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A randomized controlled clinical study of *Amrutprabha Gutika* in the management of *Kaphaja Kasa*

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ABSTRACT

Background: *Kaphaja Kasa* is one of the five types of *Kasa*, where *Kasa Vega* is associated with *Prabhuta-Snigda-Ghana-Kapha Nisteevana.* The aim of the study was to assess the efficacy of two Ayurvedic formulations, *Amrutprabha Gutika* which was unexplored *Aushadha Yoga* explained in *Yogachintamani*, *Gutikadhikara* and *Lavangadi Gutika* explained in *Vaidhyajivanam*, *Swasakasa Chikitsa* in the management of *Kaphaja Kasa.* **Materials and Methods:** 60 patients fulfilling the Diagnostic and Inclusion criteria were selected for a Single Blind Comparative study, they were randomly allocated into 2 equal groups A & B, Group A and Group B received *Amrutprabha Gutika* and *Lavangadi Gutika* respectively in the dosage of 500mg, one tablet, twice daily, after food with *Ushnodaka* (lukewarm water) for 30 days, Assessment was done at baseline i.e.; 0th day, 16th day, after treatment on 31st day and after follow up on 46th day. **Results:** While comparing both the drugs clinically, *Amrutprabha Gutika* and *Lavangadi Gutika* showed effective results in *Kaphaja Kasa.* On statistically comparison within the groups, both the groups showed significant effect in *Kasavega, Kapha Nisteevana, Aasyamadhuryata, Aruchi, Peenasa, Angagourava,* TC, DC, ESR, AEC in both the groups. **Conclusion:** On statistical comparison between the two groups there is neither significant difference between *Amrutprabha Gutika* nor *Amrutprabha Gutika* is better than *Lavangadi Gutika*.

Key words: *Amrutprabha Gutika, Lavangadi Gutika, Kaphaja Kasa*

INTRODUCTION

Kaphaja Kasa is one of the five types of *Kasa* mentioned in Ayurvedic Classics. It is a *Pranavaha Srotodusti*, where *Vata* and *Kapha* are the two key pathological factors involved in the *Samprapti* of *Kaphaja Kasa*.[1] The *Lakshanas* of *Kaphaja Kasa* are *Bahulam, Madhuram, Snigdha, Ghana Kapha Nisteeva-na, Mandagni, Aruchi, Chardi, Peenasa, Utklesha, Gourava, Lomaharsha, Aasyamadhuryata, Kleda.*[2] Based on *Lakshanas* of *Kaphaja Kasa*, it can be compared with Chronic Bronchitis.[3]

Chronic Bronchitis is a clinical condition characterized by productive cough due to excessive mucus secretion in the bronchial tree, not caused by local broncho-pulmonary disease, on most of the days, for at least 3 months of a year, for at least 2 consecutive years. [4] The estimated prevalence of chronic bronchitis is 5.0% in India.[5] Cough (*kasa*) is the most common sign of all respiratory illness. If neglected, it may lead to other illnesses like *Shwasa, Kshaya, Chardi* and *Swarabheda* etc.[6] Therefore, it should be treated carefully in the beginning. According to Ayurvedic literature, the treatment lines for *Snehana, Swedana, Shodhana, Dhoopana, Shamana,* and *Rasayana* are administered in the following order to create a holistic solution for *Kasa*. The *Shamana* treatment line includes oral medication administration, which is thought to be

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more convenient to administer than *Shodhana*. Numerous studies on the *Shamana* treatment, as recommended by Ayurveda, have been conducted, and their therapeutic value has been established. Many more herbal combinations are described in Ayurveda, and it is unknown how effective these combinations are as treatments for *Kasa.*

The medicines which have *Katu Rasa, Ushna Veerya, Kaphavatahara, Agni Deepana, Kapha Nissaraka* and *Vatanulomana* properties are effective in the management of *Kaphaja Kasa.*

Amrutprabha Gutika is mentioned in *Yogachintamani* under *Gutikadhikara.* The ingredients *are Akarkara, Saindhava, Chitraka, Shunti, Amalaki, Maricha, Haritaki, Lavanga, Matulunga Swarasa*.[7] Most of the ingredients are having *Katu Rasa, Ushna Veerya* and *Kapha- Vata Shamaka* properties. Depending upon its *Rasapanchaka* and other properties, this formulation is taken as a Trial drug.

Lavangadi Gutika is mentioned in *Vaidhyajivanam* in *Swasakasa Chikitsa*. The ingredients are *Lavanga, Maricha, Vibhitaki Twak, Khadira sara, Babula Kwatha.*[8] Most of the ingredients are having *Katu, Tikta Rasa* and *Ushna Veerya* and *Kapha-Vata Shamaka.* All the drugs in *Lavangadi Gutika* are having *Kasaghna* properties.[9] Considering its properties and previous research supporting its effectiveness on *Kaphaja kasa,* this has been taken as a Standard drug.

The present study was planned to evaluate and compare the efficacy of *Amrutprabha Gutika* and *Lavangadi Gutika* in the management of *Kaphaja Kasa.*

Aim of the Study

To explore the therapeutic effects of *Amrutprabha Gutika* in the management of *Kaphaja Kasa.*

Objectives of the Study

1. To evaluate the efficacy of *Amrutprabha Gutika* in the management of *Kaphaja Kasa.*
2. To compare the efficacy of *Amrutprabha Gutika* with *Lavangadi Gutika* in the management of *Kaphaja Kasa.*

Materials and Methods

Sample source:

A minimum of 60 patients attending the OPD and IPD of Alva's Ayurveda Medical college and Hospital, Moodubidire, Medical camps and other referrals diagnosed as *Kaphaja kasa* and fulfilling the inclusion criteria were selected. Data was collected on a detailed case proforma designed for the study.

- **Study design -** Parallel group comparative clinical study.
- **Blinding -** Single blind
- **Allocation -** Random allocation
- **Method of sampling -** Randomization Software
- **Groups -** 2 groups

Group A - *Amrutprabha Gutika*

Group B - *Lavangadi Gutika*

- **Sample size -** 30 patients in each group
- **Total sample size -** 60 patients

Diagnostic criteria

Patients were diagnosed based on *Kasa* (Cough) with *Sandra* and *Bahula Kapha Nishteevana* (Spitting of thick phlegm in large quantity) with or without following symptoms.

- *Aasyamadhuryata* (Mouth sweetness)
- *Aruchi* (Anorexia)
- *Peenasa* (Running nose)
- *Gourava* (Chest heaviness)
- *Utklesha* (Nausea)

Inclusion criteria

- Patients fulfilling the diagnostic criteria of *Kaphaja Kasa.*
- Patients having age between 16 to 70 years, inclusive of both ages.
- Patients willing to participate in the study and ready to sign informed consent form.

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Exclusion criteria

- Patients having Productive cough with complications like: Tuberculosis, Emphysema or Pneumonia etc.
- Patients with any other systemic and metabolic disorders which may interfere the study will be excluded.
- Patients suffering from Acute conditions (Acute Bronchitis, COVID19)
- Pregnant and Lactating women will be excluded.
- Patients undergoing steroid therapy.

Subjective parameters Primary

- *Kasa* (Cough)
- *Sandra-Bahula Kapha Nishteevana* (Spitting of thick phlegm in large quantity)

Secondary

- *Aasyamadhuryata* (Mouth sweetness)
- *Aruchi* (Anorexia)
- *Peenasa* (Running nose)
- *Angagourava* (Chest heaviness)
- *Utklesha* (Nausea)

Objective parameters

- TC
- DC
- ESR
- AEC

Intervention

The patients fulfilling the criteria for inclusion are randomly assigned into 2 groups.

Table 1: Intervention

Groups	Group A	Group B
Sample size	30 patients	30 patients
Study Drug	*Amrutprabha Gutika*	*Lavangadi Gutika*
Dose	500mg	500mg
Anupana	*Ushnodaka* (lukewarm water)	*Ushnodaka* (lukewarm water)
Time	Two times a day, after food	Two times a day, after food
Duration	30 days	30 days

Observation Period

The patients will be assessed clinically before treatment on 0th day and during treatment, on 16th day, after treatment on 31st day and on 46th day.

Follow Up

Follow up of the patient was done on 46th day, after the intervention period.

Investigations

Hb, TC, DC, ESR, AEC.

Chest X-ray to rule out other conditions.

Observations and Results

Table 2: Observation of 60 patients

Characteristics	Predominance	Percentage
Age	21-25 years	23.3%
Gender	Male	55%
Religion	Hindu	78.3%
Marital status	Married	55%
Occupation	Students	50%
Socioeconomic status	Middle	66.6%
Diet	Mixed	73.3%
Prakriti	*Vata-kapha*	58.3%
Satmya	*Madhyama*	73.3%
Satwa	*Madhyama*	78.3%
Abhyavarharana Shakti	*Avara*	55%

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Jarana Shakti	*Avara*	58.3%

Statistics

Statistical test applied

Descriptive Statistics was applied to each parameter first. Wilcoxon Signed Rank Test and Paired 't' Test was performed for analyzing the efficacy of medicines before and after trial within the group. Mann-Whitney Rank Sum Test and Unpaired 't' Test was performed for comparing both the groups. The summarized form of Statistical Analysis is presented below.

Table 3: Effectiveness of the medicine before and after the trial on Subjective Parameters

Assessment criteria	Group	Median score		WSRT value	p value	Remarks
		BT	AT			
Kasa vega	Group A	2	0	435	<0.001	SS
	Group B	2	0	435	<0.001	SS
Kpaha nisteevana	Group A	2	0	465	<0.001	SS
	Group B	2	0	465	<0.001	SS
Aasyamadhuryata	Group A	1	0	78	<0.001	SS
	Group B	1	0	105	<0.001	SS
Aruchi	Group A	1	0	231	<0.001	SS
	Group B	0.5	0	91	<0.001	SS
Peenasa	Group A	0.5	0	120	<0.001	SS
	Group B	1	0	105	<0.001	SS
Angagourava	Group A	1	0	21	0.031	SS
	Group B	1	0	36	0.008	SS
Utklesha	Group A	0	0	10	0.125	NS
	Group B	0	0	10	0.125	NS

Table 4: Effectiveness of the medicine before and after the trial on Objective Parameters

Criteria	Group	Mean Score		Mean Diff.	S.D. (±)		S.E.M. (±)		Paired 't' test	
		BT	AT		BT	AT	BT	AT	t value	p value
TC	Group A	8060	6483.3	1576.6	942.3	966.7	172	176.4	9.355	<0.001
	Group B	8486.6	6936.6	1550	949.3	305.2	173.3	305.2	6.382	<0.001
ESR	Group A	10.033	7.733	2.3	1.938	1.437	0.354	0.262	6.173	<0.001
	Group B	10.133	8.067	2.067	1.479	8.067	0.270	0.239	7.878	<0.001
AEC	Group A	204.167	192.700	11.467	59.657	58.834	10.892	10.742	9.985	<0.001
	Group B	189.767	178.533	11.233	62.540	60.627	11.418	11.069	9.912	<0.001
DC / N	Group A	56.4	55.567	0.833	1.404	1.135	0.256	0.207	4.475	<0.001
	Group B	56.633	55.467	1.166	1.474	1.167	0.269	0.213	5.722	<0.001

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DC	L	Group A	39.033	37.567	1.467	1.956	2.112	0.357	0.386	6.279	<0.001
		Group B	39.7	38.533	1.167	1.841	2.177	0.336	0.398	5.178	<0.001
	E	Group A	2.533	1.7	0.833	0.730	0.877	0.133	0.160	7.047	<0.001
		Group B	2.233	1.533	0.7	0.679	0.819	0.124	0.150	7.167	<0.001
	M	Group A	1.633	1	0.633	0.809	0.983	0.148	0.179	6.238	<0.001
		Group B	1.967	1.533	0.433	0.809	0.819	0.148	0.150	4.176	<0.001
	B	Group A	0	0	0	0	0	0	0	0	1.000
		Group B	0	0	0	0	0	0	0	0	1.000

Table 5: Comparative analysis of the overall effect of the treatments on Subjective Parameters

Assessment criteria	Median value BT-AT		Mann-Whitney Test		Remarks
	Group A	Group B	t value	p value	
Kasa Vega	2	2	975	0.377	NS
Kapha Nishteevana	2	2	919	0.953	NS
Aasyamadhuryata	0	0	900	0.830	NS
Aruchi	1	0	1020	0.122	NS
Peenasa	0.5	0	930	0.830	NS
Angagourava	0	0	960	0.509	NS
Utklesha	0	0	930	0.829	NS

Table 6: Comparative analysis of the overall effect of the treatments on Objective Parameters

Criteria		Group	Mean Score BT-AT	Mean Diff.	S.D. (±)	S.E.M (±)	Unpaired 't' Test		Remarks
							t value	P value	
TC		Group A	1576.667	290	923.144	168.542	1.2	0.235	NS
		Group B	1286.667		947.859	173.055			
ESR		Group A	2.3	0.233	1.601	0.292	0.594	0.555	NS
		Group B	2.067		1.437	0.262			
AEC		Group A	11.500	0.267	6.252	1.414	0.166	0.869	NS
		Group B	11.233		6.207	1.133			
DC	N	Group A	0.833	-0.333	1.020	0.186	-1.207	0.232	NS
		Group B	1.167		1.117	0.204			
	L	Group A	1.467	0.300	1.279	0.234	0.924	0.359	NS
		Group B	1.167		1.234	0.225			
	E	Group A	0.833	0.133	0.648	0.118	0.869	0.388	NS
		Group B	0.700		0.535	0.097			
DC	M	Group A	0.567	0.133	0.504	0.092	0.961	0.340	NS
		Group B	0.433		0.568	0.104			

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	B	Group A	0	0	0	0	0	1.000	NS
		Group B	0		0	0			

Effect of Therapy

60 patients of *Kaphaja Kasa* were randomly divided into two groups: Group A and Group B. The effect on Subjective and Objective parameters were analyzed here, percentage wise relief AT compared here respect to BT.

Table 7: Percentage wise relief in Subjective and Objective Parameters

Subjective Parameters	Group A (AT)	Group B (AT)
Kasa Vega	84.1%	81.6%
Kapha Nishteevana	90.4%	90%
Aasyamadhuryata	100%	100%
Aruchi	100%	80%
Peenasa	100%	100%
Angagourava	100%	100%
Utklesha	100%	100%
Objective Parameters	**Group A (AT)**	**Group B (AT)**
TC	19.5%	18.2%
DC	80.6%	62.7%
ESR	22.9%	20.3%
AEC	5.6%	5.9%

DISCUSSION

In the present study, the effect of *Amrutprabha Gutika* and *Lavangadi Gutika* on Primary outcomes *Kasa vega* and *Kapha Nishteevana* in Group A and Group B respectively were statistically significant from baseline (0^{th} day) values While comparing both the Groups statistically insignificant result at $p>0.05$ was found, indicating both treatments were effective. Other associated symptoms like *Asyamadhuryata*, *Aruchi, Peenasa*, *Angagourava* and *Utklesha* were present only in some study volunteers at baseline and showed improvement on receiving treatments in both the groups except *Utklesha*. In Objective parameters TC, AEC, ESR showed statistically significant result at $p<0.001$ in both the groups after treatment, but DC showed statistically significant result at $p<0.001$ in both the groups after treatment except Basophils ($p=1.000$). While comparing both the groups for all subjective and objective parameters showed $p>0.05$, indicates there is no statistically significant difference in the effects of treatment. Both the *Gutikas* used in this study are having *Kapha-Vata Hara* properties, *Laghu, Ruksha, Katu, Tikta Rasa Pradhana and Ushna Veerya.* which helps in *Samprapti Bhagana* of *Kaphaja Kasa.*

Probable mode of action of *Amrutprabha Gutika*

Amrutprabha Gutika contains *Katu Rasa, Ruksha, Tikshna Guna* and *Ushna Veerya Dravyas*. Also, have *Kasa hara* and *Kapha-Vata Hara* properties. Due to this *Kapha-Vata Hara Doshaghna* properties, *Kapha Vileyana* and *Chedana* properties of *Maricha* and *Saindhava* removes obstructed *Kapha* from *Pranavaha Srotas*. Also, *Vatanulomana Karma* of drug like *Haritaki* it clears the vitiated *Vata* and brings back the normal *Gati* of *Vata dosha.* Drugs like *Akarkara, Chitraka, Shunti, Maricha* and *Haritaki* have *Deepana* and *Pachana* properties. So, it does *Amapachana* and kindles *Agni. Amalaki*, *Maricha* and *Saindhava* are *Ruchya.* Thus, this formulation is effective in treating *Anubandha Lakshana Aruchi. Maricha* is directly indicated in *Peenasa*, addresses the *Anubandha Lakshana Peenasa. Shunti* contains Gingerol which helps in smooth muscle relaxation which helps in relieving the congestion.[10] Piperine has antitussive action, also both piperine[11] and eugenol[12] are anti-inflammatory in action. This reduces the inflammation and opens airway. Also, piperine and eugenol are expectorants which help in expulsion of mucus and anti-tussive action of piperine might have helped in

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suppressing the cough reflex. This combined with broncho-dilatory action and mucolytic-expectorant properties of the drugs mentioned above, might have helped in reducing the symptoms and suppressed the cough reflex. Thus, the combined action resulted in the improvement of main and associated symptoms in Group A.

Probable mode of action of *Lavangadi Gutika*

Lavangadi Gutika contains *Katu, Tikta, Kashaya Rasa Pradhana, Katu Vipaka* and *Ushna Veerya Dravyas*. So, this helps in *Kapha-Vata Shamana. Lavanaga* because of its *Katu Rasa* and *Tikshna Guna* have *Kapha Vilayana* property. *Vibhitaki* has *Bhedana* property that helps in the removal of excess *Kapha* from *Pranavaha Srotas*. *Vibhitaki* has bronchodialtory action also, so it relieves cough reflex.[13] *Lavanga, Maricha, Vibhitaki Twak* has *Deepana* and *Pachana* properties. So, they do *Amapachana* and improves *Agni*. *Maricha* because of its *Katu Rasa, Tikshna Guna. Usna Veerya* has *Kapha-Vata Hara* property. Due to its bronchodilator property *Maricha* is beneficial in cough and respiratory disorders. The eugenol content in *Lavanga* is responsible for its bronchodilator and expectorant action. This relieves the symptoms of productive cough reflex. All the drugs in the *Lavangadi Gutika* have *Kasagna* property. Thus, the combined action resulted in the improvement of main and associated symptoms in Group B.

Conclusion

In this study two *Gutika Yogas*; *Amrutprabha Gutika* and *Lavangadi Gutika* were considered, their individual therapeutic efficacy in *Kaphaja Kasa* were evaluated and comparison of their clinical efficacy was done. Clinically, both the *Gutikas* were effective in the treatment of *Kaphaja Kasa.* After treatment there was significant effect on all parameters except *Utklesha,* where statistically insignificant effect was seen within the groups. On comparison between two groups, it was found that there was no statistically significant difference, with $p>0.05$. Therefore, both the *Gutikas* are therapeutically effective in the treatment of *Kaphaja kasa* individually and on comparison there is no significant difference in their effects.

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