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A Comparative Clinical Trial on Curcuma angustifolia Roxb. Extract Versus Omeprazole in the Management of Hyperacidity W.S.R to Amlapitta Treatment

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Abstract

Peoples in developing and developed countries of contemporary era demands modern lifestyle which provides number of facilities makes the ways of daily routine much easier. But many of the modern lifestyle patterns adversely affect health physically, psychologically and socially. Especially modern diet style adopted by the people of present nuclear family is such an example for the cause of many of the gastro intestinal disorders. Hyperacidity is major aftereffects of such an unhealthy dietary healthy behaviour. The present research work is a clinical trial to evaluate the efficacy of Curcuma angustifolia Roxb. Extract prepared using Ayurvedic classical methods versus scientifically worldwide accepted stand drug of choice Omeprazole in the management of Hyperacidity in the point of view with clinical condition Amlapitta mentioned in Ayurvedic texts of Indian traditional medicine.

1.Introduction

Amlapitta is a clinical condition mentioned in Ayurveda, one of the most renowned oldest traditional system of medicine accepted worldwide with unbelievable wide range of results using Herbo mineral single and compound medicines, practicing in India since 2nd century BC. The sedentary life style, consumption of too much coffee, alcoholic drinks, carbonated beverages, fast foods etc will incrases the secretion of hcl in stomach on a daily routine will be at risk of developing amlapitta. This Acid reflux condition can be corelated with the symptoms of Hyperacidity of modern medical science presents with complaints like heart burn accompanied with bitter taste in mouth, fullness in the upper quadrants of abdomen, nausea and vomiting etc. once in the lifetime all the age groups will experiences this condition. Ontime being if not following healthy dietary lifestyle or proper medications will worsen this condition.

Amlapitta presents with same features of True Acidity or Ulcer dyspepsia with disorders like gastritis, inflammation of inner mucosa of stomach, gastric ulcer, acid reflux disease, gastroesophageal reflux disease etc.

Therefore, in the present study, on the basis of Ayurvedic traditional references, an attempt is made to provide scientifical evidence for proton pump inhibitors action or the property of profound, prolonged

reduction of acid production using Curcuma angustifolia Roxb. extract prepared using Ayurvedic traditional methods used versus standard drug of choice Omeprazole.

2.Collection and Preparation of Drugs

Authenticated for identity, quality and purity, Collected samples of Curcuma angustifolia Roxb. Rhizomes are washed thoroughly to remove the mud, dirt and made in to small pieces of 2-3 cm. Then Rhizomes smashed and grinded to paste with the help of grinder. This paste is added with 6 times of clean water in a non-reactive vessel and macerated well and filtered through a white fine cloth piece and extracted to another non-reactive vessel, fibery waste over the cloth were discarded. Then the water is kept undisturbed till the extract settles down completely and the water to turn clear. The supernatant clear water is darned carefully and the white colour sediment extract is collected carefully and again mixed with clean water and the procedure repeated till the sediment extract loses bitter taste, gains pure white colour. After this the pure white colour extract is collected and dried under shade till it becomes dry and stored in glass containers.

3. Material and Methods

Pre diagnosed hundred cases of Amlapitta, irrespective of sex were randomly selected using a random number table. Then the population is divided in to two groups i.e. group A and group B consisting of fifty patients of either sex. Group A(control) was given Omeprazole and group B(trial) is given extract of Curcuma angustifolia Roxb. for thirty days. Assessments done using subjective and objective parameters.

Collection and Preparation of the Drugs

Extract of Curcuma angustifolia Roxb. prepared following the standard operative procedures of Ayurvedic classical methods were taken 10 grams with 100 millilitres of clean water in a non-reactive vessel and reduced to half the quantity on mild fire.

Grouping of Patients

Institutional Ethical Committee ref. (PU/PIA/IEC/05/2022/174) clearance obtained and after Clinical trials registry – India (ICMR-NIMS) registration. Two random identical group of patients each with fifty volunteers with sequential numbering using opaque envelops.

[Table-2]: Grouping and posology.

S.N	Groups	Group A	Group B
1.	Drug	Omeprazole	Curcuma angustifolia Roxb.Extract
2.	Sample size	50	50
3.	Drop Out	0	0
4.	Dose	20 mg	25 g
5.	Rout	Oral	Oral

Study Design

Randomized Control Trial

Group A (Control Group)

Seventy-Five Pre diagnosed Patients of Hyper acidity cases were given with one tablet of Omeprazole 20 mg as a single dose with 25ml of water orally for four weeks during night time one hour before food.

Group B (Trial Group)

Seventy-Five Pre diagnosed Patients of Hyper acidity cases were given with 25g of Curcuma angustifolia extract twice a day one hour before food during morning and night times orally till the end of fourth week.

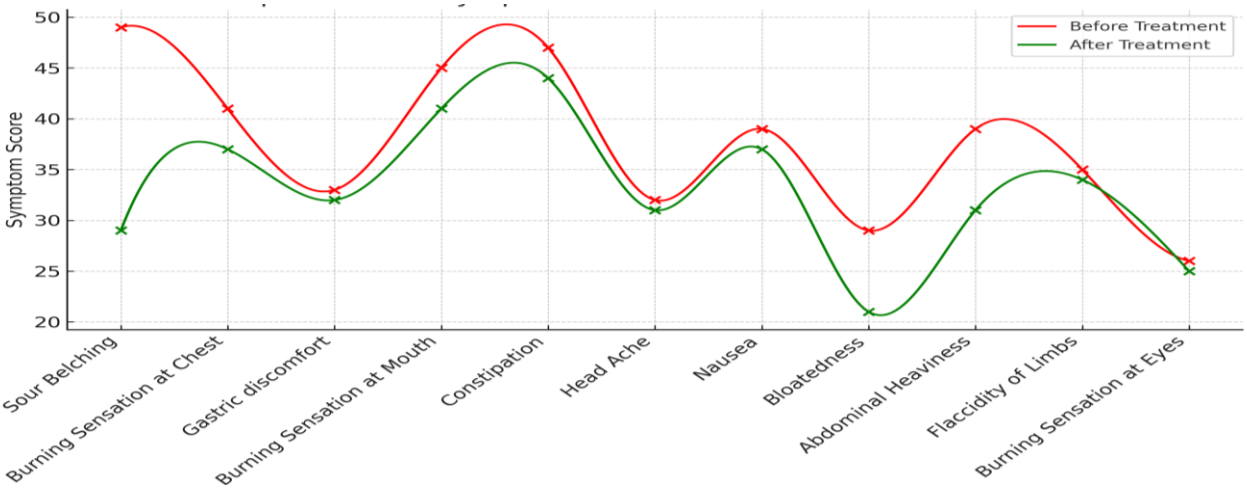
Pre operative and Post operative Assessments

Thorough assessment of patients was done after explaining about proposed research work and obtaining consent, Pre operative and post operative scale of signs and symptoms grading and efficacy was done.

[Table-2]: Pre operative and Post operative observations of Trial Group A.

S.N	Observational Criteria (Symptoms)	Group	Symptoms Score			Percentage of Relief
			Before Treatment	After Treatment	Difference	
1.	Sour Belching	A	49	29	20	59
2.	Burning Sensation at Chest	A	41	37	4	90
3.	Gastric discomfort	A	33	32	1	96
4.	Burning Sensation at Mouth	A	45	41	4	91
5.	Constipation	A	47	44	3	93
6.	Head Ache	A	32	31	1	96
7.	Nausea	A	39	37	2	94
8.	Bloatedness	A	29	21	8	72
9.	Abdominal Heaviness	A	39	31	8	79
10.	Flaccidity of Limbs	A	35	34	1	97
11.	Burning Sensation at Eyes	A	26	25	1	96
Total		A	415	362	53	87

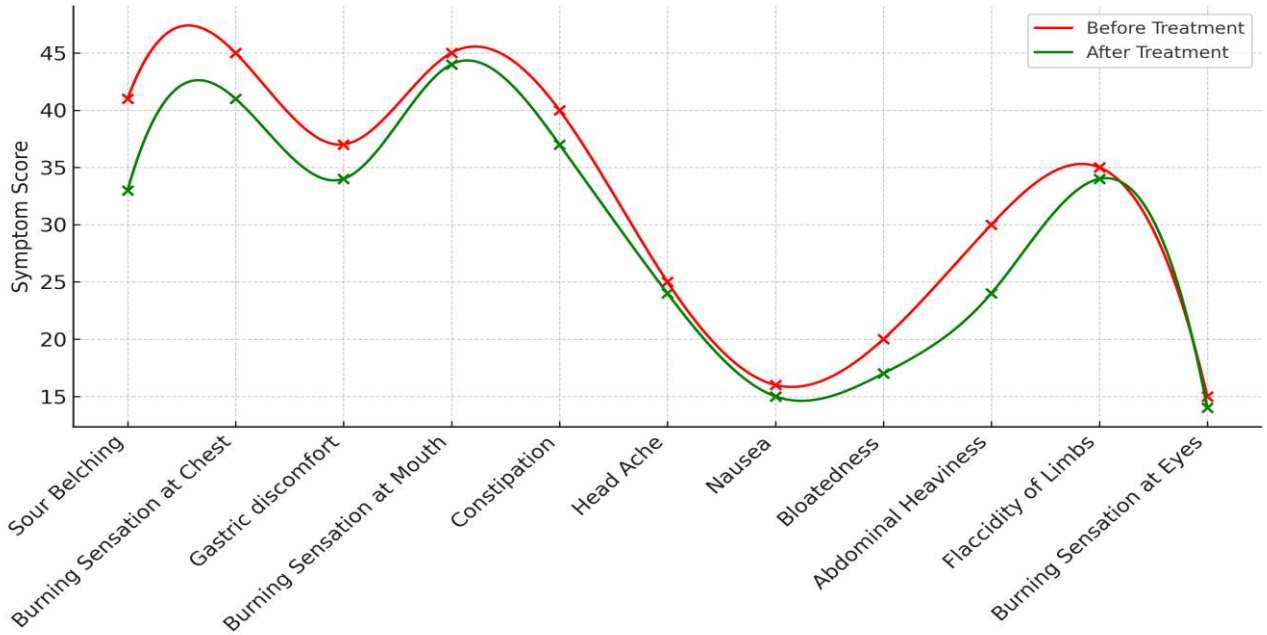
[Chart -1]: Symptom Score Before and After Treatment of Trial Group A.



[Table-3]: Pre operative and Post operative observations of Trial Group B.

S.N	Observational Criteria (Symptoms)	Group	Symptoms Score			Percentage of Relief
			Before Treatment	After Treatment	Difference	
1.	Sour Belching	B	41	33	8	80
2.	Burning Sensation at Chest	B	45	41	4	91
3.	Gastric discomfort	B	37	34	3	91
4.	Burning Sensation at Mouth	B	45	44	1	97
5.	Constipation	B	40	37	3	92
6.	Head Ache	B	25	24	1	96
7.	Nausea	B	16	15	1	93
8.	Bloatedness	B	20	17	3	85
9.	Abdominal Heaviness	B	30	24	6	80
10.	Flaccidity of Limbs	B	35	34	1	97
11.	Burning Sensation at Eyes	B	15	14	1	93
Total		B	349	317	32	90

[Chart -1] :Symptom Score Before and After Treatment of Trial Group B.



Results

While the comparison between both the groups, there was much relief in symptoms like Sour Belching, Burning Sensation at Mouth, Bloatedness after the consumption of Omeprazole 20 mg(group A) while symptoms like Gastric discomfort, Abdominal Heaviness was found less in Curcuma angustifolia extract(group B),overall results after taking treatment of both the groups found to be good.

[Table-4]: Pre operative and Post operative observations Statistics.

S.N	Symptoms	Group	W	T+	T-	Mean ± SD		P	Result
						BT	AT		
1.	Sour Belching	A	120	120	0.0	1.36±1.25	0.28±0.54	<0.0001	E. S
		B	105	105	0.0	1.19±1.167	0.30±0.47	0.0001	E. S
2.	Burning Sensation at Chest	A	171	171	0.0	1.76±1.09	0.5±0.509	<0.0001	E. S
		B	210	210	0.0	1.73±1.002	0.30±0.47	<0.0001	E. S
3.	Gastric discomfort	A	136	136	0.0	1.44±1.08	0.24±0.52	<0.0001	E. S
		B	120	120	0.0	1.42±1.33	0.307±0.47	<0.0001	E. S
4.	Burning Sensation at Mouth	A	91	91	0.0	0.96±0.93	0.28±0.45	0.0002	E. S
		B	78	78	0.0	1.07±0.97	0.34±0.62	0.0005	E. S
5.	Constipation	A	55	55	0.0	0.84±0.98	0.44±0.58	0.0020	E. S
		B	78	78	0.0	0.96±0.99	0.23±0.51	0.0005	V. S
6.	Head Ache	A	28	28	0.0	0.44±0.70	0.08±0.27	0.0156	S
		B	25	25	0.0	0.68±0.98	0.32±0.32	0.0156	S

7.	Nausea	A	28	28	0.0	1.19±1.167	0.32±0.55	0.0156	V. S
		B	55	55	0.0	0.61±0.80	0.11±0.32	0.0020	S
8.	Bloatedness	A	55	55	0.0	1.00±1.111	0.56±0.65	0.0020	V. S
		B	66	66	0.0	0.76±0.99	0.15±0.36	0.0010	V. S
9.	Abdominal Heaviness	A	21	21	0.0	0.56±0.76	0.32±0.47	0.0313	V. S
		B	36	36	0.0	0.5±0.76	0.15±0.36	0.0078	S
10.	Flaccidity of Limbs	A	10	10	0.0	0.36±0.56	0.2±0.40	0.1250	N. S
		B	15	15	0.0	0.34±0.69	0.15±0.36	0.0625	E. S
11.	Burning Sensation at Eyes	A	10	10	0.0	1.19±1.167	0.30±0.47	<0.0001	E. S
		B	6	6	0.0	1.19±1.167	0.30±0.47	<0.0001	E. S

W=sum of all rank, T+=sum of all positive rank, T-=sum of all negative rank, S.D. =Standard Deviation

P>0.05 - N.S. (Non-Significant),P=0.01-0.05 - S (Significant),P=0.001-0.01 - V.S. (Very Significant)

P<0.0001 - E.S. (Extremely Significant).

Discussion

As per the above data there was extremely significant results in Group B(trial)symptoms of Hyper acidity in comparing with Group A(control), the level of significance in Group B is good when comparing with a proven drug of choice Group A(control). Total percentage of relief in Trial group 90% was more than total percentage

of relief in control group was 87%.

Conclusion

Properties of Curcuma Angustifolia Roxb. extract has outstanding remarkable results in the management of hyper acidity symptoms in comparison over the proven control drug given to group A. Hence as the Curcuma Angustifolia Roxb. extract is of herbal origin,it will be more beneficial to mankind with out causing any further ramifications.

Conflicts of interest

There are no conflicts of interest.

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