"Study of therapeutic effect of *Kushmand Khanda* in *Urdhwaga Amlapitta*: Randomize Clinical Trial"

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Abstract:
The prevalence rate of GERD in Indian people is around 7.6% and annual cases up to 10 million. Also the annual incidence rate of PUD was 0.10 to 0.19 % for physician diagnosed PUD and 0.03 - 0.17% when based on hospitalization data. Though the society is getting more advances but it's on the cost of many GI related Problems. Work full of stress, uneven eating habits, shift duties, quality and quantity of food, various bad habits-tobacco, alcohol etc are causing many serious health related issue. We can find Amlapitta is getting more common nowadays. As we take a dip into the Samhita we may not find much about Amlapitta in Bruhtrayi but laghutrayi has covered it in every aspect. Its a disease of *Annvaha srotasa*. **Aims & Objective**: To study the therapeutic effect of "KUSHMAND KHANDA" in the management of Urdhwagat Amlapitta

Methodology: Study is based on the Ayurvedic Samhita, modern literature, different articles and websites. **Result:** Overall Kushmand Khanda was found slightly better effective than *Avipattikar Choorna* in reducing the symptoms Amlapitta. **Discussion:** Changing lifestyle, eating habits, work stress, lack of sleep & bad habits are various factors which contribute to Amlapitta Vyadhi. Some Kostha and prakruti type is related with this vyadhi.

Keywords*: Kushmand Khanda, Avipattikar Choorna, Urdhwaga Amlapitta, Annvaha srotasa, PUD, GERD*

Introduction:
Rog literally means to hurt; most of diseases and its associated alliance get originated by imbalance between daily chaos. Prevention is the main factor explained in Ayurveda from the ancient time and then treating any disease. .

Rapidly changing lifestyle, shift wise duties, overtime, night jobs, multiple businesses for better earning, desire of having luxurious and sedentary life, bad food habits, fast food, consuming goods like tobacco, alcohol, smoking are having devastating effect on GI Track. Amlpaitta is majorly a lifestyle disorder but one can wonder why the Bruhattrayi has no direct access to such disease but it is not as it seems to be. Aacharya Kashyap is one of the ancient Aacharya who described Amlapitta as a separate entity. Charak has explained the sequential progression of disease of G.I.T. Also Aacharya *sushruta* quoted *Amla Guna* (sour) property of *Vidahi* (fermented pitta). *Charak* has given anxiety, grief, fear, anger, *dukh shayya prajagare* (improper sleep), manas bhava (disturbed mental status) etc as a causative factor leading in vitiation of Agni. Aacharya Kashyap describes etio-pathogenesis of Amlapitta and classified on the bases of Dosha status. Amlapitta can be correlated with APD. Again APD is a broad term which involves GERD, oesophagitis, gastritis, gastric ulcer, hiatus hernia, duodenal ulcer, H. pylori infection etc. Also the annual incidence rate of PUD was 0.10 to 0.19 % for physician diagnosed PUD and 0.03 - 0.17% when based on hospitalization data.

AIMS AND OBJECTIVE
Aims-(Primary Objectrive)

- To study the therapeutic effect of "KUSHMAND KHANDA" in the management of Urdhwagat Amlapitta

Objective: (Secondary objectives)

1. To review and study Modern and ayurvedic literature available on Urdhwaga amlapiita
2. To Assess the disease according to etiological factors

3. To observe the adverse effects if any

Preparation Of Drug

The KUSHMAND KHAND is described by many Aachrya but in current study the reference is taken from Bhaisjya Ratnavali Grantha and the content are as follows:

Drug	Latin name	Parts Used
Kushmand	*Benincasa hispida*	Fruit (juice)
Aamalki	*Emblica officinalis*	Fruit (powder)
Ghee	--	
Milk	---	
Sugar granules (*Khanda sharkara*)	---	granules

2. Avipattikar choorna describes by Bhaijya Ratnavali

Drug	Latin Name	Parts Used
Pipali	*Piper longum*	Fruit
Sunth	*Zingiber officinale*	Rhizome
Marich	*Piper nigrum*	Fruit
Aamalki	*Emblica officinalis*	Fruit
Haritaki	*Terminalia chebula*	Fruit
Vibhitaki	*Terminalia bellirica*	Fruit
Musta	*Cyperus rotundus*	Rhizome
Vidlawan	-	salt
Vidang	*Embelia ribes*	Fruit
Ela	*Elettaria cardamomum*	Seed
Patra	*Cinnamomum tamala*	Leaves
Lavang	*Syzygium*	Flower

	aromaticum	buds
Trivrut	*Operculina turpethum*	Root
Sharkara	-	granules

Method :

Kushmand khanda was prepared by using above mentioned ingredients according to texts and final product was in granules form. Also *Avipattikar choorna* was selected from GMP certified company . Pathya – Apathya, Ahar regimen was advised to patient along with treatment.

PHARMACEUTICAL STUDY:

Drug Manufacturing

1. Kushmanda khanda is the dry granule formulation.
2. First Kushamnd was cut into pieces and with the help of juicer –mixture the juice and pulp was obtained from kushmand.It is filtered through fine mesh sieve.
3. Now milk is boiled in another vessel and cooled little bit then equal proportion of kushmand swarasa and milk were added into another vessel.
4. Control Heat (Madhyam Agni) is given with help of Stove gas.
   With help of heat and continuous stirring mixture is reduced.
5. When the mixture is reduced to half and starts becoming on thicker side the sugar is added and the mixture is stir firmly and it is reduced further till you observe thicker mixture.
6. On same hand Aamalki churna and cow ghrut was taken and aamalki was lightly sauted into ghrut.
7. Now sauted aamalki churna is added to mixture and gas is reduced to Mandagni and it is continuously stirred.
8. When mixture starts to get thick and granular in nature and Further on proper stirring granules starts forming, at that moment the vessel is taken out mixture is cooled down and stored.
9. The drug is given in a dose of 10gms once in a day after food.

GROUPING & RANDOMIZATION OF PATIENT

The study was carried out in OPD/IPD of our hospital

- 60 patients of Amlapitta was randomly selected as per protocol. They were divided in two groups based on computer generated number
- Newly diagnosed& already diagnosed patients who fulfill the criteria mentioned by Granthas were selected
- Trial and control group comprises of 30 patients each

Group A (Trial Group)
Kushmand khanda
Dose: 10 gms after meal once in a day with milk or water
Follow ups: 0,7th, 15th ,21st ,30th ,45th with drug 60th and 90th day without drug
Group B (Control Group)
Avipattikar choorna:
Dose : 5gms after meal twice in day with water
Follow ups:
0,7th, 15th ,21st ,30th ,45th with drug
60th and 90th day without drug

OBSERVATION & CRITERIA FOR GRADATION OF DISEASE

Grade	Lakshan(symptoms)

1.Avipaka	
G_0	natural appetite for food after 5-6 hrs of ingestion of mixed Indian food
G_1	appetite for food after 7- 8 hrs of taking food
G_2	appetite for food after 9 – 10 hrs of taking food
G_3	appetite for food after 10 – 12 hrs of taking food
2. Klama	
G_0	no tiredness on routine physical work
G_1	feeling tiredness on routine physical work
G_2	feeling tiredness to do normal routine work
G_3	feeling of tiredness to do any work or no interest in work
3.Utklesha	
G_0	no sensation of vomiting
G_1	nausea 1 – 3 times a wk
G_2	nausea 4 – 7 times a wk
G_3	frequent feeling of nausea with or without food
4.Chardi	
G_0	no vomiting
G_1	Occasional
G_2	2-3 times a wk
G_3	every day
5.Tiktaamlodgara	
G_0	no regurgitation of gastric content in to the mouth
G_1	rare regurgitation of gastric content in to the mouth
G_2	often regurgitation of undigested food in to the mouth
G_3	frequent regurgitation of gastric content in to the mouth
6.Aruchi	

G_0	having good appetite
G_1	loss of appetite for breakfast and snacks
G_2	loss of appetite for breakfast, lunch , dinner
G_3	aversion of any food
7.Hrit-Kanthdah	
G_0	no pyrosis
G_1	pyrosis in empty stomach
G_2	pyrosis in empty stomach as well as after 3-4 hrs of taking meal
G_3	constant or frequent pyrosis
8. .Udarashoola	
G_0	no pain in the abdomen
G_1	mild pain in the abdomen of low intensity
G_2	moderate pain causing partial interruption in the work
G_3	severe pain complete interruption of work
9. Gaurav	
G_0	Absent
G_1	Occasional Symptom
G_2	Present after meal
G_3	Persistent throughout the day
10.Shirshool	
G_0	Absent
G_1	Occasional Symptom
G_2	Present after meal
G_3	Persistent throughout the day or on fasting

Objective : No such objectives

Statistical Analysis : In Group A and In Group B

Subjective parameters (By Wilcoxon Signed Ranks Test)

A) Avipaka

Group	Day	N	Mean	Median	W	P
Group A	BT	30	1.433	1	231	<0.0001

	AT	30	0.466	0		
Group B	**BT**	**30**	1.600	1	406	<0.0001
	AT	30	0.233	0		

B) Aruchi

Group	Day	N	Mean	Median	W	P
Group A	**BT**	**30**	1.067	1	171	<0.0001
	AT	**30**	0.366	0		
Group B	**BT**	**30**	1.400	1	325	<0.0001
	AT	**30**	0.333	0		

C) Klama

Group	Day	N	Mean	Median	W	P
Group A	**BT**	**30**	0.800	0.5	78	0.0005
	AT	**30**	0.200	0		
Group B	**BT**	**30**	1.300	1.5	253	<0.0001
	AT	**30**	0.266	0		

D) Gaurava

Group	Day	N	Mean	Median	W	P
Group A	**BT**	**30**	1.167	1	136	<0.0001
	AT	**30**	0.333	0		
Group B	**BT**	**30**	1.267	1	276	<0.0001
	AT	**30**	0.333	0		

E) Utklesha

Group	Day	N	Mean	Median	W	P
Group A	**BT**	**30**	1.267	1	300	<0.0001
	AT	**30**	0.133	0		
Group B	**BT**	**30**	1.033	1	190	<0.0001
	AT	**30**	0.366	0		

F) Chardi

Group	Day	N	Mean	Median	W	P
Group A	**BT**	**30**	0.800	1	176	<0.0001
	AT	**30**	0.066	0		
Group B	**BT**	**30**	0.866	1	190	<0.0001
	AT	**30**	0.166	0		

G) Tikta-amla udgar

Group	Day	N	Mean	Median	W	P
Group A	**BT**	**30**	2.333	2	465	<0.0001
	AT	**30**	0.233	0		
Group B	**BT**	**30**	1.967	2	406	<0.0001

	AT	30	0.433	0		

H) Hrit-kantha daha

Group	Day	N	Mean	Median	W	P
Group A	BT	30	2.300	2	465	<0.0001
	AT	30	0.466	0		
Group B	BT	30	2.000	2	406	<0.0001
	AT	30	0.600	0		

I) Shirashool

Group	Day	N	Mean	Median	W	P
Group A	BT	30	0.966	1	253	<0.0001
	AT	30	0.133	0		
Group B	BT	30	0.933	1	153	<0.0001
	AT	30	0.166	0		

J) Udarshool

Group	Day	N	Mean	Median	W	P
Group A	BT	30	0.666	0	78	0.0005
	AT	30	0.133	0		
Group B	BT	30			120	<0.0001
	AT	30				

Effect of therapy according to % Relief in Patients Symptoms

Pt. No.	Group A				Pt. No	Group B			
	BT	AT	Relief	%Relief		BT	AT	Relief	%Relief
1	16	0	16	100	1	14	5	9	64.3
2	17	2	15	88.2	2	13	1	12	92.3
3	18	2	16	88.9	3	19	3	16	84.2
4	7	1	6	85.7	4	7	2	5	71.4
5	15	3	12	80	5	11	1	10	90.9
6	18	4	14	77.8	6	18	6	12	66.7
7	12	2	10	83.3	7	12	3	9	75
8	20	3	17	85	8	15	2	13	86.7
9	21	3	18	85.7	9	13	2	11	84.6
10	7	1	6	85.7	10	15	4	11	73.3
11	10	1	9	90	11	17	3	14	82.4
12	13	2	11	84.6	12	9	1	8	88.9
13	9	1	8	88.9	13	17	5	12	70.6
14	8	2	6	75	14	15	3	12	80
15	21	4	17	81	15	13	4	9	69.2
16	9	1	8	88.9	16	13	2	11	84.6
17	9	1	8	88.9	17	15	3	12	80
18	17	7	10	58.8	18	16	4	12	75
19	10	6	4	40	19	12	2	10	83.3
20	12	2	10	83.3	20	16	4	12	75

21	7	0	7	100	21	13	4	9	69.2
22	16	7	9	56.3	22	12	3	9	75
23	16	2	14	87.5	23	17	5	12	70.6
24	15	2	13	86.7	24	13	3	10	76.9
25	9	1	8	88.9	25	13	3	10	76.9
26	16	5	11	68.8	26	4	2	2	50
27	7	2	5	71.4	27	10	3	7	70
28	8	2	6	75	28	8	2	6	75
29	10	4	6	60	29	9	3	6	66.7
30	8	3	5	62.5	30	13	2	11	84.6

Discussion:

Rapid change in eating pattern ,not following DIncharya regimen, fast food ,stress are throwing an individual into various diseases. Amlapitta Vyadhi is basically belongs to life style disorder which ultimately requires an individual to have command over his tongue and Indriyas. Spicy ,Vidahi ,Abhishyandi which may looks good on taste buds causes exacerbation of Amlapitta related condition. According to a quote mentioned by Aacharya if a vessel containing Curd is not washed properly and reused for keeping milk then it results into fermentation of milk.Like that if one keeps on taking continuous assault on his GI tract by consuming goods like abhishyandi ahar etc then Pathyakara ahar also turns into Shukta paka.

Ayurveda is the oldest science and its wisdom still stands strong as it was in earlier centuries. The concept of Nidan parivarjana stands still tall apart. One needs various shaman and shodhan therapies to tackle such disease. Also Kushmand khand is mentioned as a part of shaman therapy . The contents of Kushmand khanda are Madhura ,amla ,katu ,tikta ,kashya rasa with the property of Pittashaman,Vatpittaghna, vrushya, basti shudhikar,Amlapitaghna,daha shaman, ruchikar. Also it contains Laghu, ruksha ,Snigdha guna .With help of all these properties it helps to hamper the samprapti of Amlapitta. Also Nidan parivarjan and Langhan enlightens the Agni which is the core of any disease.

RESULTS :

The Treatment shows that both Drug are effective in managing the symptoms of Urdhwaga Amlapitta.The results of Kushmand Khanda is slightly on better side as compare to the Avipattikar Choorna.

CONCLUSION:

Urdhwaga Amlapitta is common illness in daily practice.Urdhwaga Amlapitta in present study was found in all age groups and equally incident in males and females.Service as occupation, Vata-Pitta prakruti; Mandaagni, Krura Koshtha, Tea addiction and mixed diet were found to be most culprit factor in Urdhwaga Amlapitta.Kushmand Khanda is significantly effective than AvipattikarChoorna in Urdhwaga Amalpiita to reduce Utklesha, Tikta-amla udgar and Hrit-kantha daha symptoms and Avipattikar Choorna is significantly effective than Kushmand Khanda in Urdhwaga Amalpiita to reduce Avipaka, Aruchi and Klama symptoms.

But overall effect of Kushmand Khanda was better than the Avipattikar Choorna. As it gave quick relief from the symptoms of Amlapitta.No single medication is complete thus addition of Aahara-vihar regimen according to Ayurveda is important in managing the disease. Therefore it is concluded that Kushmand khand might be useful in treating Amlapittta due to its quick onset.

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