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A CONCEPTUAL STUDY ON AUSADHA SEVANA KALA (MADHYABHAKTA) W.S.R TO MANDAGNI BY USING HARITAKI-SUNTHI-SAINDHAVA CHURNA

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ABSTRACT

***Background** – The proper functioning of Agni depends on the functioning of Samana Vayu[1]as it has prime role in Pachana of Ahara. So, in order to correct Mandagni, Samana Vayu has to be corrected. With this point of view, drugs which are cost effective, easily available will be given in Madhyabhakta Kala[2]. For that reasonthe present study was designed and carried out to establish the justification and efficacy of the treatment principlethis topic had selected.*

***Aims**- The aim of study was to find out the effect of Ausadha sevana kala (Madhyabhakta) in Mandagni by using Haritaki-Sunthi-Saindhava Churna.*

***Material and methods**-This is a Open level randomasized control trial study. For this study patients of Mandagni were selected randomly from the O.P.D. and I.P.D. of the Govt. Ayurvedic College and Hospital, Balangir.*

***Observation and Results**- During the entire duration of therapy, there was not any adverse/untoward effect or adverse drug reactions observed for both the trial groups. Here, Group A showed better result in overall total parameters.*

***Conclusion**- The effect of the medicine, that is, Haritaki – Sunthi – Saindhava churna in Madhyabhakta kala is more significant in reducing the subjective and objective parameters and significant results found in Madhyabhakta kala.*

KEYWORDS- *Ausadha sevana kala, Madhyabhakta kala , Mandagni,Haritaki-Sunthi-Saindhava churna*

INTRODUCTION

In the present scenario, People are suffering from many diseases and the main cause behind the occurrence of disease is Mandagni, which is occurring due to People's faulty lifestyle. So, there is a need to study vividly on Mandagni is necessary.

Ausadha Sevana kala[3] is one such idea based on this principle. AstangaSangrahakara has stated that "Kalo AusadhaYogakrit" which means Kalo fulfills the aim of Administration of Ausadha.ThusAusadha given at appropriate kala is more efficacious than one given at in appropriate kalo. Hence implementation of Ausadhasevana Kala in each and every disease will be helpful to treat it in an appropriate way.

According to Sarangdhara, Ausadha administered in Madhyabhakata corrects Samana Vayu and also Mandagni[4].As per Madhyabhakta is concerned, administration of medicine in between the food is Madhyabhakta mentioned by Astanga Hrudaya[5.]

As Kala is a supreme factor and plays an important role in curative purpose, hence to get proper result in treatment "Ausadha Sevana Kala"[6] has to be followed.

AIM AND OBJECTIVES OF STUDY

- To study the concept of Ausadhasevana kala described by different Acharyas.
- To explain the relationship between Agni and Ausadhasevanakaala in the management of Mandagni.
- To find out the effectiveness and establishment of the MadhyabhaktaAusadhasevana kala in Mandagni from other Ausadhasevanakalas.
- To evaluate the efficacy of Haritaki-sunthi-saindhavachurna in the management of Mandagni.

MATERIALS AND METHODS

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Clinical Source
40 number of *Mandagni* patients were selected from OPD, IPD of Govt. Ayurvedic College & Hospital, Balangir and Saradeswari Govt. Ayurvedic Hospital, Balangir (Which comes under Govt. Ayurvedic College & Hospital, Balangir) and the health camps organised by Govt. Ayurvedic College & Hospital, Balangir.

Ethical Clearance
With due approval by IEC (Institutional Ethical Committee) with ref. no.– **1798/29.08.2022**, Govt. Ayurvedic College & Hospital, Balangir, the study has been conducted among the patients registered for the purpose. Written consent was obtained from each patient participate in the study with prior proper information.

Methodology - Randomized controlled Trial study (Open Label)

Grouping
40 no. of patients, satisfying the inclusion as well as exclusion criteria, were taken for the present study and all patients were divided into 2 equal groups i.e. Group A and Group B. And the assement was made before and after treatment.

Group A: - 20 patients were treated with Haritaki-Sunthi-Saindhava Churna at Madhyabhakta kala.
Group B: - 20 patients were treated Haritaki-Sunthi-Saindhava Churna at Pragbhakta kala.

A comparison was done among Group A and Group B before and after treatment.

DIAGNOSTIC CRITERIA
- The patients were diagnosed on the basis of both subjective and objective parameters.
- The subjective and objective parameters was examined through Trividha Pariksha.

INCLUSION CRITERIA
- Patient age between 20 to 50 years of either sex.
- Patient with the sign and symptoms of Mandagni was included.

EXCLUSION CRITERIA
- Patients below 20 years and above 50 years.
- Patients suffering from any other systemic chronic diseases.
- Madyapidita,Visa pidita, and Garbhini

ASSESSMENT CRITERIA
Assessment of the effect of therapy was done on the basis of various subjective and objective criteria. For the purpose of assessment, a detailed research proforma in corporating various parameters like Dashvidha parikhsa, Astavidha pariksha etc. were created. Patient were thoroughly assessed after every 15 days during the entire study period. Improvement in the signs and symptoms will be graded as 0, 1, 2, 3 grade for normal (0), mild (1), moderate (2), severe (3) accordingly.

CLINICAL ASSESSMENT
The average percentage improvement in the severity of different clinical sign and symptoms was calculated. The overall clinical assessment was done considering the sign and symptoms as follows-
- Marked improvement – Above 75% relief in sign and symptoms
- Moderate improvement – 51%- 75% relief in sign and symptoms
- Mild improvement – 26%-50% relief in sign and symptoms
- Unsatisfactory – 0-25% relief in sign and symptoms

SUBJECTIVE CRITERIA
- Aruchi
- Apakti
- Gatrasadana
- Udaragaurava
- Avhyavaharana Shakti
- Jaranashakti

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OBJECTIVE CRITERIA

- Mala Parikshya
- Lab investigation-Stool examination (RE&ME)

DRUGS SELECTION CRITERIA

Haritaki-Sunthi-Saindhava churna was taken for Mandagni on the basis of description mentioned in Bhaisajya Ratnavali for clinical trials.

The treatment modalities used in this study was Haritaki-Sunthi-Saindhava churna in Madhyabhakta kala in Group-A and this churna was taken in Pragbhakta kala in Group-B as trial drug.

The trial drugs were identified by the experts of Dept. of *Dravyaguna* which were approved by DRC and IEC of college and Sambalpur University.Medicine were prepared in the GMP certified Mini Pharmacy of College under the supervision of expert of Rasashastra and Bhaisajya Kalpana. The Sample of research trial were sent to Sambalpur University for their analytical study before the clinical trial.

DOSE AND ADMINISTRATION PROCEDURE

GROUP A (MADHYABHAKTA)

Dose – 6gm (Twice daily)
Anupana – Ushna jala (Luke warm water)
Method of application -Haritaki-Suthi-Saindhava churna was taken at Madhyabhakta kala

GROUP B (PRAGBHAKTA)

Dose – 6gm (Twice daily)
Anupana – Ushna jala (lukewarm water)
Method of application- Haritaki-Suthi-Saindhava churna was taken at Pragbhakta kala

DURATION OF STUDY - 30 days

FOLLOW UP

Follow up was done in every 15 days interval i.e. 15th and 30th day in the two groups. During the follow up both subjective and objective parameters of assessment was done to assess the result.

OBSERVATION AND RESULTS

In this study 42 numbers of patients were registered. 22 patients were registered for treatment of Haritaki-Sunthi-Saindhava churna (Madhyabhakta) in Group-A ,20 patients were registered for treatment of Haritaki-Sunthi-Saindhava churna (Pragbhakta) in Group-B. Out of these 2 patients were left the study.

The research work was conducted after scrutinized by DRC and IEC and approved by competent authority of Sambalpur university. During research work the data were observed time to time and assessment was recorded as authentic document for dissertation. The constitutional data related to ayurvedic and demographic data related to age, sex, educational qualification etc. were observed during clinical study and put forth here in table and graphical form for easy understanding and proper presentation.

Table No 01: Showing the Demographic data of all patients

Observations	Maximum	Category
Age	45%	31-40
Sex	52.50%	Male
Religion	100%	Hindu
Education	90%	Literate
Marrital status	72.50%	Married
Socio-economic	92.50	Middle class
Occupation	30%	Housewife
Mode of onset	100%	Gradual
Diet	85%	Mixed
Diet habit	57.50	Visamasana
Dominant Rasa	37.50	Madhura+amla

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Appetite	62.50%	Poor
Agni	100%	Mandagni
Ama	100%	Sama
Desha	100%	Jangala
VyayamaShakti	77.50%	OnlyRoutinework
Sleep	70.00%	Normal
Addictuion	55.00%	Tea
Urine habit	100%	Normal
Bowel habit	100%	Irregular
Prakriti	67.50%	kv

Table no.2 - Showing Effect of Madhyabhakta & Pragbhakta kala on Aruchi

Aruchi		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	2.50	3.00	0.61	0.14	-4.021^{c}	0.000058	96.00	Sig
	AT	0.10	0.00	0.31	0.07				
Group B	BT	2.40	2.00	0.60	0.13	-4.030^{c}	0.000056	79.17	Sig
	AT	0.50	0.00	0.61	0.14				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Table no. 3 - Showing Effect of Madhyabhakta & Pragbhakta kala on Apakti

Apakti		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	2.15	2.00	0.49	0.11	-4.128^{c}	0.000037	95.35	Sig
	AT	0.10	0.00	0.31	0.07				
Group B	BT	2.00	2.00	0.56	0.13	-4.041^{c}	0.000053	77.50	Sig
	AT	0.45	0.00	0.51	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Table no.4 - Showing Effect of Madhyabhakta & Pragbhakta kala on Udara Gaurava

Udara Gaurava		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.65	2.00	0.59	0.13	-3.963^{c}	0.000074	78.79	Sig
	AT	0.35	0.00	0.49	0.11				
Group B	BT	1.50	1.50	0.51	0.11	-3.624^{c}	0.000290	76.67	Sig
	AT	0.35	0.00	0.49	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Table no. 5- Showing Effect of Madhyabhakta & Pragbhakta kala on Gatra Sadana

Gatra Sadana		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.45	1.50	0.76	0.17	-3.624^{c}	0.000290	86.21	Sig
	AT	0.20	0.00	0.41	0.09				
Group B	BT	1.40	1.00	0.82	0.18	-3.827^{c}	0.000130	75.00	Sig
	AT	0.35	0.00	0.49	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Tableno.6-Showing Effect of Madhyabhakta &PragbhaktakalaonAvhyavaharanaShakti

Avhyavaharana Shakti		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.75	2.00	0.64	0.14	-3.946^{c}	0.000079	77.14	Sig
	AT	0.40	0.00	0.50	0.11				
Group B	BT	1.85	2.00	0.67	0.15	-3.601^{c}	0.000316	67.57	Sig
	AT	0.60	1.00	0.50	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

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Table no.7 - Showing Effect of Madhyabhakta & Pragbhakta kala on Jarana Shakti

Jarana Shakti		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.70	2.00	0.57	0.13	-3.817[c]	0.000135	85.29	Sig
	AT	0.25	0.00	0.44	0.10				
Group B	BT	1.70	2.00	0.57	0.13	-3.729[c]	0.000192	76.47	Sig
	AT	0.40	0.00	0.50	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Table no. - 8 Showing Effect of Madhyabhakta & Pragbhakta kala on Subjective criteria

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	P-Value
Aruchi	Group A	20	24.45	489.00	121.000	0.00171	Sig
	Group B	20	16.55	331.00			
	Total	40					
Apakti	Group A	20	24.83	496.50	113.500	0.00053	Sig
	Group B	20	16.18	323.50			
	Total	40					
Udara Gaurava	Group A	20	21.48	429.50	180.500	0.03558	Sig
	Group B	20	19.53	390.50			
	Total	40					
Gatra Sadana	Group A	20	22.23	444.50	165.500	0.03074	Sig
	Group B	20	18.78	375.50			
	Total	40					
Avhyavaharana Shakti	Group A	20	21.20	424.00	186.000	0.03679	Sig
	Group B	20	19.80	396.00			
	Total	40					
Jarana Shakti	Group A	20	21.43	428.50	181.500	0.03586	Sig
	Group B	20	19.58	391.50			
	Total	40					

Mann Whitney U Test is carried out for comparison between Group A and Group B. From above table, we can observe that, P-Value for almost parameters is less than 0.05. Hence, we can conclude that, there is significant difference between Group A and Group B.

Further, we can observe that mean rank for Group A is greater than Group B. Hence, we can conclude that, effect observed in Group A is better than Group B.

Table no. 9 - Showing distribution table of Daily Evacuation in patients

Daily Evacuation		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	0.60	1.00	0.60	0.13	-3.207[c]	0.001341	100.00	Sig
	AT	0.00	0.00	0.00	0.00				
Group B	BT	0.40	0.00	0.60	0.13	-2.530[c]	0.011412	100.00	Sig
	AT	0.00	0.00	0.00	0.00				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Table no.10 - Showing distribution table of Consistency of stool in patients

Consistency of stool		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.95	2.00	0.60	0.14	-4.017[c]	0.000059	89.74	Sig
	AT	0.20	0.00	0.41	0.09				
Group B	BT	1.80	2.00	0.62	0.14	-3.816[c]	0.000136	77.78	Sig
	AT	0.40	0.00	0.50	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

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Table no. 11 - Showing distribution table of Nature of Evacuation

Nature of evacuation		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.95	2.00	0.51	0.11	-3.987[c]	0.000067	82.05	Sig
	AT	0.35	0.00	0.49	0.11				
Group B	BT	1.85	2.00	0.49	0.11	-4.053[c]	0.000051	75.68	Sig
	AT	0.45	0.00	0.51	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Table no.12 - Showing distribution table of Jalanimajjana Prisha pariksha

Jalanimajjana Purisha Pariksha		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.85	2.00	0.37	0.08	-4.072[c]	0.000047	89.19	Sig
	AT	0.20	0.00	0.41	0.09				
Group B	BT	1.80	2.00	0.41	0.09	-4.041[c]	0.000053	80.56	Sig
	AT	0.35	0.00	0.49	0.11				

From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant

Table no.13 - Showing Effect of Madhyabhakta & Pragbhakta kala on Objective criteria

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	P-Value
Daily Evacuation	Group A	20	22.40	448.00	162.000	0.02414	Sig
	Group B	20	18.60	372.00			
	Total	40					
Consistency of stool	Group A	20	23.40	468.00	142.000	0.00854	Sig
	Group B	20	17.60	352.00			
	Total	40					
Nature of evacuation	Group A	20	22.70	454.00	156.000	0.01735	Sig
	Group B	20	18.30	366.00			
	Total	40					
jalanimajjana purisha pariksha	Group A	20	22.50	450.00	160.000	0.02094	Sig
	Group B	20	18.50	370.00			
	Total	40					

Mann Whitney U Test is carried out for comparison between Group A and Group B. From above table, we can observe that, P-Value for almost parameters is less than 0.05. Hence, we can conclude that, there is significant difference between Group A and Group B. Further, we can observe that mean rank for Group A is greater than Group B. Hence, we can conclude that, effect observed in Group A is better than Group B.

Table no.14 - Table No 04: Showing the Overall effect of treatment on Group A and Group B

Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	16	80.00%	11	55.00%
Moderate Improvement	2	10.00%	7	35.00%
Mild Improvement	2	10.00%	2	10.00%
No Improvement	0	0.00%	0	0.00%
TOTAL	20	100.00%	20	100.00%

It has been revealed that 2 patients i.e. 10% from Group – A & 2 patients i.e. 10% from Group – B were shown Mild improvement. 2 patients i.e. 10.00% from Group-A and 7 patients i.e. 35.00% from Group- B were shown Moderate improvement, 16 Patients i.e. 80.00% from Group -A and 11 Patients i.e. 55.00% from Group – B were shown marked improvement.

DISCUSSION

EFFECT OF THE DRUG ON SUBJECTIVES PARAMETERS

Aruchi

In the group A,the relief in Aruchi was 96.00% and Group B 79.17%.Thus better relief was obtained in Aruchi in the Group-A(Madhyabhakta).So,the results of Group-A are found significant in Mandagni. Medicine used in Madhyabhakta kala has Rochana

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property and Ushna veerya which gave better result as it acts over the samana vayu. Therefore Madhyanhakta kala probably helped in loss of taste and showing statistically significant result.

Apakti

In the Group-A Relief in Apakti was 95.35% which has highly significant and Group-B was 77.50%. From above table we can observe that, P-Value for Group A and Group B was less than 0.05. The patients taken medicine in Madhyabhakta kala found more results as the given medicine has Agnideepana property which pacify the Samana vayu.Therefore it probably helped in indigestion and showing significant result.

Udara Gourava

In the group-A relief in Udara gourava was 78.79% which is highlysignificant.It was because of regularisation of bowel due to ushna virya, vata anulomaka property of medicine applied in Madhyabhakta kala probably helped in Udara gourava which was statistically highly significant.

Gatrasadana

In the group-A relief in Gatrasadana was 86.21% which is highly significant.Katu rasa,Laghu guna, Ushna virya, Kaphavatahara Prabhava of Medicine taken in Madhyabhakta kala act over the symptom and probably helped to relief from Gatrasadana .

Avhyavaharana Shakti

Effect observed in Group A and Group B was significant. Group-A was more significant than Group-B. Avhyavaharana shakti was increased in Group A because of the effect of Madhyabhakta kala increased the samana vayu and pachaka pitta that pacified Mandagni significantly.

Jarana Shakti

Jarana Shakti was also significantly increased in Group A than Group B that shows that administration of medicines in Madhyabhakta kala increased digestive power by increasing pachakagni and normalising samana vayu with pacification of Ama.

EFFECT OF THE DRUG ON OBJECTIVES PARAMETERS

Daily Evacuation

Significant result found more in Group- A.The Effect of Madhyabhakta kala helped in the samana of Samanavayu so that it clears the channels . Due to Vata Anulomana property probably helped in daily evacuation which was significant.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Consistency of stool

Medicine given at Madhybhakta kala having Mala bhedana property,vata anulomana poperty ,ama pachaka property probably helped and found significant result.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Nature of evacuation

As the action of Madhyabhakta kala and the vata anulomaka, deepnapachana property probably helped in natural evacuation of mala.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. From above table we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Jalanimajjana purisha pariksha

Medicine given at Madhyabhakta kala helped in good digestion, metabolism and it also helped in eliminate Ama from the body. It probably helped in found significant result in Group-A patients.

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EFFECT OF MADHYABHAKTA IN MANDAGNI

- The consumed food initiates the process of digestion, which in turn activates samana vayu and pachak pitta. Samāna Vāyu augments the gastric fire. The functions of it are Grahaṇa (receives Anna), Pācana, Vivecana (Separation of chyme and faecal matters) and Muńcana (propelling). Thus saman vayu will act over the medicine taken and helps to give the expected result. Then again food is consumed, which covers the medicine and prevents the regurgitation of medicine.
- Madya bhakta aushadhi due to its quality of not spreading (avisari bhava), subsides the diseases of Madhya sharir, which means medicine administered during this kala acts on samana vata.
- Once this samana vata is corrected, agni or pachaka pitta starts working properly. The pachaka pitta nourishes all the other pitas. If pachak pitta is corrected all the other pittas will start functioning properly. After that with the help of Apāna Vāyu it eliminates the waste products of gastro intestinal digestion and by these indirectly enhances the Pācana Kriyā.
- The main function of koshtha is digestion and metabolism. Once the samana vata and pachaka pitta are starts functioning normally, the function of koshtha get corrected. Hence it is indicated in koshta gata vyadhis & Samana vayu dusti.
- So here in the present study medicine given in Madhyabhakta kala were working on the sign symptoms taken in Mandagni effectively.

DISCUSSION ON OVERALL EFFECT OF THERAPY

When the data analysed for overall result of therapy the following observations are made-

- Marked improvement was seen in 16 patients (80.00%) in Group A and 11 patients (55.00%) in Group B.
- Moderate improvement was seen in 2 patients (10.00%) in Group A and 7 patients (35.00%) in Group B.
- Mild improvement was seen in 2(10.00%) in Group A and 2(10.00%) improvement in group-B.

CONCLUSION

The main object of the study was to see the efficacy of the appropriate treatment viz. Dipana Pācana and management at the specific status of the diseases i.e. Jaţharāgnimāńdya, to get decide the role of Kāla in the efficacy of the treatment. Finally, it can be concluded that group -A (Madhyabhakta kala) found more effective than group B.

Forth coming researcher may pursue further study in this aspect in a large sample size over alonger period of longer duration. Finally it can be said that the formulation i.e Haritaki-Sunthi-Saindhava churna could be best tools for management of Mandagni and it also justify the concept of Ausadhasevana kala in Madhyabhakta kala in Mandagni. So, the research needs further studies with larger samples, increased duration of medicine could be more informative.

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