13% of patients were having depression in the study. Regarding addiction (6.67%) were addicted to smoking (23.3%) to tobacco chewing and (3.33%) to consumption to alcohol. [Table 2]

Most common symptoms observed were *udar shoola* (epigastric pain), *hrikantha daha* (burning in epigastric region), *utklesh* (nausea), *adhmaan* (flatulence) along with these, *aruchi* (loss of appetite), *vibandha* (constipation) and *praseka* (water brash) were also present in the patients of *Parinama shoola.*

In Group A significant improvement was observed in epigastric pain ($p<0.001$), heart burn ($p<0.01$), loss of appetite ($p<0.01$), water brash ($p<0.02$), flatulence ($p<0.02$), constipation, ($p<0.02$), nausea ($p<0.01$). [Table-3].

In Group B significant improvement was observed in epigastric pain ($p<0.001$), heart burn ($p<0.001$), loss of appetite ($p<0.01$), water brash ($p<0.05$), flatulence ($p<0.01$), constipation, ($p<0.001$), nausea ($p<0.01$). [Table-3]

Table 2: Demographic profile

Observations	Percentage
Age 20 years-50 years	86.6
Sex Male Female	 60 40
Habitat Rural Urban	 63.33 36.66
Addiction Tobacco Smoking Alcohol	 23.33 6.67 3.33
Deha prakruti *Vataja* *Pittaja* *Vāta-paittika*	 18.33 21.66 43.66
Manasa Prikriti *Rajas* *Tamas*	 66.6 33.3
Psyche phenomenon Anxiety Depression	 20 13.33
Dietary habits Spicy food	 37
Kala *Sarad ritu* *Hemanta ritu* *Vasanta ritu*	 33.3 23.3 16.6

Table 3: Effect of treatment on clinical sign and symptoms

Clinical signs & symptoms	Group	BT Mean ± SD	AT Mean ± SD	T	P
Udarasu-la	A	2.58 ±0.51	0.75 ±0.45	11.0	P<0.001
	B	2.58 ±0.51	1.74 ±0.45	9.8	p<0.001
Aruchi	A	1.33 ±0.98	0.42 ±0.51	4.0	p<0.01
	B	1.05 ±1.18	0.58 ±0.69	3.37	p<0.01
Utklesa	A	1.08 ±1.00	0.42 ±0.67	4.69	p<0.01
	B	1.37 ±0.90	0.95 ±0.71	3.62	p<0.01
Hritkan-thadaha	A	1.83 ±0.94	0.92 ±0.67	4.75	p<0.001
	B	1.89 ±0.81	1.26 ±0.69	5.53	p<0.001
Adhmana	A	0.75 ±0.62	0.33 ±0.49	2.80	p<0.02
	B	1.21 ±0.79	0.74 ±0.56	2.96	p<0.001
Praseka	A	0.83 ±0.83	0.42 ±0.51	2.80	P<0.02
	B	0.42 ±0.77	0.21 ±0.45	2.14	p<0.05
Vibandha	A	1.17 ±1.03	0.58 ±0.67	3.02	p<0.02
	B	1.21 ±0.71	0.58 ±0.51	5.55	p<0.001

Discussion:

Acid peptic disorder becomes a significant problem in the medical world because of its higher incidence, incomplete aetio-pathogenesis, relapse and severe consequences. In spite of phenomenal process in H. pylori researches a great relapses in APD are found. A relative failure of modern medicine has made the majority of population to turn towards alternative system of medicine.

In the present study regarding age, high incidence was observed in between 2nd, 3rd and 4th decade of age group which may be due to pitta predominance in this age. In this study males were 60% and 40% were females. Thus it appears the disease of male predominance.

Vata-pitta trait of *deha prakriti* (43.33%) and *rajasika* type of *manasa prikriti* (63.33%) persons are more prone to acid-peptic –diseases. Thus suggesting that *Parinama shoola* is a *vata-pitta* predominant disease.

Certainly, the influence of *kala* (season) is present in *Parinamashoola.*It has been indicated in this study in the form of high incidence (33.33%) of the disease in patients during *Sharad ritu* (autumn season). *Sharad ritu* has been considered as the *pitta prakopaka kala*, thus the incidence of the disease in this *kala* suggests the prominence of *pitta* in *Parinama shool*.

Observations regarding dietary habits showed that people who used to take spicy diet were more prone to develop this disease than those patients who were taking ordinary diet, thus suggesting that *pitta prakopaka ahara* (aggravating diet) aggravates the disease, indicating that *Parinama shoola* is a *pitta* predominant disease.

Statistical data revealed that the trial drugs showed statistically significant improvement in *udar sholoa, aruchi, utklesha, hritkantha daha, adhmana, vibandha,* and *praseka* ($p<0.01$)

In *udarshoola* (epigastric pain), both the trial drugs showed statistically highly significant improvement($p<0.001$), but the mean decrease in the intensity of epigastric pain of group B was found lesser as compared to group A, which suggested that trial drug *Shatavari mandoor* is more effective in improving epigastric pain in comparison to *Pippali ghrita* in patients of *Parinama shoola.*

Similarly, both the trial drugs also showed statistically significant improvement ($p<0.001$) in *hrit kantha daha* (epigastric burning), but the mean decrease in this symptom in group A was more in comparison to group B, thus indicating that *Shatavari mandoor* is having more *pitta shamak* action in comparison to *Pippali ghrita.*

Statistical data revealed that, constipation is significantly reduced in both groups at the end of the treatment but highly significant improvement was observed in group B ($p<0.001$). Also, group B showed highly significant improvement in flatulence ($p<0.001$) in comparison to group A ($p<0.01$), thus indicating the *vata shamak* action of *Pippali ghrita*.

Mode of action of trial drugs:

Trial drug *Shatavari mandoor* is a herbomineral compound which consists of *Mandoor bhasma*, *Shatavari swaras, Goghrit*, *Godugha,* and *Gavya dahi*. (7)

Pharmacological properties of *Shatavari* (*Asparagus racemosus*) are *madhur tikta rasa, pichala-snigdha guna, sheeta veerya and madhur vipaka* (8).

Several clinical studies showed the antiulcer effect of *Shatavari*. (9,10)

Mandoor is *kashaya* in *rasa*, *sheeta*, *guru*, *pitta shamak* in *guna* (property). *Go dudha* and *Go ghrita* are *sheeta*, *madhur* and *vata-pitta nashaka*.

These properties of *Shatavari Mandoor* helps in pacification of *pitta* and *vata*,(7) which are the main aggravating factors in the pathogenesis of *Parinama shoola*.

Also several clinical studies regarding the antiulcer properties of *Shatavari mandoor* have been conducted and revealed its antiulcer effect owing to strengthen mucosal defence mechanism in acid peptic disorders. (4,5)

Second trial drug is *Pippali ghrita* which consists of *Pippali kawatha, Pippali kalka*, *Go ghrita.*(6)

Pippai (*Piper longum*) is *katu rasa pradhan, snigdha and ushna in guna* (property) and *vatanulomak in* action. (11)

Pippali can act as *vatanulomak* (pacifies abdominal gases) and *shoola prashmak* due to its *snigdha –ushna guna*, *agni deepan* (improving digestive fire) due to *katu rasa. Ghrita* is having the property of *vata- pittahara*, *shoola-prasamana* (pain relieving), *snehana*, *agnideepan* (improving digestive fire). *Ghrita* has also been claimed a good *vranaropak*.(ulcer protective property). Thus drug may act as cyto-protective (barrier of acid-pepsin in the epithelial lining of stomach, duodenum) in the patients of *Parinama shoola*.

An experimental study, has also showed antiulcer effect of *Piper longum* in rats. (12)

Thus, the antiulcer property of the trial drugs *Shatavari Mandoor* and *Pippali ghrita*, is probably owing to their cytoprotective, *shoola prashmak* and *vatanulomaka* action.

Conclusion:

This is evident from both clinical and statistical improvement that the drugs *Shatavari mandoor* and *Pippali ghrita* are effective in the treatment of *Parinama shoola* and their ulcer protective effect may be through promotion of defensive mucosal mechanism rather than affecting the offensive acid-pepsin secretion.

It was observed that, *Shatavari mandoor* is more effective in relieving symptoms like burning sensation whereas *Pippali ghrita* is more effective in relieving symptoms like flatulence and constipation in patients of

Parinaam shoola.

Thus, it can be concluded from the present study that *Pippali ghrita* would be effective in vata predominant *Parinaam shoola* and *Shatavari mandoor* would be effective in pitta predominant *Parinaam shoola*.

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