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## Clinical Evaluation of a Novel Formulation: *Banarasi Tambula (Piper Betle L.) Patra Swarasa* with *Bhimseni Karpura Choorna (Dryobalanops Aromatica Gaertn.F.)* in the Management of *Kaphaja Kasa (Productive Cough)*

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### ABSTRACT:

During high waves of SARS Covid-19 and post-covid period there is increase in respiratory tract diseases in population. It was noted that Ayurvedic management was having encouraging results with comparative cure rate higher and with lesser complications. '*Tambula Patra* (Betel leaf) along with *Bhimseni Karpura*' (Camphor) is one of the commonest combination drug of choice used especially in *Kapha* dominant *Kasa* by *Vruddha Vaidyas* from a long period of time. The preparation was named as "*NagaSphatika*" based on combination of basonym and synonym of components. It was made using *Banarasi Tambula* leaf's *Swarasa* with *Bhimseni Karpura* as a *Prakshepa* (additive) in liquid form dispensable medicine for *Kaphaja Kasa*. Single arm Clinical study was undertaken to evaluate its efficacy in *Kaphaja Kasa* in 52 patients. *NagaSphatika* was significantly effective in the management of *Kaphaja Kasa*. The disease involves *Kapha* and *Vata dosha dushti* predominantly. *Tambula* due to its *Katu, Tikta, Kashaya rasa, Ushna Virya, Katu Vipaka, Laghu, Ruksha, Tikshna* and *Vishada guna* pacifies *Kapha Dosha* leading to removal of *Avarodh* in the *Srotas* bringing *Prakruta gati* to *Vata Dosha* and also ignites *Agni* which further digests the *Ama* or *Dushta Rasa Dhatu*. *Bhimseni Karpura* having *Tikta, Katu Rasa, Madhura Rasa and Katu Vipaka, Laghu, Tikshna Guna* alleviates *Kapha Dosha* by its *Lekhan Karma* occurring in *Kantha* and *Urah*. *NagaSphatika* had significant effects on signs and symptoms of *Kaphaja Kasa*, hence is effective in its management.

**Keywords:** *Banarasi Tambula Patra, Bhimseni Karpura, Swarasa, Kaphaja Kasa*

### INTRODUCTION

During high waves of SARS Covid-19 and post-covid period there is increase in respiratory tract diseases in population. Most of the antibiotics and antiviral drugs were also failing in various clinical trials<sup>10</sup>. It was noted that Ayurvedic management was having encouraging results

with comparative recovery rate higher and with lesser complications. Complications were higher in patients treated with steroids. Major deadlier complications were Mucormycosis, Avascular necrosis of femur and sudden cardiac arrest in young generation were on rise. Ayurveda



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have shown good results with simple home remedies like turmeric and spices in prevention and treatment of such clinical conditions. Thus a combination was selected which is recommended to use daily through *Tambula sevana* which can act as preventive as well as treatment of respiratory tract.

In *Dinacharya* a specific practice called as *Tambula sevana* i.e. eating leaf of a creeper *Tambula / Betel (Piper betle L.)* with other specific drugs like camphor, betel nut, etc. is recommended to maintain the health of a person.<sup>1</sup> This *Tambula Sevana* can also be used in the management of diseases of *Pranvaha Srotas* such as *Kasa* (Bronchitis), *Shwasa* (Bronchial Asthma), *Rajayakshma* (Pulmonary Tuberculosis), etc. *Karpura* is *Katu* (Pungent), *Tikta* (Bitter), *Madhura* (Sweet) in *Rasa* (taste), *Katu Vipaki*, *Shita Virya*, *Laghu in Guna*, *Lekhana*, beneficial for eyes, *Vrushya* (Aphrodisiac), alleviates *Kapha*, *Pitta* and *Visha* (Poison) and can be used in burning sensation, excessive thirst, *Aasya vairasya* (Perception of abnormal taste), *Dushta Meda* and bad odour.<sup>2</sup> *Karpura* reduces feeling of suffocation in *Kasa*, *Kapha* is expelled out in the form of expectoration which increases strength of heart.<sup>3</sup> *Tambula* is *Katu* (Pungent), *Tikta* (Bitter), *Kashaya* (Astringent) in *Rasa* (taste), *Ushna Virya*, *Katu Vipaki*, *Laghu*, *Tikshana*, *Vishada*, *Ruchikarak* (increases appetite), *Vashya*, *Kshara*, increases *Rakta* and *Pitta*, *Balya* (giving strength); alleviates *Kapha*, *Vata*, bad odour of mouth, all bodily excretions and fatigue.<sup>4</sup>

According to Ayurveda, *Kha-Vaigunya* is the reason for recurrence of *Kaphaja Kasa*. And almost 70-80% people in a society were having mild to moderate to severe episodes of covid. So it can be considered that many the sufferers are having *Kha-vaigunya*<sup>12, 13</sup>. If control over *Kasa Vyadhi* is not achieved in time it can give rise to life threatening diseases like *Shwasa* (Bronchial Asthma), *Kshaya* (Pulmonary Tuberculosis), *Chardi* (Vomitting), *Swarasada* (Hoarseness of voice) etc.<sup>5</sup> To overcome this more specific management protocols and ayurvedic drugs which breaks the etiopathology (*Samprapti Bhanga*) and which treats the disease from the root level itself should be taken into consideration. This combination of *Tambula Patra* and *Bhimseni Karpoor* becomes a drug of choice in such conditions which may bring not only symptomatic relief to the patient but also will uproot the cause of the disease. This combination of drug for oral route administration has been converted into easily dispensable dosage liquid from where *Swarasa* derived was mixed with powdered Camphor (*Bhimseni* variety) as *Prakshepa Dravya* and named as “*NagSphatika*”. ‘*Nagvalli*’ is name

for betel leaf<sup>4</sup> and ‘*Sphatika*’ a synonym given to camphor<sup>6</sup> for its crystalline nature.

## MATERIALS & METHODS

### Pharmaceutical Phase:

Raw drugs were standardized at Agharkar research Institute, Pune. *NagaSphatika* was prepared by researcher’s effort and help at GMP certified Pharmacy – ‘*Rasamruta*’ affiliated to Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune.

### Table No. 1: Proportion of Contents in the Preparation of *NagaSphatika*

So each 200 ml bottle of *NagaSphatika* contains 3.2 gm of *Bhimseni Karpura*.

*Swarasa* of *Tambula (Piper betle L.) Patra* was prepared according to standard preparation method according to *Sharangadhara Samhita*<sup>11</sup>. The uninjured, freshly cut leaves of *Banarasi* variant of betel vine were finely minced in Multi Mill Machine and the collected juice was filtered through a clean cloth. For preparing *Swarasa*, *Banarsi* sub-species of *Tambula (Piper betle L.) patra* which is *Purana* i.e. plucked and kept for a period of time was used as it is of superior quality mentioned in *Bhavprakash Nighantu*.<sup>7</sup> This *Banarasi* variety was used as it possesses the best anti-bacterial and anti-oxidant properties in comparison with other sub-species available in India.<sup>8</sup>

The above mentioned proportion was calculated based on method of dispensing fresh single leaf with pinch of *Bhimseni Karpura* by measuring weight of 100 leaves and calculating amount of *Swarasa* obtained thereby and average of *Swarasa* in single leaf was considered to decide dose. *Bhimseni Karpura* 80 mg was added in a proportion of approximately 1.6% of *Swarasa* measuring amount of *Karpura* as one pinch by electronic balance (.001gm sensitive).

### Clinical Phase:

Type of Study Design: Single arm open label clinical study

**Registration:** The clinical trial was registered in the Clinical Trials Registry – India (CTRI) – No. CTRI/2021/08/035881

Approval from the ethical clearance committee was obtained (Ref. No. – MAM/SSAYU/122-44)

**Place of Work:** The patients were selected from out-patient departments of Kayachikitsa (Medicine) and Kaumarbhutyaya (Pediatrics) of Sane Guruji Arogya Kendra, hospital attached to SSAM, Hadapsar, Pune.

Calculated sample of 52 patients were selected according to inclusion and exclusion criteria and enrolled excluding

drop outs which were 5 in numbers, (patients who did not turned up for 1st follow up).

Written Consent and/or assent from enrolled patient wherever applicable was taken from each patient before the trial.

**Inclusion Criteria:**

1. Patient of age group 6 to 40 years irrespective of sex, religion and socio-economic status.
2. Patient with signs and symptoms of *Kaphaja Kasa* (According to Ayurvedic classics/texts).
3. All patients were selected irrespective of *Prakruti* and season.

**Exclusion Criteria:**

- 1) K/C/O acute clinical conditions in Cardiac Disease, Renal Failure, CVA, Pneumonia, etc. were excluded.
- 2) K/C/O chronic diseases like Asthma, Tuberculosis, Bronchiectasis, CA Lungs, HIV, etc were excluded.
- 3) Pregnant women and Lactating mother.
- 4) Patients contraindicated for *Tambula Sevana* such as *Raktapitta*, *Trushna* (excessive thirst), *Murccha* (unconsciousness), eye diseases such as *Abhishyanda* (conjunctivitis), Poisoning, and patients with conditions like chronic alcoholics, *Kshat*, *Kshina* (Pulmonary Tuberculosis), *Ruksha* (excessive body dryness), *Durbala* (weak) and *Mukhashosha* (dryness of mouth).

**Assessment Criteria:**

**Subjective:**

1. *Aruchi* (Loss of taste) – Present / Absent
2. *Kanthe Kandu* (Irritation in throat) – Present / Absent
3. *Pinasa* (Coryza) – Present / Absent
4. *Utklesha* (Excitement) – Present / Absent
5. *Gaurava* (Heaviness) – Present / Absent
6. *Lomaharsha* (Horripilation) – Present / Absent
7. *Aasya Madhurya* (Sweetness in mouth) – Present / Absent
8. *Sansadana* (Asthenia) – Present / Absent
9. *Vaksha Sampurnata* (Fullness of chest) – Present / Absent

Table No. 2: Subjective Parameters of Assessment Criteria

Table No.3: Plan of treatment

Assessment was done on 0<sup>th</sup>, 7<sup>th</sup> and 15<sup>th</sup> day (post-test group)

**OBSERVATIONS & RESULTS**

We had used McNemar’s test and Wilcoxon signed rank test as a statistical too to test the efficacy.

Table No. 4: Follow-up wise effect of *NagaSphatika* in the management of *Kaphaja Kasa*

Graph No.1: Follow-up wise effect of *NagaSphatika* in the management of *Kaphaja Kasa* - There has been no untoward effect found during or after the treatment.

Table No.5: Overall effect of *NagaSphatika* on *Kaphaja Kasa*

Graph No. 2: Overall effect of *NagaSphatika* on *Kaphaja Kasa*

**DISCUSSION**

As mentioned in *Ashtang Sangraha*, *Kasa Vyadhi* occurs due to *Vata Prakopa* leading to *Pratiloma gati* of *Apana Vayu* i.e. it goes in upward direction which gives more *gati* to *Udana Vayu* which normally goes in upward direction. Thus this aggravated *Udana vayu* along with *Prana Vayu* enters lungs, trachea and throat and this vitiated *Prana Vayu* comes out from the mouth making a specific shrill sound like a broken bronze vessel.<sup>9</sup> Along with this *Kapha Prakopa* is also a main factor which leads to *Srotorodha* (obstruction in bodily channels) and *Rasavaha srotas Dushti* which leads to *pratiloma gati* of *Apana Vayu* and *Prana Vayu*. Also *Urah* (thorax), *Kantha* (throat) and *Aamashaya* (stomach) are the main *Sthana* of *Kapha Dosha*. So in *Kaphaja Kasa* a *Dravya* which will suppress both *Vata* and *Kapha Dosha* is of utmost importance in its management. Thus *Tambula* and *Bhimseni Karpura* were selected in this study where both alleviate *Vata* and *Kapha Dosha* and are specifically useful in *Kasa vyadhi*. *Tambula* by its *Sara Guna* enables downward movement of this *Apana Vayu* and by its *Ushna Guna* which is opposite of *Shita* alleviates *Vata*. *Tambula* due to its *Katu* (pungent), *Tikta* (bitter), *Kashaya* (astringent) *rasa* (taste), *Ushna Virya*, *Katu Vipaka*, *Laghu*, *Ruksha*, *Tikshna* and *Vishada guna* pacifies this *Kapha Dosha* leading to removal of *avarodh* in the *Srotas* bringing *Prakruta gati* to *Vata Dosha* and also ignites *Agni* which further digests the *Ama* (toxic material in body) or *Dushta Rasa Dhatu*. *Bhimseni Karpura* by its *Madhura* (Sweet) *AnuRasa* (aftertaste) alleviates *Vata Dosha*. *Bhimseni Karpura* having *Tikta* (bitter), *Katu* (pungent) *Rasa* (taste), *Katu Vipaka*, *laghu*, *tikshna guna* and *lekhana karma* alleviates *Kapha Dosha* by this *lekhana karma* occurring in *Kantha* (throat) and *Urah* (lungs). It also reduces feeling of suffocation and *Kapha* is expelled out in the form of expectoration which increases strength of heart. Thus this *Amayika Yoga* of *Tambula Patra swarasa* with *Bhimseni Karpura* as *Prakshepa* helps in breaking the *Samprapti* of *Kaphaja Kasa*.

## CONCLUSION

*NagaSphatika (Tambula Patra Swarasa with Bhimseni Karpura)* had significant effect on subjective parameters of *Kaphaja Kasa*. These are *Kasa Vega, Sthivan, Chardi Vega, Mandagni, Aruchi, Kanthe Kandu, Pinasa, Utklesha, Gaurava, Lomaharsha, Aasya Madhurya, Sansadana, Shirah Shula* and *Vaksha Sampurnata*. Hence *NagaSphatika (Tambula Patra Swarasa with Bhimseni Karpura)* is effective in the management of *Kaphaja Kasa*. There has been no untoward effect found during or after the treatment. The therapy was well tolerated.

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**Table No. 1: Proportion of Contents in the Preparation of *NagaSphatika***

Drug Contents	Proportion
1. <i>Tambula Patra Swaras</i>	1 Part
2. <i>Bhimseni Karpura</i>	1.6% of <i>Swarasa</i>
3. Potassium sorbate	0.16% of <i>Swarasa</i>

**Table No. 2: Subjective Parameters of Assessment Criteria**

Sr. No.	Symptoms	Criteria	Grade
1.	<i>Kasa Vega</i> (Cough Attack)	No <i>Kasa Vega</i> / normal	0
		<i>Kasa Vega</i> 2-4 bouts in a day	1
		<i>Kasa Vega</i> 5-7 bouts in a day	2
		<i>Kasa Vega</i> recurrent times in a day	3
2	<i>Sthivan</i> (Consistency of expectorated sputum)	<i>Sthivan</i> watery in consistency	0
		<i>Alpa Ghana</i> and <i>alpa Picchila</i>	1
		<i>Madhyam Ghana</i> and <i>Madhyam Picchila</i>	2
		Expectorated <i>Kapha</i> – totally <i>Ghana</i> and <i>Picchila</i>	3
3.	<i>Sthivan</i> (Quantity of expectorated sputum)	No quantity of cough in expectoration	0
		After lot of coughing – slight cough was expectorated	1
		After each attack of cough slight <i>kapha</i> was expectorated	2
		After each attack of cough, expectorated <i>kapha</i> is in excess	3
4.	<i>Chhardi Vega</i> (Episodes of Vomitting)	No feeling of <i>Chhardi</i>	0
		<i>Chhardi</i> 1 – 3 times in a day	1
		<i>Chhardi</i> 3 – 5 times in a day	2
		<i>Chhardi</i> more than 5 times in a day	3
5.	<i>Mandagni</i> (Loss of appetite)	No loss of appetite	0
		Mild loss of appetite	1
		Moderate loss of appetite	2
		Severe loss of appetite	3
6.	<i>Shirahshool</i> (Headache)	No severity of pain while coughing	0
		Slight headache	1
		Headache but bearable to patient and do not disturb sleep	2
		Piercing pain in Head and does not allow sleep	3

**Table No.3: Plan of treatment**

<i>Tambula Patra Swarasa with Bhimseni Karpura as a Prakshepa Dravya</i>	
No. of Patients	52
Time of Medication	Thrice a day
<i>Kala</i>	After breakfast and meals ( <i>Vyanodana</i> )
Dose	Age group: 6 – 12 year : 2.5 – 5 mL 13 – 40 year : 5 – 7.5 mL
Route of administration	Oral
Duration	15 days

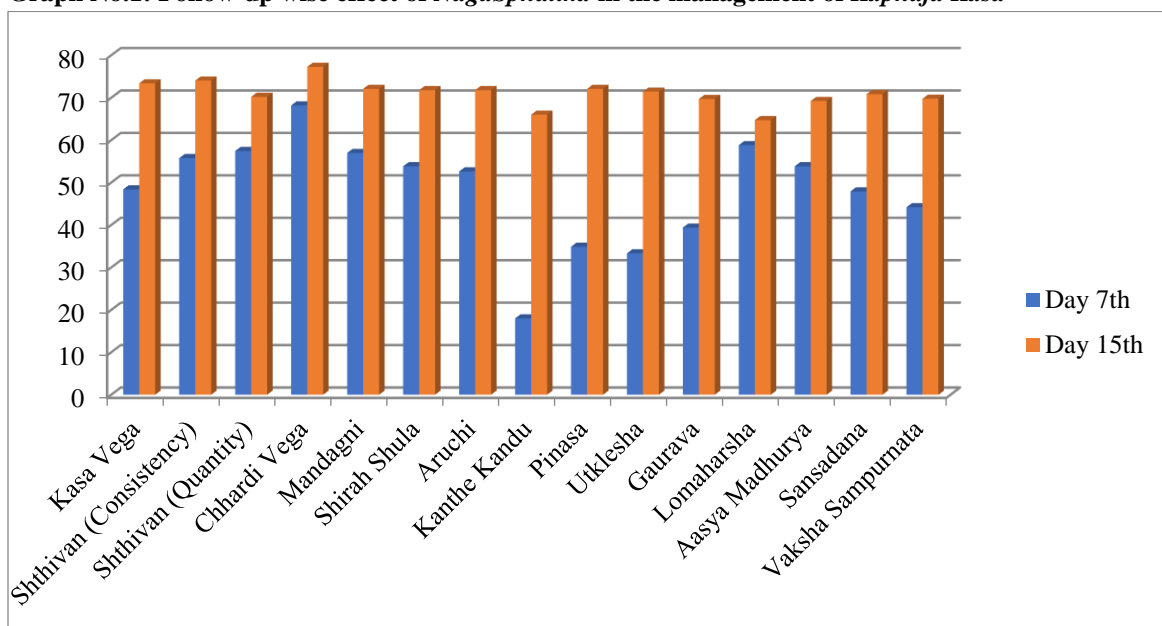
**Table No. 4: Follow-up wise effect of *NagaSphatika* in the management of *Kaphaja Kasa***

Symptoms	Relief (In Percentage)			Result
	Day 1 <sup>st</sup>	Day 7 <sup>th</sup>	Day 15 <sup>th</sup>	
<i>Kasa Vega</i>	-	48.39	73.39	Significant
<i>Sthivan (Consistency)</i>	-	55.77	74.04	Significant
<i>Sthivan (Quantity)</i>	-	57.45	70.21	Significant
<i>Chhardi Vega</i>	-	68.18	77.27	Significant
<i>Mandagni</i>	-	56.98	72.09	Significant
<i>Shirah Shula</i>	-	53.85	71.79	Significant
<i>Aruchi</i>	-	52.63	71.79	Significant
<i>Kanthe Kandua</i>	-	18.00	66.00	Significant
<i>Pinasa</i>	-	34.88	72.09	Significant
<i>Utklesha</i>	-	33.33	71.43	Significant
<i>Gaurava</i>	-	39.39	69.70	Significant
<i>Lomaharsha</i>	-	58.82	64.71	Significant
<i>Aasya Madhurya</i>	-	53.85	69.23	Significant
<i>Sansadana</i>	-	47.92	70.83	Significant
<i>Vaksha Sampurnata</i>	-	44.19	69.77	Significant

**Table No.5: Overall effect of *NagaSphatika* on *Kaphaja Kasa***

Overall Effect	Frequency	Percentage
Marked Improvement	25	48.08%
Moderate Improvement	19	36.54%
Mild Improvement	6	11.54%
No Change	2	3.85%
TOTAL	52	100.00%

**Graph No.1: Follow-up wise effect of *NagaSphatika* in the management of *Kaphaja Kasa***



**Graph No. 2: Overall effect of *NagaSphatika* on *Kaphaja Kasa***

