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A Comparative Study on the Efficacy of *Kantkari* and *Vasa* Lozenges in Children with *Kasa (Cough)*-Study Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. Author SA, being PG scholar designed the study, wrote the protocol manuscript with the core help and support in editing the rough draft to make it final by coordinating Author RR, being Guide of this PG research work and Author BR managed the preparation part of both the drugs, analyses of the study. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: *Kasa* is the outcome due to release of obstructed *Vayu* resulting in the production of abnormal sound, which may be productive or dry. *Kasa* is one of the primary diseases of *Pranavaha srotas,* and can cause disturbances in other body functions. Prevalence of cough in India is 5% to 10% while acute cases of cough is 39% and chronic cases of cough is 29% reported in Maharashtra. This research drug is taken to check its efficacy on both the types of cough, dry as well as productive with acute or chronic origin. It has a good palatability and liked by children as it appears as candy. Many studies have been carried out on *Kasa* with different formulations so far like *vati*, *churna*, *ghrita* but they have no fast and long lasting action with different level of efficacy. Many lozenges are also available in the market but no studies have been done.

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Objective: Comparative Study on the efficacy of *Kantakari lozenges* with *Vasa* lozenges in the clinical features of *Kasa by* subjective criteria such as *Peenasa*-(running nose), *Kasa, Aruchi-(taste impliedness), kanthkandu(*throat itching*), kaphnishthivan (Sputum)* and objective criteria as adventitious sound and AEC-absolute eosinophil count, TLC-total leucocytes count, and DLC-differential leucocyte count.

Materials and Methods: The present study is designed as a Double Blind, Randomized Controlled Study in which total 60 patients will be enrolled. Patients will be randomly divided (by computer generated sequence method) in two with 30 patients in each group. In group A, *Vasa lozenges* and in group B *Kantkari lozenges* will be given for 7 days. Assessment of the patients will be done on 3rd and 7th day during study after intervention and post treatment follow up will be taken on 14th& 21st day from the enrolled date.

Results: Efficacy of both the lozenges will be observed in subjective and objective outcomes.

Conclusion: *Kantkari* lozenges (trial group) is expected to be more effective than *Vasa* lozenges (control group) in the management of *Kasa* as *Vata, Kapha* are more dominant in the pathology of Kasa in children and Kantakari is a good Vatakaphahar drug added with Pippali to act synergistically.

Keywords: Vasa lozenges; kantkari lozenges; kasa, cough; vatakaphahara; kaphanishitivan;; speenasa.

1. INTRODUCTION

Acharya Charaka has defined *Kasa* as release of obstructed *Vayu* resulting in the production of abnormal sound in the process, which may be productive or dry [1]. *Kasa* has been described under various categories in the classics of *Ayurveda* as independent disease [2]. *Kasa* is one of the primary diseases of *Pranavahasrotas (*Respiratory system*),* and hence can cause disturbances in other body functions [3]. Cough is one of the most common symptoms in children [4-5] and additionally the common cause for which parents are seeking relief for their children [6] In maximum children, acute cough pharyngitis is because of viral upper respiratory tract infection (URTI) [7]. It is one of the most common viral infections [8,9] because of unhealthy lifestyle, food habits, polluted air and low immunity having the symptoms like dry cough or with bouts of sputam, common cold or coryza is communal disease in today's era. It is identified that preschool and school going young children may be afflicted by acute respiratory infections with approximately six to eight instances in every year. bouts. Pediatric age has greater susceptibility because of anatomical and physiological peculiarities such as inclusive of hypertrophied lymphoid tissues [9] mucous hyper secretion, small cage[10], distinctiveness of Eustachian tube [11], immunological considerations [12] (first exposure, immature immunological defenses, etc.) and social factors (attending school, mistaken meals and Fast food consuming habits [13] etc. Prevalence of cough in India is 5% to 10% [14]. Cough can be taken into consideration for an outcome of some diverse diseases, such as asthma/eosinophilic bronchitis, rhinitis and gastro-esophageal acid reflux disorder. Cough is a product of the critical defense mechanism. However, continual cough is a large motive of morbidity, severely impairing quality of life [15].

Cough can be voluntary or involuntary, painful, disruptive and debilitating. Cough can be viewed as a continuum of fitness through sickness and is a beneficial host defense mechanism. Cough offers safety to the tracheobronchial tree from potentially injurious materials and through elimination of endogenous secretions and other materials, along with pus, necrotic tissue and overseas bodies. Chronic cough needs to be evaluated for the underlying sickness in a scientific way concerning the nature, timing, and the onset of cough, its pathology and associated clinical features. It may be reaction to preceding medications and sequel of the primary disease, therefore must be confirmed with the differential diagnosis and investigations. Therapy needs to be primarily based on physiologic derangement and etiology. In this scientific study, we have planned to assess the comparative efficacy of herbal lozenges which is easily acceptable and palatable to children in continuous cough [16]. Among all the allergic diseases, it is most frequently troubling condition and it requires more care because growth and development may be affected due to disturbed daily activities [17-19] There is high prevalence of both the varieties of cough in children which commonly

found in all over the Maharashtra like acute case of cough 39% and chronic cough 29% was reported.

Vata and *Kapha* are the two key pathological factors involved in the *Samprapti* of *Kasa* [20-21]. In *Kasa,* trial drug has *Kantakari* (*Solanum xanthocarpum* Schrad and Wendl), *Pippali (Piper longum* L.*)* and sugar while there is a previous study on *Vasa* lozenges having ingredients Vasa (*Adhatoda vasica* Nees) with Pippali and sugar had proven efficacy in cough hence Vasa lozenges are taken as standard control [22]. Therefore, comparative study is planned to prove the efficacy of *Kantakari* lozenges as compared to *Vasa* lozenges. *Kantkari* has *Kasaghna (cough reliever), Kanthya(soothing)* property because of *Kaphshamak* and *Kanthya Vishodhak, Ushna Virya* and *Katu Vipak. Pippali has Kasaghna* property because of *Vatkaphshamak Anushna sheet virya (*mild potency) and *Madhur Vipak* (metabolism)*,* hence *act as Rasayana (*immunomodulator*)* [23]. The Rasayana therapy improves the merits of rasa, build up to it with nutrients so one can attain prolonged existence, memories, intellect, freedom from diseases, quality in luster, complexion and voice, optimal improvement of physique and all sense organs. *Rasayana i*s very useful to increase the immunity of the person to keep him away from any disease [24]. According to the action of above drugs, in combination it would act synergistically to break the *Samprapti* of *Kasa (pathogenesis of cough). Kasa* is seen as a common condition of pediatric age group. If sole presenting symptom of cough is ignored, it could result in not on time prognosis and development of a severe infection or persistent breathing morbidity, which includes bronchiectasis [25-26]. Many herbal combinations are described in Ayurveda and their therapeutic effects in *Kasa* which are yet to be explored. There is lot of previous work done but not found at excellent level with some pros and cons. They all were of small sample size and different studies show different level of effectiveness. Lozenges are faster absorption local & systematic due to directly absorb from sub-mucosa. Hence, to check the effect of *Kantakari* lozenges in *Kasa* present study is planned in comparison with Vasa lozenges. The outcome of *lozenges* compound containing *Kantakari* and *Pippali* likely to be efficient in combating the signs and symptoms of *Kasa* owing to drug action [27-28]. The ingredients are easily available, cheap, safe and lozenges are easy for administration with soothing action. Many conventional cough syrups cause side effects especially in children. Ayurved herbs are in use to treat many health conditions since thousands of years and no any adverse effects are noticed and hence safe. Therefore, its needful to evident a quickly effective, palatable, and economic formulation proven by all subjective and objective criteria.

2. METHODOLOGY

The present study is designed as a randomized, double blind, prospective, comparative, parallel group clinical study on 5-14 years age group. Randomized standard controlled study in which 60 patients will be enrolled in which computer generated random allocation software method to avoid bias in the study. The allocation sequences will be generated in advance, which are then sealed in consecutively numbered opaque envelopes. The packing of both the interventions will be kept very identical thereby both investigator and supervisor could not know about intervention. The allocation sequence will be generated by 3rd person in the department by coding envelop method Double Blind means Researcher and Participants both will be blinded. Diagnosed patients will be selected from Kaumarabhritya OPD & IPD of M.G.A.C.H. and R.C. Wardha & special camps.

Study Setting: Diagnosed patients will be selected from Kaumarabhritya OPD & IPD of M.G.A.C.H. and R.C. Wardha & special camps will be conducted. (Fig. 1).

Study Design: Double Blind, Standard Controlled Study.

Eligibility Criteria: Diagnosed patients of *Kasa* between the age of 5 to 14 years presenting with clinical signs and symptoms given Parent's consent irrespective of gender, caste, religion & socio-economic background. patient having following disease like Known cases of Pneumonia, Bronchial Asthma, Bronchiectasis, Pleurisy, Tuberculosis Malignancy and other systemic diseases with cough, Congenital anomalies of Respiratory Tract, Bronchial Asthma will be excluded.

Intervention: In present study, patients will be randomly divided in two groups with 30 patients in each. In group V, *Vasa lozenges* and in group K, *Kantkari lozenges* will be given for 7 days. Assessment of the patients will be done on 3rd and 7th day during study after intervention and post treatment follow up will be taken on 14th& 21st day from the enrolled date.

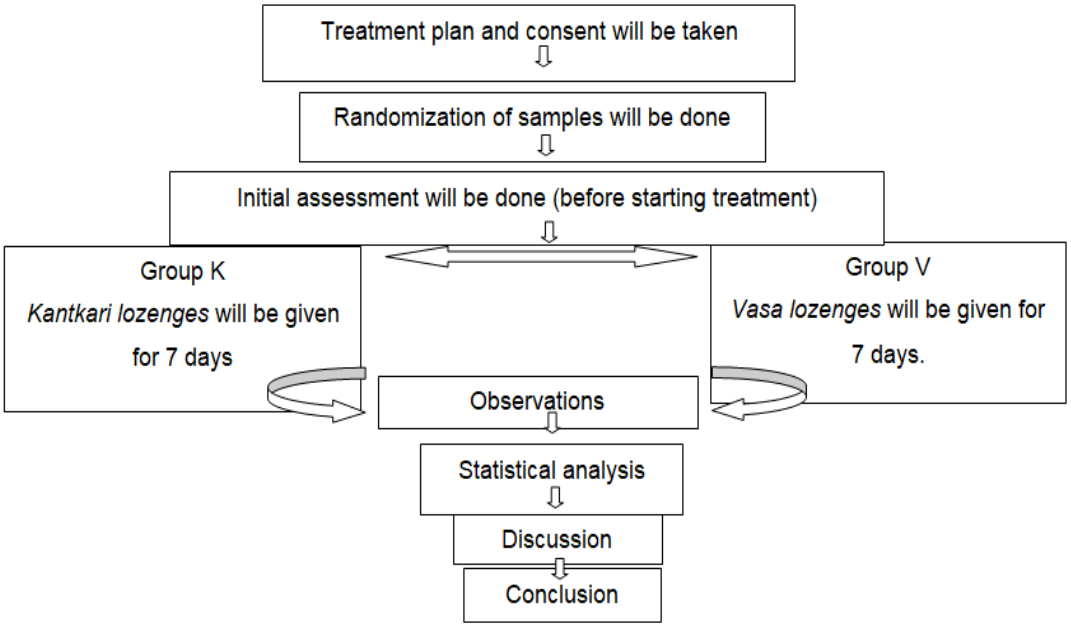

Fig. 1. Flow diagram of the study process

Table no 1. showing the details of group's name, its size and intervention

Group	Sample Size	*Intervention*
*Group K	*30*	*Kantkari Lozenges*
**Group V	*30*	*Vasa Lozenges*

**Group K –Kantkari lozenges, **Group V - Vasa lozenges*

Table no 2. Depicting the properties and action of trial drug and standard control

Sl.no.	Name of Drug	Rasa	Guna	Virya	Vipaka	Karma
1	Pippali	Katu	Laghu Ruksha, Snigdha	Anushnasheet	Madhur	Shwasaghankasghna Increases bioavailability
2	Kantkari	Tikta, Katu	Laghu, Ruksha, Tikshna	Ushna	Katu	Kanthaya, Kasahar Dipan, Pachan, Vata-kapha shamak
3	Sita	Sugar		Sheet	Madhur	Vatpitttashamak Kasahar
4	Vasa	Tikta; Katu	Vikasi, pramathi;	Sheeta	Katu;	Pittakaphashamak, mucolytic, expectorant (Kasahar)

Posology:

- The patients of age group of 5- 10 years will be given one lozenge of 7.5 gm for three times a Day

- The patients of age group of 11-14 years will be given two lozenges equal to 15gm for three times a Day.

Preparation of the Formulation: *Kantkari and Vasadi lozenges* will be prepared in the Dattatraya Rasashala of Mahatma Gandhi Ayurved College, Hospital & Research Centre; Salod (H) Wardha. The procedure will be same for Vasa lozenges as that of Kantakari lozenges

1. Preparation of *Kantkari Kwatha* and *Ghan*

Kwatha and *Ghan* will be prepared as per mentioned in *Sharangadhara Samhita*.[21]

Preparation of *Kantkari* lozenges

Properly dried *KantkariGhana* will be mixed with sugar and water in prescribed quantity.

⇩

Formed thick syrup, later will be convert into thick mass.

⇩

This prepared thick mass will be then subjected to plate followed by addition of mint/menthol

⇩

Mixture will be properly mixed by kneading with the help of batch roller. The mold will be utilized to manufacture *Kantkari* lozenges.

⇩

The mold will be further subject to Pillow pack machine to form *Kantakari* lozenges

⇩

Prepared lozenges will be wrapped in aluminum foil to protect from dust and moisture.

Fig. 2. Flow chart of the preparation of research drug intervention

Mode of administration: Every time lozenges will be consumed orally for sucking*(Chushnarth)*

Aushadhakala: After food

Duration: 7day

Investigations Proposed: Hematological-TLC DLC and AEC (Absolute Eosinophil count)

Inclusion Criteria:

- Diagnosed patients of *Kasa* between the age group of 5 to 14 years presenting with clinical signs and symptoms will be enrolled after taking parent's consent irrespective of gender, caste, religion & socio-economic background.

Exclusion Criteria:

- Known cases of Pneumonia, Bronchiectasis, Pleurisy, Tuberculosis, Malignancy and other systemic diseases with cough
- Congenital anomalies of Respiratory Tract
- Bronchial Asthma

Criteria for discontinuing or modifying allocated interventions: Patients will be withdrawn from intervention if any harmful incidence, signs of drug allergy or any problem will occur; patient will be offered treatment at free of cost till the disease subsides.

Follow up: 3rd day and 7thdays and during study. Follow up post treatment will be taken on 14th& 21st day from the enrolled date.

Primary Outcomes: Will be assessed on the Reduction of *Kasa* (Frequency), *Pinas*, *Kanthkandu, Aruchi, Kaphanistivanam* and changes in the values of DLC, TLC, AEC.

Secondary Outcomes: To check the comparative efficacy of both the lozenges against dry in nature and acute in origin versus productive and chronic basis.

Implementation: Primary Investigator will allocate and enroll the patient.

- The trial drug may be effective in management of *Kasa*.
- Lozenges are faster in absorption by local & systemic circulation due to directly absorption from sub-mucosa
- The outcome of *lozenges* compound containing of *Kantakari* and *Pippali* likely to be efficient in combating the signs and symptoms of *Kasa.*
- In the present research work we will rule out the Effectiveness of *kantkari lonzens* in comparison of *Vasa lozenges* in management of *Kasa*.

Methods: Data collection, management and analysis.

Subjective Parameters: Clinical presentations of Kasa is describe as*)*

Subjective Criteria : The gradation is depicted in table no. 3 to 8

1] Kasa(Frequency)

- *Pinasa*
- *Kanthkandu*
- *Aruchi*
- *Kapha Nistivanam (*Sputum*)*

Table no 3. Showing gradation of Kasa (cough)1] Kasa

Sl.No.	Grade	Frequency
01	1	Absent
02	2	Occasional(slight 2-4 Hour)
03	3	Frequent (4-6 hour)
04	4	Continuous (disturb day to day activity)

Table no 4. Showing gradation of Peenasa

Sl. No.	Grade	Frequency
01	1	Absent
02	2	Present (on and off)
03	3	Continuously with slight blockage
04	4	Continuously which disturbs day to day activity

Table no 5. Showing gradation of Kaphanisthivana- Frequency

Sl. No.	Grade	Frequency
01	1	Absent
02	2	Occasional
03	3	Persistent

Table no 6. Showing gradation of Kaphanisthivana- Consistency & Quantity

Sl. No.	Grade	Consistency
01	1	Absent
02	2	Less quantity, thin
03	3	More quantity, thick

Table no 7. Showing gradation of Aruchi (Tastelessness in Food)

Sl. No.	Grade	Parameter
01	1	Normal desire of taking food
02	2	Though the person is hungry he had dislike for food due to disease, anger or fear but takes small quantity in a day
03	3	Child even Dislikes the touch or smell of food, not allow one sip/bite also

Table no 8. showing gradation of Kanthkandu

Sl. No.	Grade	Frequency
01	1	Absent
02	2	Mild
03	3	Moderate
04	4	Severe

Objective Parameters:

b) Objective Criteria

- CBC
- AEC
- Adventitious sounds

Overall Assessment: Overall assessment will be done on basis of improvement in cardinal signs and symptoms before and after completion of treatment.

1. Maximum improvement: - more than 75% improvement of the clinical signs and symptoms.
2. Moderate improvement: - 50-75% improvement of the clinical signs and symptoms
3. Mild improvement: - 25-50% improvement of the clinical signs and symptoms.
4. No improvement: - 0-25% improvement of the clinical signs and symptoms

Data collection, management, and Analysis methods: Data will be collected as per inclusion and exclusion criteria. 3rd person in the department will do coding of data. Required information will be gathered from CRF-clinical research format of all participants and managed and analyzed with the help of appropriate statistical tests using SSPS-Statistical package for social sciences. Statistical analysis: Wilcoxon Sign Rank Sum, Paired t-test and unpaired t-test with 90 % confidence interval.

Adverse drug events if occurred reported by patients will be recorded with details of severity and association with study. It will be treated at free of cost.

Dissemination policy: For future research results will be disseminated and research will be published in reputed journal

3. RESULTS

The expected result of this study is that Group K with *Kantkari* lozenges will be more effective as compared to Group V with *Vasa* lozenges. It will effective in relieving the symptoms of Kasa like *Peenasa, Kasa, Aruchi, kanthkandu, kaphnishthivan* owing to its opposite action from *Samprapti (pathogenesis) of Kasa.* Participants who will take all follow-ups during the treatment will have good chances of recovery from *kasa.*

4. DISCUSSION

Kasa is very common symptom in children. Many studies have been carried out on *Kasa* with different formulations so far like *vati*, *churna*, *ghan* but they have no fast and long-lasting action. Many lozenges are also available in market but no authentic studies have been done till date. Lozenges are faster in absorption through local & systematic circulation directly from sub-mucosa. Hence, to check the effect of *Kantakari* lozenges in *Kasa* present study is planned to assess the effect of *Vasa* versus *Kantakari* lozenges in *Kasa*. In this study, two groups will be made Group K with *Kantkari* lozenges and in Group V with *Vasa* lozenges will be taken where *Kantakari* lozenges is expected to be more effective in *kasa* in children. The patients of age group of 5- 10 years will be given one lozenge of 7.5 gm will be given three times a Day. The patients of age group of 11-14 years will be given two lozenges of 15gm will be given three times a Day. The interventional drug

Kantakari shows *Kasghna, Kanthya* property because of *Kaphshamak* and *Kanthya Vishodhak,Ushna Virya* and *Katu Vipak. Pippali* has *Kasaghna* property because of *Vatkaphshamak* due to *Anushna sheet virya* and *Madhur Vipak.* According to the action of above drugs, in combination it would act synergistically to break the *Samprapti* of *Kasa.* The outcome of *lozenges* compound containing of *Kantakari* and *Pippali* with mint and sugar likely to be efficient in combating the signs and symptoms of Kasa.

5. CONCLUSION

As *Kantkari* has *Kasaghna, Kanthya* property because of *Kaphshamak (Kapha* suppresants*)* and *Kanthya Vishodhak, Ushna Virya* and *Katu Vipak. Pippali* has property of *kasaghna* because of *Vatkaphshamak* due to *Anushna sheet virya* and *Madhur Vipak.* According to the action of above drugs, in combination it would act synergistically to break the *Samprapti* of *Kasa.* Lozenges are rapidly absorbable from sub-mucosa. The interventional drug *Kantkari* lozenges would be more effective than *Vasa* lozenges in *kasa* in children as per mode of action.

CONSENT

Written informed consent from parents of the patients (instead of ascent by child patients) will be obtained instead of child participants ascents.

ETHICAL CONSIDERATION

Institutional Ethical Clearance is taken (MGACHRC/IEC/2020-58) and registered in CTRI also, CTRI/2021/02/031483.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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