Clinival study of Maha Shankha Vati with special reference to its effect on Amlapitta, Parinamshula and Annadravshula

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Abstract

Background: In today's sinario Amlapitta, Parinama Shula and Annadrava Shula are burning topics among all the health related problems. Here, we present a clinical study to evaluate the efficacy of 'maha shankh vati' on amlapitta, parinamshula and annadravshula Methods: In this study, Amlapitta, Parinama Shula and Annadrava Shula patients having age:group of 16 to 60 years were selected irrespective of their sex and religion. A total number of 40 patients were taken for the study and were randomly placed in Group A, Group B, Group C and Group D. The study was carried out for 30 days. The Group A patients prescribe Self made Maha Sankha Vati in Amlapitta patient. In group B Self made Maha Sankha Vati in Parinam Shula / Annadrav Shula, in group C Market sample of Maha Sankha Vati in Amlapitta patient, In group D Market sample of Maha Sankha Vati in Parinam Shula / Annadrav Shula Trial was conducted for thirty days and follow:up was taken after every seventh day. Patients of this group were told to take 'Milk' every day as a Anupana. Result: It was observed that, self made sample was found more effective in 'group A', compare to market sample, and market sample was found more effective in 'group D' compare to self made sample.

Keywords: Maha Shankha Vati, Amlapitta, Parinamshula, Annadravshula.

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INTRODUCTION

The popularity of any medicinal disciplines, of course depend upon the efficacy, safety, affordability and availability of the drug used in that disciplines of these qualities, efficacy is most important. If one observes an prescription on any Ayurvedic Physician, notices that, there are at least one or two drugs which belongs to category of "Rasaushadhi" because these are the compounds which are real result oriented. In Rasendra mangal stated that "may the combination of all be kept by some mischievous way on one side but that cannot stand

in a fraction of one hundredth but even of one carorth in its comparison in front of the mercurial combination". The mercury is the only drug originated from botanical, animal, mineral and marine resources, a Maha Shankha vati is also among them.

- In today's sinario Amlapitta, Parinama Shula and Annadrava Shula are burning topics among all the health related problems.
- Panchakarma measures cannot be recommended as a routine treatment so only shaman chikitsa is the routine line of treatment for these diseases.
- Modern medicine is neither having coplete medicine for Amlapitta and nor for Annadrava Shula and Parinama Shula too.

Keeping these points in view, it was decided to conduct a study, on most prevalent disorders in present time called "Amlapitta, Parinama Shula and Annadrava Shula" The drug chosen for the present study is **Maha Shankha Vati** which is mostly used in the treatment of Agnimandhya, Ajirna, but it is used in the treatment of Amlapitta, Parinama Shula and Annadrava Shula is not very popular in spite of the fact. Hence the study is conducted with an

attempt to prove the practical implication as well as clinical efficacy of Maha Shankha Vati in Amlapitta, Parinama Shula and Annadrya Shula.

MATERIAL AND METHODS

Aims and Objective

- Comparative evaluation of Self Made Sample of Maha Sankha Vati and MARKET SAMPLE Maha Sankha Vati on Amlapitta, Parinam Shula and Annadray Shula.
- 2. To study aetiopathogenesis of Amlapitta, Parinam Shula, Annadrav Shula according to Ayurvedic Literature and its modern counter part.

Table 1: Contents of MAHA SHANKH VATI

101	JIC 21 CONTENTED OF IVITALITY CONTENTS	,
1	Shuddha sanskarita parada	75 gms
2	Shuddha Gandhaka	75 gms
3	Shankha bhasma	75 gms
4	Shuddha Vatsanabha	75 gms
5	Shuddha Hingu	75 gms
6	Cincha ksara	75 gms
7	Sunthi	75 gms
8	Maricha	75 gms
9	Pippali	75 gms
10	Saindhava lavana	75 gms
11	Samudra Lavana	75 gms
12	Vida Lavana	75 gms
13	Sauvachala Lavana	75 gms
14	Romak Lavana	75 gms

 Table 2: Showing drugs using for bhavana in Maha Shankha Vati

Bhavana	Part	Usable	Amout for 7 Bhavana in
dravya	used	form	all 3 samples
Chitraka	Root	Kwath	7.350 Lt
Apamarga	Plant	Kwath	7.350 Lt
Nimbu	Fruit	Swaras	7.350 Lt
			•

The therapeutic protocol in the present study includes 36 patients in 4 different groups, selected from OPD/ IPD of NIA Hospital, Jaipur. Using randomized single blind method of trial.

Exclusive Criteria

- 1. Acid peptic disorder associated with other systemic diseases like IHD, Severe HT and DM.
- 2. Extensive burn, intracranial lesion.
- 3. Drug intake like Aspirin, steroids, butazolidine, indomethacin.
- 4. Patients with age below 16 yrs and above 60 yrs.
- 5. Pregnant and lactating mother.

Inclusive Criteria

- 1. Classical Signs and Symptoms will be included.
- 2. Age: between 16 to 60 yrs.
- 3. Sex: both.

Diagnosis Criteria

Clinical sign and symptoms: For Amlapitta

- 1. Amlatikta Udgara
- 2. Aruchi
- 3. Avipak
- 4. Klama
- 5. Amla Utklesh
- 6. Urakantha Daha
- 7 Gauray

For Parinam Shula and Annadrav Shula

- 1. Shula(Epigastric pain during digestion in midline region
- 2. Shula(Epigastric pain after taking meal in right side of the midline region)
- 3. Chhardi (Nausea with or without vomiting)
- 4. Night Pain
- 5. Haematemesis or Malena

POSOLOGY

Table 47: Shows about posology of four group

Group	Drug Administered	Dose	Anupana	Time of administration	Duration of treatment
А	Self made Maha Sankha Vati in Amlapitta patient	500 mg	Milk	After meal twice a day	30 Days
В	Self made Maha Sankha Vati in Parinam Shula / Annadrav Shula	500 mg	Milk	After meal twice a day	30 Days
С	Market sample of Maha Sankha Vati in Amlapitta patient	500 mg	Milk	After meal twice a day	30 Days
D	Market sample of Maha Sankha Vati in Parinam Shula / Annadrav Shula	500 mg	Milk	After meal twice a day	30 Days

Follow up study

During the trial all patients were regularly analyzed and advise to attend O.P.D. after every 7 days till the end of the trial and notable changes were duly recorded.

Clinical assessment

Criteria for results assessment:

The total effect of the therapy was assessed considering the following criteria.

- 1. Marked Improvement: 76% to 100% relief in the signs and symptoms.
- 2. Moderate Improvement: 51% to 75% relief in the signs and symptoms.
- 3. Mild Improvement: 26:50% relief in the signs and symptoms.
- 4. Unchanged: Below 25% was considered as unchanged.

Statistical analysis

The information collected on the basis of observation were analysed by ANOVA (parametric wilcoxon signed rank test and non parametric kruskal wallis) to evaluate significances at different levels that is, at 0.05, 0.01, 0.001, and obtained results were interpreted as follows;

Insignificant: p>0.05
Significant: p<0.05
More significant: p<0.01
Highly significant: p<0.001
Scoring Pattern for Amlapitta

1) Amlatikta Udgara

- 0: No amlodgara at all
- 1: Sometimes during the day
- 2: Amlodgara of moderate severity but does not disturb the patients.
- 3: Severe amlodgara disturbing the patient.
- 4: Small amount of fluid regurgitating from patients mouth.

2) Aruchi:

- 0: Willing towards all Bhojya Padarth.
- 1: Unwilling towards some specific Ahara but less than normal.
- 2: Unwilling towards some specific Rasa i.e. Katu/ Amla/ Madhura food.
- 3: Unwilling for food but could take the meal.
- 4: Unwilling toward unliking foods but not to other. Sometime totally unwilling for meal.

3) Avipaka

- **0:** Proper digestion followed by Kshudha Prabodh.
- 1: Occasional episode of improper digestion.
- **2:** Improper digestion manifest as udargaurava and udgarabahulya and which subsides within hours.
- **3:** Improper digestion which manifest with symptomatology like udargaura and udgarabahulya which disturb the routine but relieves spontaneously.
- **4:** Frequent improper digestion which disturbs the routine of patients, and medication is required to relieve it.

4) Klama

- 0: No klama.
- 1: Occasionally feeling of lassitude without Shrama and remains for sometimes and vanishes.
- 2: Lassitude without Shrama daily for sometimes.
- 3: Lassitude without Shrama daily for long duration.
- 4: Always feels tired and have no enthusiasms.

5) Amla Utklesh

- **0:** No any symptoms.
- 1: Occasionally felling nausea with Amla salivation.
- **2:** Felling nausea with Presek and Sthivana.
- **3:** Felling nausea and occasionally vomiting.
- 4: Nausea with vomiting.

6) Urakantha Daha

0: No daha at all

- 1: Daha of mild degree in any of the area of Kantha, Hrit, Ura
- 2: Daha of moderate degree which subsides after taking milk, cold or antacids.
- **3**: Severe degree of Daha involving two or three places like Hrit:Kantha, Ura etc.
- 4: Severe degree of Daha which does not relieve by any means.

7) Gaurava

- 0: No heaviness
- 1: Occasionally feeling of heaviness.
- 2: Sometimes feeling of heaviness but not affecting activities of daily living.
- **3**: Daily feeling of heaviness over body, which leads to Akarmanyata.
- 4: Most part of the body for long duration.

Scoring pattern for parinam shula and annadrava shula

1) Shula (Epigastric pain during digestion) in midline region: Parinam Shula:

- **0**: No pain
- 1: Slight pain which does not need any medication
- 2: Pain of some degree which subsides after taking some cold, sweet, alkali food or antacids etc.
- **3**: Severe colicky, unbearable pain but relieves after digestion of food.
- 4: Severe unbearable pain which does not subsides by any measures

2) Shula (Epigastric pain after taking meal) in right side of the midline region): Annadrava Shula:

- 0: No pain
- 1: Slight pain which does not need any medication
- 2: Pain of some degree which subsides after vomiting.
- 3: Severe colicky, unbearable pain but relieves after vomiting of taken food.
- **4**: Severe unbearable pain which does not subsides by any measures.

3) Chhardi (Nausea with or without vomiting):

- **0**: No vomiting at all
- 1: Feels sense of nausea daily, but vomit comes occasionally, frequency is not more than 2 to 3 times per month.
- 2: Frequency of vomiting is much more and comes whenever Daha or pain is aggravated i.e. 2 to 3 times per week.
- **3**: Frequency of vomiting is 5: 6 times per week.
- **4**: Much frequent vomiting after taking large or small meals, even in the morning and evening without taking any meals.

4) Night Pain:

- 0: No night pain
- 1: Mild night abdominal pain, occasionally in weeks

- 2: Mild night abdominal pain, two to three times in a week
- 3: Severe but occasional night abdominal pain, disturbance in sleep because of night pain.
- 4: Frequently occurring severe night pain, total sleep disturbance.

5) Haematemesis or Malena:

- 1: No haematemesis or malena
- 2: Occasional in months haematemesis or malena
- 3: Occasional in weeks haematemesis or malena
- **4**: Frequently occurring haematemesis or malena to other. Sometime totally unwilling for meal.

3) Avipaka:

- **0:** Proper digestion followed by Kshudha Prabodh.
- 1: Occasional episode of improper digestion.
- **2:** Improper digestion manifest as udargaurava and udgarabahulya and which subsides within hours.
- **3:** Improper digestion which manifest with symptomatology like udargaura and udgarabahulya which disturb the routine but relieves spontaneously.
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- 1: Occasionally feeling of lassitude without Shrama and remains for sometimes and vanishes.
- 2: Lassitude without Shrama daily for sometimes.
- 3: Lassitude without Shrama daily for long duration.
- 4: Always feels tired and have no enthusiasms.

5) Amla Utklesh:

- **0:** No any symptoms.
- 1: Occasionally felling nausea with Amla salivation.
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- 3: Felling nausea and occasionally vomiting.
- 4: Nausea with vomiting.

6) Urakantha Daha:

- 0: No daha at all
- 1: Daha of mild degree in any of the area of Kantha, Hrit, Ura.
- 2: Daha of moderate degree which subsides after taking milk, cold or antacids.
- **3**: Severe degree of Daha involving two or three places like Hrit:Kantha, Ura etc.
- 4: Severe degree of Daha which does not relieve by any means.

7) Gaurava

- 0: No heaviness
- 1: Occasionally feeling of heaviness.
- 2: Sometimes feeling of heaviness but not affecting activities of daily living.
- **3**: Daily feeling of heaviness over body, which leads to Akarmanyata.
- 4: Most part of the body for long duration.

Presentation of data:

The data collected from various clinical trial was completed and subjected to stastical technique and presented under the following section: Results incorporates the EFFECT of therapy.

OBSERVATION AND RESULTS

Table 48: Showing Group wise distribution of patient registered for the study

0 1				
Group	Complete	Lama	Total	
Group A	10	00	10	
Group B	10	00	10	
Group C	08	02	10	
Group D	08	02	10	

L.A.M.A.: Left Against Medical Advice

Table 65: Shows, effects of the test drug of Group – A on various subjective symptoms

Cumantana	NI	Me	ean	Differ:ence	% of Relief	S.D.	S.E.	't'	Р
Symptoms	N	BT	AT	Diller.ence	ier.ence % or keller		3.E.		r
Amlatikta Udgara	10	2.10	0.20	1.90	90.48	0.57	0.18	10.58	< 0.01
Aruchi	10	1.20	0.40	0.80	66.67	0.63	0.20	4.00	< 0.01
Avipaka	10	1.10	0.40	0.70	63.64	0.67	0.21	3.28	< 0.01
Klama	10	1.00	0.50	0.50	50.00	0.53	0.17	3.00	< 0.01
Amla Utklesh	10	1.60	0.50	1.10	68.75	0.32	0.10	11.00	< 0.01
Urah kantha Daha	10	1.70	0.10	1.60	94.12	0.70	0.22	7.24	< 0.01
Gaurav	10	1.00	0.40	0.60	60.00	0.70	0.22	2.71	< 0.01

Above table shows that, the effect of drug of group A revails that, maximum relief on the basis of percentage of change after treatment was observed in the parameter of Urah Kanth Daha, that is 94.12%, in Amlatikta Udgara 90.48%, in Amla Utklesh 68.75%, in Aruchi 66.67%, in Avipaka 63.64% and in Gaurav 60.00% change was found. Percentage of change is statistically significant in all the symptoms in group A patients.

Table 66: Shows that, effects of the test drug of Group – B on various subjective symptoms

S	N	Me	ean	Difference	% of Poliof	C D	C.F.	(4)	P	
Symptoms	N	ВТ	AT	Differ:ence	% of Relief	S.D.	S.E.	't'	۲	
Shula (Epigastric pain):midline region	10	1.50	1.00	0.50	33.33	0.71	0.22	2.24	<0.01	
Shula(Epigastric pain):Rt. side of the midline	10	1.50	0.70	0.80	53.33	0.79	0.25	3.21	<0.01	
Chhardi (Vomiting)	10	1.40	1.00	0.40	28.57	1.07	0.34	1.18	<0.01	
Night Pain	10	0.60	0.40	0.20	33.33	0.42	0.13	1.50	<0.01	
Haematemesis or Malena	10	0.20	0.10	0.10	50.00	0.32	0.10	1.00	<0.01	

Table no. 66 shows that, the effect of drug of group B reveals that, maximum relief on the basis of percentage of change after treatment was observed in the parameter of Shula (Epigastric pain) in right side of the midline, that is 53.33%, in Haematemesis or Malena 50.00%, in Shula (Epigastric pain) in midline region 33.33%, in Night pain 33.33% and in Chhardi (Vomiting) 28.57% change was found. Percentage of change is statistically significant in all the symptoms in group B patients.

Table 67: Shows effects of the test drug of Group – C on various subjective symptoms

Cumptoms N		Mean		Differ:ence	% of Relief	S.D.	S.E.	4)	Р
Symptoms	N	ВТ	AT	Differ effice	% Of Relief	3.D.	3.E.		Р
Amlatikta Udgara	8	2.25	0.75	1.50	66.67	0.93	0.33	4.58	< 0.01
Aruchi	8	1.38	0.88	0.50	36.36	0.53	0.19	2.65	< 0.01
Avipaka	8	1.63	1.00	0.63	38.46	0.52	0.18	3.42	< 0.01
Klama	8	1.00	0.75	0.25	25.00	0.46	0.16	1.53	< 0.01
Amla Utklesh	8	1.00	0.50	0.50	50.00	0.53	0.19	2.65	< 0.01
Urah kantha Daha	8	1.50	0.25	1.25	83.33	0.46	0.16	7.64	< 0.01
Gaurav	8	1.25	0.75	0.50	40.00	0.53	0.19	2.65	< 0.01

Table 68: Shows effects of the test drug of Group – D on various subjective symptoms:

Symptoms	N	Mean		Differ:ence	% of Relief	S.D.	S.E.	't'	P
Symptoms	IN	ВТ	AT	Differ effice	% of Keller	3.D.	3.E.		P
Shula (Epigastric pain):midline region	8	1.25	0.75	0.50	40.00	0.53	0.19	2.65	<0.01
Shula(Epigastric pain):Rt. side of the midline	8	1.38	0.88	0.50	36.36	0.53	0.19	2.65	<0.01
Chhardi (Vomiting)	8	1.25	0.63	0.63	50.00	0.52	0.18	3.42	<0.01
Night Pain	8	0.38	0.25	0.13	33.33	0.35	0.13	1.00	<0.01
Haematemesis or Malena	8	0.38	0.13	0.25	66.67	0.71	0.25	1.00	< 0.01

 Table 70: Showing comparision of % of change in two groups of parinam shula and annadrava shula:

Sumntoms	% Of Change			
Symptoms	Group B	Group D		
Shula (Epigastric pain):midline region	33.33	40.00		
Shula(Epigastric pain):Rt. side of the midline	53.33	36.36		
Chhardi (Vomiting)	28.57	50.00		
Night Pain	33.33	33.33		
Haematemesis or Malena	50.00	66.67		

Table 71: Total effect of therapy in 36 patients (subjective Symptoms)

	1 / 1
Groups	Total effects (%)
Group A	70.45
Group B	39.71
Group C	48.54
Group D	45.27

DISCUSSION ON TOTAL EFFECT OF THERAPY

Among the four groups, combination of drug and disease in group A, proved to be best therapy. It was observed that, self made sample was found more effective in 'group A', compare to market sample, and market sample was found more effective in 'group D' compare to self made sample. Self made Maha Shankha Vati at the given dose was well tolerated in the patients of Kapha and Vataj Prakruti, but in case of Pittaj Prakruti, some patients complaining nausea; it may be because of extract of Nimbu Swarasa. In case of market sample patients complaining about tingling sensation in throat during chewing, it may be because of improper Shodhana of Vatsanabha, for the subsiding this side effect in the form of Godugdha was prescribed in present study.

Mode of action

In Ayurveda pharmacokinetics of drugs are depends upon Panchamahabhut Sanghatan, dealing with five aspects viz, Rasa, Guna, Virya, Vipaka and Prabhava. But in compound formulation, action depends upon Prabhava, were combination of drugs may either enhance (Prakrutisama Samvet / Synergism) or antagonize (Vikrutivisham Samvet), the response of individual components. Apart from these, drug action also depends upon incompatibilities between the constituents that is, Manavirudha (Quantititive antagonism), Gunavirudha (physicochemical antagonism) and Karmavirudha (physiological antagonism) as well as incompatibility in the constitutents itself, that is Samanya Pratyarabdha (Pharmacological action, according to Rasa due to similar physical components in Rasa and Dravya) and Vichitra Pratvarabdha (pharmacological action not in accordance to Rasa due to dissimilarity in physical components of Rasa and Dravya). In the present study drug used is herbo:mineral formulation having chief ingredients as Kajjali, due to which it acts as Yogvahi that means, potentiating the effect of various other drugs (which are added with kajjali) and Bhavana Dravya. Further it is administered with Kramana (Anupana) of Godugdha / Ushnodaka, which bring about quick action and increase the bioavailability of the formulation.



Considering the actions of drugs, due to their five properties, these are Rasa, Guna, Virya, Vipaka and Karma. It was observed that, this formulation posses Amla, Katu, Tikta as predominant Rasa. Laghu, Tikshana and Sukshama as predominant Guna and having Ushna Virya with Katu Vipaka.

Samprapti Vighatana

1. **Dosha:** Predomonant Dosha responsible for diseases are Pitta, Kapha (Kledak Kapha) and Saman Vayu. Main pathology occurs in the disease is Ama Nirmiti. It may be because of Agnimandhya (in the above pathogenesis Ushna Guna of Pitta decreases, which is useful in digestion and Amla and Drava Guna of Pitta increases). Further most of the drugs used in this formulation were Katu in Rasa and Ushana Virya, which can increases Ushna Guna of Pitta, enhancing digestion power, which control Ama Nirmiti. Kshara used in this preparation control Drava and Amla Guna of Pitta. Katu Rasa, Ushna Virya of Maha Shankha Vati also played role in the pacifying the elevated Vata and Kapha.

- Dushya: Most of the drugs in the Maha Sankha Vati are Agnidipaka these are, Trikatu, Panchalavana, Hingu, Shankha Bhasma, Nimbu, Apamarga and Chitraka having Dipana and Pachana Property, which may played a role in Amapachana of Rasa Dhatu by their action on Jatharagni.
- 3. Adhisthan and Strotas: Most of the drugs in the formulation are Rechana, Krumihara, Amanashana. Which are helpful in Strotashodhana and Amashaya Shodhana, by this way, they reduce inflammation as well as infection due to its purgative property.

CONCLUSION

Clinical study shows Pittasamana, Amanashaka and Amlatanashana properties of both self made and market samples in four different groups on Amlapitta, Parinama Shula andAnnadrava Shuala at varying levels with better results in group A. It was observed that, self made sample was found more effective in 'group A', compare to

market sample, and market sample was found more effective in 'group D' compare to self made sample.

SUGGESTIONS

For scientific validation of finding in the clinical study, objective parameters such as barium meal, endoscopy, LFT, KFT, calcium level in blood should also be included. For proper evaluation of efficacy of drug, clinical trial should be planed with large number of patients for greater duration, to conform the idea about Samprapti Vighatana

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