

CLINICAL EVALUATION OF DHATRILAUHA IN PARINAMASULA

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ABSTRACT: *Parinamashoola is a very common clinical problem in our day to day practice. Its clinical picture is very much similar to non ulcer dyspepsia and peptic ulcer disease. Dhatri Lauha is herbomineral compound drug. Which is being used in Ayurveda for same. The present study was planned to assess the efficacy of Dhatri Lauha on scientific parameters in this study total number of cases were taken into account and divided in to trial and control group in control group a modern proved drug ranitidine is taken to compare the results this study produced very promising results of trial drug.*

INTRODUCTION

Parinamashoola is one common clinical problem of our day to day practice, it is very well described in ayurvedic texts of latter periods. On analyzing it in modern light, its description is very much similar to peptic ulcer disease and which is well known established entity. Its incidence is increasing rapidly day by day, since last few decades, most appropriate explanation for this, may be due to more stresses and strain in today's life because of rapid urbanization and modernization. It commonly affects 5-10% of people, at any stage of their life.

Introduction of endoscopy in the field of medicine, revolutionized the diagnosis of peptic ulcer and also differentiated from other similar disease (like Non Ulcer dyspepsia).

The study and use of crude drugs is one of the oldest of medical sciences. Crude drugs have always constituted more than half of the remedial agents in use at any time (Ferguson 1958). A number of drugs are

available for treatment of peptic ulcer disease, including non ulcer dyspepsia. These are not easily available to all the patients, due to their high cost and some of them can not be used due to certain side effects also permanent cure of this disease is not possible yet, because of its nature of recurrence.

Various drugs are also described in Ayurvedic texts, for management of *Parinamashoola*. These are being commonly used by Ayurvedic clinician, since long time. *Dhatri Lauha*, is very popular herbomineral compound (drug) and described for management of *Parinamashoola*.

In the present clinical study, *Dhatri Lauha* is taken into account, to see, its effect in patients of *Parinamashoola*, on the basis of scientific parameters. Effect of *Dhatri Lauha* was also compared with ranitidine, a modern drug.

MATERIALS AND METHODS

The present clinical study was conducted in uncomplicated cases of *Parinamashoola*. Selection of patients was done randomly from Kayachikitsa (O.P.D and I.P.D) and gastroenterology, O.P.D., S.S. Hospital, B.H.U., Varanasi. Cases for this study were selected during the September 1991 to November 1992.

The detailed symptomatic case history, demographic profile was recorded according to proforma prepared. After clinical examination, they were subjected to necessary modern laboratory, radiological (Barium contrast examination) and endoscopic examination, then diagnosis was confirmed and trial drug was given.

In this study total number of 30 cases were taken and they were divided into two groups:

(a) Group 'A'

This group was comprised of 20 patients. Out of 20 cases, there were 5 cases of peptic ulcer (Gastric or duodenal) and 15 cases of Non ulcer dyspepsia, having no peptic ulcer dyspepsia, having no peptic ulcer like finding on radiological and endoscopic examination, all of these patients were subjected to trial drug, *Dhatrilauha*, in the dose of 1 gm x 3, divided doses per day. The duration of treatment was kept 6 weeks.

(b) Group 'B'

This group was comprised of 3 cases of peptic ulcer and 7 cases of Non- ulcer – dyspepsia. Thus total number of cases was 10. All these patients were kept on ranitidine, 150 mg x b.d. for six weeks.

Clinical Profile

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

0-Absent 2-Moderate 1- Mild 3- Severe

Grading of common symptomatology was done in above manners.

Drug

Dhatrilauha is very popular herbomineral compound. It is being used in the cases of *parinamashoola* since ears. In the present clinical study, this compound drug is taken, to see the efficacy of this drug is taken, to see the efficacy of this drug in the patients of *parinamashoola*. The drug was prepared in Ayurvedic pharmacy, I.M.S., B.H.U., Its constituents are:

1. *Amalaki* powder (4 part)
2. *Yashtimadhu* Powder (1 Part)
3. *Lauha Bhasma* (2 part)

The dose of drug was given in this clinical study, 1 gm in 3 divided doses per day with honey. The duration was kept 6 weeks.

Parameters of Assessment of Result

The effect of *Dhatrilauha* was compared with modern drug ranitidine. The following parameters were adopted for the assessment of response and its comparison.

1. **Clinical:** Symptomatic relief, in terms of relief in major symptom like pain in abdomen, heartburn, nausea, Vomiting etc. This was evaluated on the basis of favorable shift of grades of symptom and signs in terms of statistical analysis.
2. **Radiological:** in the positive cases, improvement was assessed on the basis of

healing of ulcer by demonstration of well formed duodenal cap, decreased size of ulcer crater, fibrotic changes and increases distensibility.

3. **Endoscopic:** Assessment of peptic ulcer was done on the basis of healing of ulcer (complete or partical), decreased hyperaemia and reduced surrounding oedema.

In the cases of non ulcer dyspepsia, there was no ulcer like finding, but there was presence of reflex oesophagitis, gastritis (antral or fundal), duodenitis or deformed pylorus and duodenal bulb. In these cases assessment was done on the basis of reduction or absence of above lesion.

Criteria of response of Drug

The result of drug was assessed n the basis of clinical symptomatology and improvement in radiological and endoscopic findings:

1. Excellent
2. Good
3. Poor
4. Unchanged

RESULTS

A total number of 30 patients of Parinamashoola are included in this study. The relevant data in respect of demographic and clinical profile were recorded and in each case evaluated. Some of the observations are exhibited in following tales. Demographic and clinical profile was recorded with a view to define the type of patients selected for present study.

Table I
Age in 8 cases of peptic ulcer and 22 cases of non ulcer dyspepsia

Age Group		Peptic ulcer	Non Ulcer Dyspepsia	
(In years)	No. of patients	% age	No. of patients	% age
11-20	1	12.50	1	4.54
21-30	3	37.50	8	36.36
31-40	2	25.00	8	36.36
41-50	2	25.00	--	--
51-60	--	--	5	22.72
61 and above	--	--	--	--
Total	8	100	22	100

Table II
Sex incidence in 8 cases of peptic ulcer and 22 cases of non ulcer dyspepsia

Age Group		Peptic ulcer	Non Ulcer Dyspepsia	
(In years)	No. of patients	% age	No. of patients	% age
Male	4	50.00	9	40.91
Female	4	50.00	13	59.09
Total	8	100.00	22	100.00

Table III

Deha Prakrti in 8 cases of peptic ulcer and 22 cases of non ulcer dyspepsia

Deha Prakrti	Peptic ulcer		Non Ulcer Dyspepsia	
	No. of patients	% age	No. of patients	% age
Vatika	--	--	3	13.64
Paittika	1	12.50	4	18.18
Kaphaja	--	--	1	4.55
Vata-Paittika	6	75.00	9	40.91
Vata-Kaphaja	1	12.50	3	13.64
Pitta-Kaphaja	--	--	2	9.04
Total	8	100	22	100

Table IV

Dietary incidence in 8 cases of peptic ulcer and 22 cases of non ulcer dyspepsia

Type of Diet	Peptic ulcer		Non Ulcer Dyspepsia	
	No. of patients	% age	No. of patients	% age
Vegetarian	1	12.50	12	54.55
Non Vegetarian	7	87.50	10	45.55
Total	8	100.00	22	100.00

Table V

Addiction in 8 cases of peptic ulcer and 22 cases of non ulcer dyspepsia

Addition	Peptic ulcer		Non Ulcer Dyspepsia	
	No. of patients	% age	No. of patients	% age
Tea and Coffee	4	50.00	8	36.36
Smoking	2	25.00	3	13.63
Tobacco and betal chewing	1	12.50	4	18.10
None	1	12.50	7	31.80
Total	8	100	22	100

Table VI

Blood group in 8 cases of peptic ulcer and 22 cases of non ulcer dyspepsia

Blood group	Peptic ulcer		Non Ulcer Dyspepsia	
	No. of patients	% age	No. of patients	% age
A*	1	12.50	2	9.09
B*	1	12.50	14	63.64
AB*	3	37.50	1	4.55

O*	3	37.50	5	22.73
Total	8	100	22	100

Radiological and Endoscopic Examination

In the present clinical stud, each and every case of parinamashoola, i.e. diagnosed on clinical examination (symptomatic basis), is further subjected to radiological examination (Barium meal examination) and endoscopic examination for stomach and duodenum. Cases having positive findings of peptic ulcer were kept in peptic ulcer were kept in peptic ulcer group.

Some of them having no positive findings of peptic ulcer, these cases were kept in non ulcer dyspepsia group. Despite the positive radiological findings, only endoscopic confirmation of peptic ulcer was considered as of final criteria for diagnosis.

The study reveals that, most commonly observed radiological findings in cases of Non Ulcer Dyspepsia are deformity of pylorus and duodenal bulb. In same cases, this is also accompanied by surrounding oedematous appearance. Before the introduction of endoscopy, marked deformity and irregularity of duodenal bulb was considered due to peptic ulcer, On endoscopic examination these cases showed findings like oesophagitis, gastritis (antral/

fundla) or duodenitis. Positive findings of peptic ulcer were absent. Some cases also showed normal radiological and endoscopic findings.

Cases of peptic ulcer group showed radiological findings of peptic ulcer, like ulcer crater I lesser curvature or I part of duodenum and irregular, deformed and oedematous pylorus or duodenal bulb. The endoscopic examination revealed positive findings of peptic ulcer (maximum of duodenal ulcer in this study) in all the cases.

Response of treatment

Response of treatment of non Ulcer Dyspepsia (diagnose on radiological and edoscopic examination criteria) cases assessed on the symptomatic improvement. And Peptic Ulcer cases assessed on clinical, radiological and endoscopic improvement.

(a) Clinical Improvement

The following observations have been made form the response of treatment on reduction of mean symptoms score (Table VII).

Table VII
Reduction of Mean Difference of Symptom score in response to Treatment

Symptoms	<u>Trial Group</u>		<u>Control Group</u>	
	Non Ulcer Dyspepsia	Peptic Ulcer	Non Ulcer Dyspepsia	Peptic Ulcer
1. Pain in abdomen Mean ± SE t Value p value	1.33 ± 0.23 5.733 <0.001	1.4 ± 0.245 5.714 <0.01	1.87 ± 0.245 7.114 <0.001	1.667 ± 0.33 5.006 <0.05
2. Acid eructation Mean ± SE	0.93 ± 0.21	0.8 ± 0.37	0.572 ± 0.202	1.0

t Value	4.529	2.139	2.831	--
p value	<0.001	<0.05	<0.02	--
3. Nausea				
Mean ± SE	0.667± 0.21	0	0.429 ± 0.202	0.33 ± 0.33
t Value	3.176	--	2.123	1.0
p value	<0.01	--	>0.05	>0.05
4. Vomiting				
Mean ± SE	0.8 ± 0.17	0.2 ± 0.2	0.857 ± 0.340	1.33 ± 0.667
t Value	4.598	1.0	2.520	1.999
p value	<0.001	>0.05	<0.05	>0.05
5. Anorexia				
Mean ± SE	0.4 ± 0.16	0.4 ± 0.245	0.429 ± 0.202	0.33 ± 0.333
t Value	2.454	1.633	2.112	2.003
p value	<0.05	>0.05	>0.05	>0.05
6. Flatulence				
Mean ± SE	0.533 ± 0.133	0.4 ± 0.4	0.714 ± 0.488	0.667 ± 0.333
t Value	4.008	1.0	3.880	2.003
p value	<0.01	>0.05	<0.01	>0.05
7. Constipation				
Mean ± SE	0.4 ± 0.131	0.6 ± 0.4	0.29 ± 0.202	1.333 ± 0.333
t Value	3.053	1.5	2.124	4.003
p value	<0.01	>0.05	<0.05	<0.05
8. Indigestion				
Mean ± SE	0.667 ± 0.159	0.6 ± 0.4	0.429 ± 0.297	0
t Value	4.195	1.5	2.124	--
p value	<0.001	>0.05	<0.05	--
9. Heartburn				
Mean ± SE	1.33 ± 0.186	1.2 ± 0.374	1.143 ± 0.261	1.33 ± 0.333
t Value	7.151	3.209	4.379	3.993
p value	<0.001	<0.05	<0.01	<0.05
10. Water brash				
Mean ± SE	0.133±0.091	0.2±0.2	0.143 ±0.143	0.333 ± 0.333
t Value	1.462	1.0	1.0	1.0
p value	>0.05	>0.05	>0.05	>0.05
11. Belching				
Mean ± SE	0.6 ±0.190	1.0 ±0.316	0.286 ±0.184	0.333 ± 0.333
t Value	3.158	3.165	1.554	1.0
p value	<0.01	<0.05	>0.05	>0.05
12. Thirst				
Mean ± SE	0.333 ± 0.187	0.4 ± 0.245	0.286 ± 0.184	0.667 ± 0.667
t Value	1.781	1.633	1.554	1.000
p value	>0.05	>0.05	>0.05	>0.05
13. Discomfort				
Mean ± SE	0.2 ± 0.107	0.2 ± 0.2	0.143 ± 0.143	0.333 ± 0.333
t Value	1.869	1.0	1.0	1.0
p value	>0.05	>0.05	>0.05	>0.05
14. Heaviness				
Mean ± SE	0.267 ± 0.118	0.4 ± 0.245	0.286 ± 0.184	0
t Value	2.263	1.633	1.554	--

p value	>0.05	>0.05	> 0.05	--
15. Buring Sensation all over body				
Mean ± SE	0.333 ± 0.159	1.0 ± 0.159	0.429 ± 0.202	0.333 ± 0.333
t Value	2.094	2.0 3.165	2.124	1.0
p value	>0.05	3.0 <0.05	>0.05	>0.05

Regarding pain in abdomen reduction of mean score is 1.33 ± 0.23 in Non Ulcer Dyspepsia, whereas in control group 1.857 ± 0.26 . The peptic ulcer group as shown mean reduction of 1.4 ± 0.25 in trial group, whereas in control group it was 1.67 ± 0.33 . It is evident that relief of pain in abdomen was statistically significant in all groups on Non Ulcer Dyspepsia and peptic ulcer, but comparatively more significant in control group.

The response of acid eructation with the trial drug was highly significant ($p < 0.001$) in the Non Ulcer Dyspepsia and peptic ulcer and in the control group it was significant in peptic ulcer, but comparatively less in Non Ulcer Dyspepsia cases.

The clinical symptom vomiting was responded well in Non Ulcer Dyspepsia cases of trial group ($p < 0.001$), than control group ($p < 0.05$). Whereas in peptic ulcer the symptom ad not sown any significant improvement ($p < 0.05$).

The another symptom, heartburn was responded well in Non Ulcer Dyspepsia and peptic ulcer cases of both trial and control

groups, but statistically highly significant response was seen in Non Ulcer Dyspepsia cases of trial group.

Mild to moderate response was observed in symptom belching by the trial dug, whereas in control group the response was insignificant statistically. The details of the remaining symptoms, their statistical values sown in table VII.

(ii) Net response of clinical improvement in also assessed. For this, first of all total score of symptoms before and after treatment is calculated for each patient, then difference of total score of reduction is recorded. After this; percentage of total difference of score reduction from before total score is calculated. If reduction of percentage is:

- 75% or above – Excellent
- between 75 – 35% - Good
- Between 35 – 10% - Partial
- <10% - Unchanged

On the above methods, net results of clinics improvement is calculated and given in table VIII.

Table VIII
Net response of clinical improvement

	Trial Group		Control Group	
	Non Ulcer Dyspepsia	Peptic Ulcer	Non Ulcer Dyspepsia	Peptic Ulcer
Excellent	4.67%	60.00%	71.42%	100.00%
Good	53.33%	20.00%	28.58%	--

Partial	--	20.00%	--	--
Unchanged	--	--	--	--

(B) Radiological Improvement

This was assessed in all the cases of peptic ulcer by repeat barium meal examination, in both trial and control group (Table IX)

improvement, in both the groups. It may be due to that it required stud of long term duration.

The present study sows tat, there is mixed response obtained in radiological

Table IX
Radiological Improvement in 8 cases of peptic Ulcer

Patient Name	Before Treatment	After Treatment	Conclusion
<u>TRIAL GROUP</u>			
1.JC	Markedly deformed duodenal bulb	Some rounding of duodenal bulb	Partial Healing
2. V	Irregular duodenal bulb with ulcer crater in I part	Shallow ulcer crater with persistant deformity of duodenal bulb	Good healing
3.GN	Markedly deformed duodenal bulb with mucosal oedema	Persistant deformity of duodenal bulb with absent oedema	Partial healing
4. A	Small ulcer crater is seen in lesser curvature	Persistant ulcer crater	Persistant ulcer
5.C	Markedly deformed duodenal bulb	Rounding of duodenal bulb wit increased dispensability	Marked healing
<u>CONTROL GROUP</u>			
1.U	Small ulcer crater in I part of duodenon	Shallow ulcer wit widened base	Marked healing Of ulcer
2.R	Mildly deformed duodenal bulb	Deformity of duodenal bulb persisting with some improvement	Partial healing
3.B	A ulcer crater on the lesser curvature of pyloric antrum with some deformity of	Sallow ulcer crater with some increase dispensability	Good healing

	duodenal bulb		
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(C)Endoscopic Improvement

This was assessed in all the cases of peptic ulcer repeat endoscopic examination to see the effect on trial and control group (Table X)

Table X
Radiological Improvement in 8 Cases of Peptic Ulcer

Patient Name	Before Treatment	After Treatment	Conclusion
<u>TRIAL GROUP</u>			
1.JC	A small ulcer in I part of duodenum with marked oedema	Decreased sized of ulcer granulation tissue seen, oedema present	Partial Healing
2. V	Deformed duodenum bulb with 2 small ulcer in anterior wall	No ulcer seen, same deformity present	Good healing
3.GN	Moderate antral gastritis with an ulcer in I part and erosion	Oesophagus and stomach normal, mild duodenitis, no ulcer seen	Good healing
4. A	A Small prepyloric ulcer seen wit oedematous pylorus	Healing of prepyloric ulcer seen with minimal granulation tissue and some oedema is persisting	Good healing
5.C	Deformed pylorus hyperaemic erosion, an ulcer in I part of duodenum	Not co-operated	--
<u>CONTROL GROUP</u>			
1.K	Lower end mild oesophagitis, antral gastritis, deformed pylorus, a small ulcer in I part	Oesophagus and stomach normal, mildly deformed pylorus, no ulcer some granulation tissue present	Marked healing
2.R	Mild antral gastritis, an ulcer seen in ante. Wall wit mild bleeding, pylorus deformed & thickening of mucosal fold.	Not Co-operated	--
3.B	Lower end oesophagitis, antral gastritis with erosion and a prepyloric ulcer with deformed and oedematouspylorus speed post	Oesophagus and stomach normal, no ulcer seen wit decreased oedema, granulation tissue present	Good healing

There is significant improvement in endoscopic findings in both trial and control group, despite the persistent radiological findings in some cases.

It is not significant to calculate percentage of improvement in radiological and endoscopic findings, due to less number of case in peptic ulcer group.

Discussion

By considering the efficacy of Dhatri-lauha, it was decided to perform a study on scientific parameters and evaluate the efficacy of drug in parinamashoola, as, it has been already said that clinical description of parinamashoola was gradually evolved in altered texts first of all, by madhavkar and further scientific input was added by vijayarakshita, Bhavprkasha & Yogaratnaker.

Hundreds of therapeutic recipes are described in Ayurvedic classics for management of parinamashoola, Dhatri-lauha is among such a formulae and contains three important ingredients, i.e. Amalaki, Yasthimadhu and lauha bhasma. Amalaki is a very popular drug and having wide range of actions., But in this regard, its ulcer healing, mucoprotective and enhance the effect of lauha are worth to be noted. Yasthimadhu (Liquorice) is also an effective ingredient, which has several actions, Anticholinergic, cytoprotective, ulcer healing are important to quote, lauha Bhasma has quality of Ramayana and also having pacifying effect of pitta and kappa Dhatri-lauha is such a unique compound, which possess all such ingredients, by realizing all these unique qualities, Dhatri-lauha is such a unique compound, which possess all such ingredients. By realizing all these unique qualities

Dhatri-lauha was taken for clinical evaluation under present study.

Regarding the various observation, incidence of Age was most common in third and fourth decades in both the groups. This can be due to predominance of pitta. Observation of sex incidence, Non ulcer dyspepsia is more common in female cases (59.09%) than males (40.91%) and peptic ulcer cases, ratio is equally distributed, study of dehaprakriti showed maximum number of cases from vata- Pittika constitution in peptic ulcer and Non – ulcer dyspepsia both.

Response of treatment was assessed in terms of clinical, radiological and endoscopic improvement, clinical improvement was calculated statistically and by reduction of mean difference of symptoms score (Table VII)

Significant to highly significant improvement was found in symptom like pain in abdomen, acid eructation, vomiting, flatulence, heart burn and constipation etc, in all the groups of trial and control statistically. By this results of certain symptoms was not significant ($p > 0.05$), more in control group than trial. It may be due to less number of cases in peptic ulcer and non ulcer dyspepsia of control group.

It is found that trial drug (Dhatri-lauha) was good to excellent response in almost all of the symptoms of peptic ulcer and non ulcer dyspepsia. And control drug (Ranitidine) also showed similar results, but comparatively it was better in some symptoms. Total clinical response was also calculated in each patient and then percentage of reduction was calculated and it is shown in table No VIII.

Radiological and endoscopic improvement was also assessed in positive cases of peptic

ulcer by repeat examination, Radiologically, there was mixed response from partial to good healing, it may be due to that, it requires long term treatment and further study., in repeat endoscopic examination, there was significant improvement in trial group and marked to good healing in cases of control group.

Conclusion

It can be concluded that, the present study proved the efficacy of Dhatri-lauha in management of parinamashoola (peptic Ulcer and Non Ulcer Dyspepsia). The mode of its action may be cytoprotective, antisecretory, increases the mucosal resistance and prokinetic action etc.

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