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A RANDOMIZED CLINICAL STUDY TO EVALUATE AND COMPARE THE EFFICACY OF TWAGELADI CHURNA AND BRUHATSHARKARASAMA CHURNA IN KAPHAJA KASA

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ABSTRACT

Background and Objectives: *Kaphaja Kasa* is one among *panchakasa,* where *kasavega* is associated with *prabhuta-snigda-ghana kapha nishteevana*. *Kasa*, if untreated or mismanaged may lead to disorders like *kshaya, shwasa* etc which are difficult to manage. Based on *nidana, samprapti* and *lakshana, Kaphaja Kasa* can be correlated with chronic bronchitis. The medic-83ines which have *katu rasa, ushnavirya, kapha-vatahara* properties are effective in the management of *Kaphaja Kasa*. **Materials and Methods:** In this clinical trial, 60 patients fulfilling the diagnostic and inclusion criteria were selected and were randomly assigned into two groups; group A (*Twageladi churna*) and group B (*Bruhatsharkarasama churna*). **Results:** The effect of treatment was statistically significant in both the groups. When statistical comparison was done between the two groups, no significant difference was found. **Conclusion:** Both the *Churna yogas* are therapeutically effective in the treatment of *Kaphaja kasa* individually and on comparison there is no significant difference in their effects. H_{03} is accepted.

KEYWORDS: *Kaphaja kasa, Twageladi churna, Bruhatsharkarasama churna.*

INTRODUCTION

Respiratory diseases are an enormous challenge to life, health and productive human activity. Lungs are more vulnerable to infection because of its constant exposure to dust particles,

chemicals and infectious organisms in ambient air.[1] Cough is the most frequent symptom of respiratory disease.[2] 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 atleast 3 months of the year, for atleast 2 consecutive years.[3] According to estimates from national interviews taken by the National Center for Health Statistics, approximately 9.5 million people or 4% of the population were diagnosed with Chronic Bronchitis.[4]

Kaphaja Kasa is one among *panchakasa,* where *kasavega* is associated with *prabhuta, snigda, ghanakapha nishtivana*. *Kasa,* if untreated or mismanaged may lead to disorders like *kshaya, shwasa* etc which are difficult to manage. Based on *nidana, samprapti* and *lakshana, Kaphaja Kasa* can be correlated with chronic bronchitis.[5] This study was planned to evaluate and compare the efficacy of *Twageladi churna* with *Bruhatsharkarasama churna* in *Kaphaja Kasa.*

MATERIALS AND METHODS

Objectives of the study

1. To evaluate the individual therapeutic effect of *Twageladi churna* in the treatment of *Kaphaja Kasa*.
2. To evaluate the individual therapeutic effect of *Bruhatsharkarasama churna* in the treatment of *Kaphaja Kasa.*
3. To compare the therapeutic effects of *Twageladi churna with Bruhatsharkarasama churna* in the treatment of *Kaphaja Kasa*.

Source of data

a. Literary source: All Ayurvedic, Modern Medical literatures, Contemporary texts including Journals and Websites about the disease and Medicine were reviewed and documented for the planned study.

b. Drug source: Raw drugs required were identified and collected from the source of availability and the medicines were prepared according to the classical references at Alva's Pharmacy, Mijar.

c. Sample source: Patients diagnosed with *Kaphaja Kasa* were randomly selected and allocated into 2 groups from;

- Kayachikitsa Out-Patient Department and In-Patient Department of Alva's Ayurveda Medical College and Hospital, Moodbidri.

- Medical camps and other referrals.

Method of collection of data

a. Sample Size and Grouping: 60 patients were randomly divided into 2 groups; A and B comprising minimum of 30 patients in each group.

Study design: Parallel group comparative clinical study

Blinding: Single blind

Method of Sampling: Lottery method

b. Plan of study

Group a	**Group b**
Twageladi churna	*Bruhatsharkarasama churna*
Dose: 12g/day (2g, 6 times a day)	Dose: 12g/day (2g, 6 times a day)
Anupana: madhu	*Anupana: madhu*
Duration - 7 days medication + 7 days follow up	Duration - 7 days medication + 7 days follow up

Observation period

- Treatment period: 7 days
- Follow up: 7 days after completion of treatment i.e; 14^{th} day
- Total Study duration: 14 days
- Days of assessment: Observation were done at baseline, 4th, 8th and 14th day.

Diagnostic criteria

Patients were diagnosed on the basis of;

- *Kasa* with *Sandra* and *bahula kapha nishteevana* with or without following symptoms.
- *Aasyamadhuryatha*
- *Aruchi*
- *Peenasa*
- *Gourava*
- *Utklesha*

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 give informed consent.

Exclusion criteria

- Patients with Chest X-Ray finding of hyperinflation of lungs or consolidation.
- Patients with *Kaphaja Kasa lakshana* associated with complications like Tuberculosis, Emphysema or Pneumonia.
- Patients with other systemic and metabolic diseases which may interfere with the course of treatment.
- Patients undergoing steroid therapy.
- Pregnant women and lactating mothers.

Assessment criteria

- Assessment of the condition was done based on detailed case proforma adopting scoring methods for subjective parameters.
- Statistical test of significance: It was analyzed using Wilcoxon Signed Rank Test and Mann-Whitney Rank Sum Test for within group analysis and comparing both groups respectively.

Subjective parameters

Primary

- *Kasa*
- *Sandra-bahula kapha nishteevana.*

Secondary

- *Aasyamadhuryatha*
- *Aruchi*
- *Peenasa*
- *Angagourava*
- *Utklesha*

Investigations

- Blood investigations – Hb, TC, DC, ESR, AEC
- Chest X-ray (PA view)
- AFB test if necessary

Statistical test

For evaluation of the effect of both the treatments, within group comparison before and after treatment was done with Wilcoxon Signed Rank Test and comparative analysis of overall effect of the treatments in both the groups was done statistically with Mann-Whitney Rank Sum Test.

RESULTS

Table no. 1: Effect of *Twageladi churna* on parameters in Group A.

Criteria	Median Bt	Median At	%	S.d.	S.e.	Wsrt value	P value
Kasa vega	2	0	79.38	0.504	0.092	465	<0.001
Kapha nishteevana	2.5	1	61.12	0.785	0.143	435	<0.001
Aasyamadhuryatha	1	0	100	0	0	66	<0.001
Aruchi	1	0	82.36	0.305	0.056	105	<0.001
Peenasa	1	0	76.14	0.379	0.0692	136	<0.001
Angagourava	1	0	72.16	0.379	0.0692	91	<0.001
Utklesha	1	0	100	0	0	6	0.25

Table no. 2: Effect of *Bruhatsharkarasama churna* on parameters in Group B.

Criteria	Median Bt	Median At	%	S.d.	S.e.	Wsrt value	P value
Kasa vega	2	0	83.89	0.661	0.121	465	<0.001
Kapha nishteevana	2	0	66.65	0.774	0.141	465	<0.001
Aasyamadhuryatha	1	0	100	0	0	66	<0.001
Aruchi	1	0	79.12	0.379	0.069	190	<0.001
Peenasa	1	0	84.52	0.254	0.046	66	<0.001
Angagourava	1	0	100	0	0	91	<0.001
Utklesha	1	0	75	0.5	0.25	6	0.25

Table No. 3: Comparative effect of Group A and Group B.

Criteria	Group a	Group b	T value	P value	Remarks
Kasa vega	2	2	880	0.609	Ns
Kapha nishteevana	1.5	2	878	0.589	Ns
Aasyamadhuryatha	0	0	915	0.994	Ns
Aruchi	0	1	840	0.27	Ns
Peenasa	1	0	975	0.378	Ns
Angagourava	0	0	915	0.994	Ns
Utklesha	1	0.5	15	0.4	Ns

Table no. 4: Comparison between the percentage relief of Group A and Group B.

Criteria	% of relief in Group A	% of relief in Group B
Kasa vega	79.4%	83.9%
Kapha nishteevana	61%	66.6%
Aasyamadhuryatha	100%	100%

Aruchi	82.4%	79%
Peenasa	76.1%	84.5%
Angagourava	72.1%	100%
Utklesha	100%	90%

DISCUSSION

In the present study, 28.3% of the subjects were house-wives, it may be because of their exposure to dust and smoke while doing house-hold activities, 26.7% of the subjects were cotton-mill workers; they may be prone to the condition due to their occupational exposure to respiratory allergens, dust, micro-fibre etc. 40% of the subjects belonged to low socio-economic class. The impact of low SES on respiratory disease has been attributed to poorer housing, more hazardous occupational exposure, poorer diet, a higher prevalence of active or passive smoking and respiratory infections in childhood.[6] 70% of the subjects consumed mixed diet. Non-veg diet is *guru* and *abhishyandi* when compared to vegetarian diet. It may lead to *ama-utpatti* and *srotorodha* which aggravates *kapha* and cause *pratilomagati* of *vata*.[7] Studies have proven that consumption of saturated fat, meat and sugar adversely affects the lung function.[8] Maximum patients, 50% of the subjects were belonging to *Vata-Kapha prakrithi*. *Kaphaja kasa* is a disease which is primarily caused by *vata* and *kapha dosha*. Hence, people with *vata-kapha prakrithi* are more prone to this condition.

Twageladi churna is mentioned in *Ashtangahrudaya Rajayakshmadi chikitsa*, the ingredients are *Twak, Ela, Pippali, Tugaksheeri* and *Sharkara*.[9] *Bruhatsharkarasama churna* is mentioned in *Vangasena samhitha Kasa chikitsa* and it contains *Lavanga, Jatiphala, Pippali, Maricha, Shunti* and *Sharkara.*[10]

In *Twageladi churna*, the drugs *Twak, Ela* and *Pippali* have *katu rasa* and *ruksha guna*. *Twak* and *Pippali* possess *ushna veerya* and *Twak* is *theeksha*. All these properties pacify vitiated *Vata* and *Kapha*, performing *Kapha vilayana, Kapha nirharana* and *Vatashamana*. The drugs *Ela* and *Pippali* are *deepana*, which aids in *Agnideepana* and thereby *Amapachana. Ela* and *Pippali* being *ruchya* and *Twak* being indicated in *Peenasa*, addresses the *anubandha lakshanas Aruchi* and *Peenasa*. In *Bruhatsharkarasama churna*, all the ingredients have *katu rasa, theekshna guna* and are *Kapha-Vata hara*. All the drugs in the formulation possess *Deepana* property, which helps in kindling the *Agni* and *Lavanga* and *Shunti* possess *Pachana* action, and performs *Aamapachana.* The drugs *Jatiphala* and *Maricha* are indicated in *Peenasa*, and *Jatiphala, Pippali* and *Lavanga* have *Ruchya* property. Thus, the formulation is highly effective in treating *anubandha lakshanas* like *Aruchi* and *Peenasa*. The common

ingredient in both the *churnas*, *sharkara* is *Kaphahrt* and *chedaka*, which will also help in pacifying morbid *Kaphadosha.*

The *anupana* used is *Madhu*, which possess *Tridoshahara* properties and is *Deepana*, *Chedana* and *Lekhana* and which helps in *Aamapachana*, *Kapha vilayana* and *Kapha visravana*. Also, the *Yogavahi* property of *Madhu* increases the bio-availability of other drugs in the formulation.[11] The formulation is in the form of *Sukshma churna.* The particle size is small which helps in easy absorption of the drugs when compared to other solid *Kalpanas*.[12] The *aushadhasevana kala* advised is *muhurmuhu*. This is mentioned by Acharyas specially in *Pranavahasroto-vikaras* like *Kasa* and *shwasa*. Also, the benefit of this particular *annakala* is, it pacifies the dosha during *Sanchayavastha* and *Vegakala*. Also, frequent administration of medicine aids the sublingual absorption of medicine, increases it's bio-availability and provides faster relief.[13]

Though statistically there was no significant difference between the effects of treatments in both the groups, clinically Group B (*Bruhatsharkarasama churna*) showed better results than Group A (*Twageladi churna*). Drugs in *Bruhatsharkarasama churna*, on comparison has more *ushna guna* and also possess *pachana* property due to the ingredients *Lavanga* and *Shunti* and performs *Chedana* action due to *Maricha*; unlike *Twageladi churna*. In contemporary terms, expectorant action is possessed more by the drugs of *Bruhatsharkarasama churna* than *Twageladi churna*. This might be the reason why clinically more result and less recurrence were seen in Group B.

CONCLUSION

Kaphaja kasa is the type of *Kasa* where *Kapha* and *Vata dosha* are involved. Considering the *nidana panchaka* and comparing, in the present study, it was compared with Chronic bronchitis.

Clinically and statistically, both the formulations were effective in treating the condition. On comparison, clinically *Bruhatsharkarasama churna* gave better results and less recurrence of symptoms, than in *Twageladi churna*. While comparing the effect statistically, both groups were equally effective. On statistical evaluation within the group, both *churnas* showed significant results before and after treatment with $p<0.001$. On comparison between two groups, it was found that there was no statistically significant difference, with $p>0.05$.

Hence null hypothesis H_{03} is accepted. There is no significant difference between the effect of *Twageladi churna* and *Bruhatsharkarasama churna* in the management of *Kaphaja kasa.*

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