A Study on the Efficacy of Shwasa Kasadi Gutika in the Management of Kasa

Research Article

Akshay Patankar¹, Renu Rathi²*, Bharat Rathi³
1. P.G Scholar, 2. Professor, Kaumarbhritya Department
3. Professor, PG Department of Rasashastra and Bhaishajya Kalpana
Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha.

Abstract

Kasa (Cough) is one of the most frequent symptoms in pediatric age group for which parents look for medical care. It indicates that even after advancements in current medical science, cough is not being effectively controlled in children. With the above background, the present trial was aimed to study the efficacy of herbal tablet named as Shwasa Kasadi gutika in the management of Kasa. The objectives of the study were to assess the efficacy of trial drug on Kasa and its subjective and objective parameters. The study was a single group, single centre, fixed dose, interventional study. The subjective parameters were as per the clinical features of Kasa. Their grading was done as per their intensity. School going age group was more likely to suffer from the cough and male children were more in the study. There was significant improvement in all subjective criteria where as significant changes were noted in adventitious sounds and total leukocyte count. However, as it was conducted in limited samples, further large sample multi-centre studies would be preferable. Developing pharmaceutical standards of the tablet would also be a newer area of research.

Key Words: Kasa, Shwasa Kasadi gutika, Cough in children, Ayurveda, Adventitious sounds.

Introduction

Kasa has been described under various sets in the classics of Ayurveda as independent disease, (1-2) symptom (3) and as complication (3). Numerous lakshana (sign and symptoms) of Kasa are explained in the classics of Ayurveda according to Dosha. In the pathogenesis of Kasa, vitiated Kapha blocks the free movement of Prana Vata in throat and chest (1) Kapha is the main offender in production of Kasa which is the leading Dosha in pediatric age group, (4) hence the incidence is more in this age group.

Pediatric age group is more prone because of anatomical and physiological individualities (hypertrophied lymphoid tissues (5) mucous hyper secretion (6) peculiarities of eustachian tube etc.) (7), immunological poor status (8) and social issues (appearing at school, improper food and eating habits (9) etc.). Recurrent cough is the common appearance of recurrent respiratory tract infections (RRTI) which is more parallel to the disease Kasa explained in Ayurveda classics.

Initial intervention is vital in case of Kasa as it is a probably Nidanarthakara Vyadhi (disease having affinity to create secondary diseases) to produce Kshaya (10) (a disease considered with severe leanness). It is noted that children suffering from RRTI show suggestively troubled growth and development with poor intellectual and social up-gradation (11). Kasa may be observed as a common complaint of pediatric age without serious consequences, overlooking cough that may be the sole existing symptom of a primary respiratory disease can lead to late diagnosis and progression of a serious illness or chronic respiratory morbidity, such as bronchiectasis (12).

Shaman (Pacifying therapy) line of management that contains oral administration of medicine and pre-procedures of Panchkarma (5 purificatory procedures) is of prime importance as the administration is very easy as related to Shodhana (purificatory therapy) in children. Many herbal medicines are described in Ayurveda and their valuable effects in Kasa are yet to be explored. The effect of gutika containing equal quantities of Shunti, Nagarmotha, Haritaki (Herbal Drugs) and double of Jaggery is likely to be very effective in treating the signs and symptoms of Kasa. (13-14)

The present trial was aimed at studying the efficacy of herbal tablet named as Shwasa Kasadi gutika in the management of Kasa. The objectives of study were to assess the efficacy of Shwas Kasadi...
Gutika on Kasa frequency, Kantha Kandu (Throat itching), Peenasa (Nasal Discharge), Kapha Nishitivana (Sputum) and Adventitious Sound, TLC, DLC, ESR.

**Material and Methods**

It was a single group single center fixed dose interventional study. Before commencement of study, it was approved by Institutional Ethics committee (DMIMS (DU) /IEC/2017-2018/6371). The Shwas-Kasadi Gutika prepared and tested in analytical lab of Dattatray Rashashala of MGAC&RC salod (H), Wardha. Total 34 patients accomplishing the inclusion criteria were enrolled from the OPD and IPD of Kaumarabhritya and also from specialized peripheral camps. Informed consent was taken from parents. The data was analyzed by using paired t test (Parametric), Wilcoxon sign rank (non-parametric) statistical tests.

**Inclusion Criteria**

- Subjects irrespective of gender, religion, socioeconomic status and between the age group of 4-15 years were being taken.
- Subjects having classical signs and symptoms of Kasa.
- Subjects of Kasa with chronicity of less than 15 days duration (Acute cases only).

**Exclusion Criteria**

- Subjects with complications of Kasa i.e. Fever (>100°F), Chronic obstructive Bronchitis, Tuberculosis, Bronchiecstasy, Lung abscess, Pulmonary edema resulting from Cardiac & Renal disease, Pneumonia and Bronchiolitis.
- Subjects with other systemic disorders and metabolic diseases.

**Source of Drug**

For the present study, the poly herbal formulation was taken from Ayurveda classic (13-14) which contain the following ingredients.

**Table No 1: Ingredients of Shwas-Kasadi Gutika:**

| S1. No. | Ingredients                                   | Part used | Quantity per 900gm of drug |
|---------|-----------------------------------------------|-----------|----------------------------|
| 1       | Haritaki Terminalia chebula (Retz.)           | Phala     | 100gm                      |
| 2       | Nagar Zingiber officinale (Rosc.)             | Kanda     | 100gm                      |
| 3       | Musta Cyperus rotundus (Linn.)                | Stoloniferous roots | 100gm                      |
| 4       | Jaggery Saggaram officinaram (Linn.)          | Jaggery   | 600 gm                     |

**Dosage** - 100mg/kg/day,
**Mode of administration** – Oral (licking)

**Method of study**

After taking the informed consent from the parents /guardian, 34 subjects were enrolled as per the inclusion criteria. The trial drug was administered for a period of 7 days during which assessment of both subjective and objective parameters and other observations were recorded on 0th, 3rd and 7th day in a specially prepared research proforma other than hematomal parameters which were performed before and after trial. Follow up was for a period of 14 days post trial.

Withdrawal criteria was fixed as any aggravation of symptoms or occurrence of any other clinical condition during treatment for which participants would be withdrawn from study and suitable alternative would be provided free of cost till the children were symptom free.

**Criteria for Assessment**

Assessment of the clinical trial was done based upon the changes in both subjective (Numerical gradation as per severity) [Baghail book] and objective parameters.

Initial assessment was done before the study, followed by assessment of only subjective parameters on 4th day of the study. Final assessment was done after the course of the trial i.e. on 7th day and follow-up at 15 days after completion of treatment. Hematological investigations were done only before and after the clinical trial.

**Table No 2: Subjective and Objective parameter**

| Subjective Parameters | Objective Parameters |
|-----------------------|----------------------|
| Kasa – nature in general with overall discomfort | Adventitious sounds as they are signs for type, severity & frequency to be checked by doctor |
| Kasa (Frequency)      | TLC, DLC             |
| Kanthkandu (itching inside throat) | ESR                      |
| Peenasa (Nasal Discharge) |                         |
| Kapha Nistivanal (Expectoration) |                          |

The obtained data was analyzed statistically with the help of Wilcoxon Signed Rank Test and Paired t test. P value of < 0.05 was considered as statistically significant and p value < 0.01 and < 0.001 were considered as highly significant. Level of significance was noted and interpreted accordingly. Overall assessment of the study was done by calculating the mean of parameters.

**Observations and result**

Total 34 subjects were enrolled in the study among which 2 had left against medical advice due to personal reasons. 2 children reported with high grade fever soon after enrollment in the trial hence they were withdrawn from study and suitable alternative was provided free of cost till they were symptom free.

Maximum number of children i.e. 20 belonged to the age group of 8-10 years and there were 20 male
and 14 female children in this study. Among 34 participants-30 Hindu and 4 Buddhist were enrolled. Maximum numbers of children were from middle class followed by lower class and no children were from upper class family. 15 children had average personal hygiene whereas 15 had poor. Maximum numbers of children were having history of gradual mode of onset, intermittent time of occurrence, irregular periodicity with expectoration of white sputum.

Table No 3: Effect of Shwasa Kasadi Gutika in Kasa nature

| Day              | Mean | N  | SD  | SE  | Mean Difference | z-value |
|------------------|------|----|-----|-----|-----------------|---------|
| 0 day-before treatment | 2.43 | 30 | 0.50| 0.09| -               | -       |
| 3rd day          | 2.10 | 30 | 0.30| 0.05| 0.33±0.47 (13.58%) | 3.16 p=0.002,*** |
| 7th day          | 1.33 | 30 | 0.47| 0.08| 1.10±0.30 (45.26%) | 5.26 p=0.0001,*** |
| 22nd day         | 1.03 | 30 | 0.18| 0.03| 1.40±0.56       | 4.85 p=0.0001,*** |

*Insignificant, **Significant, ***Highly Significant

Table No 4 - Effect of Shwasa Kasadi Gutika in Kasa (Frequency)

| Day              | Mean | N  | SD  | SE  | Mean Difference | z-value |
|------------------|------|----|-----|-----|-----------------|---------|
| 0 day-before treatment | 3.16 | 30 | 0.46| 0.08| -               | -       |
| 3rd day          | 2.06 | 30 | 0.25| 0.04| 1.10±0.40 (34.81%) | 4.69 p=0.001,* |
| 7th day          | 1.33 | 30 | 0.47| 0.08| 1.83±0.37 (57.91%) | 10.38 p=0.0001,*** |
| 22nd day         | 1.03 | 30 | 0.18| 0.03| 2.13±0.50       | 10.38 p=0.0001,*** |

Table No 5: Effect of Shwasa Kasadi Gutika in Kantha Kandu

| Day              | Mean | N  | SD  | SE  | Mean Difference | z-value |
|------------------|------|----|-----|-----|-----------------|---------|
| 0 day-before treatment | 2.07 | 14 | 0.26| 0.07| -               | -       |
| 3rd day          | 1.64 | 14 | 0.49| 0.13| 0.42±0.51 (20.77%) | 3.12 p=0.008,** |
| 7th day          | 1.07 | 14 | 0.26| 0.07| 1.00±0.39 (93.45%) | 9.53 p=0.0001,*** |
| 22nd day         | 1.00 | 14 | 0.00| 0.00| 1.07±0.26       | 15.00 p=0.0001,*** |

Table No 6: Effect of Shwasa Kasadi Gutika Peenasa (Nasal Discharge)

| Day              | Mean | N  | SD  | SE  | Mean Difference | z-value |
|------------------|------|----|-----|-----|-----------------|---------|
| 0 day-before treatment | 2.27 | 22 | 0.45| 0.09| -               | -       |
| 3rd day          | 2.04 | 22 | 0.48| 0.10| 0.22±0.42 (10.13%) | 2.48 p=0.021,** |
| 7th day          | 1.09 | 22 | 0.29| 0.06| 1.18±0.39 (51.98%) | 14.04 p=0.0001,*** |
| 22nd day         | 1.13 | 22 | 0.35| 0.07| 1.13±0.35       | 15.17 p=0.0001,*** |
Assessment of objective Criteria

Table No 7: Effect of Shwasa Kasadi Gutika on Adventitious Sound

| Day                  | Mean | N  | SD  | SE  | Mean Difference | z-value |
|----------------------|------|----|-----|-----|-----------------|---------|
| 0 day-before treatment| 2.16 | 12 | 0.38| 0.11| -               | -       |
| 3rd day              | 1.50 | 12 | 0.52| 0.15| 0.66±0.49 (30.55%)| 4.69 p=0.001,** |
| 7th day              | 1.00 | 12 | 0.00| 0.00| 1.16±0.38 (53.70%)| 10.38 p=0.0001,*** |
| 22nd day             | 1.00 | 12 | 0.00| 0.00| 1.16±0.38       | 10.38 p=0.0001,*** |

Hematological Parameters: Total Leukocyte count shows significant result (p=0.011) all other hematological parameters shows not significant result.

Table no. 8 showing details on objective criteria- Hematological parameters

| Parameter Pre& Post t/t | Mean | N  | SD  | SE  | Mean Difference | t-value |
|-------------------------|------|----|-----|-----|-----------------|---------|
| Hb                      | 11.03| 30 | 1.63| 0.29| 0.05±0.36 (0.45%)| 0.79, p=0.43 |
| Leukocyte               | 8120 | 7316 | 2400 | 197.20 | 803.33 ± 1619.90 (9.89%) | 2.71 p=0.011** |
| Neutrophil              | 56.46| 56.20 | 10.84 | 2.20 | 0.26±7.55 (0.46%) | 0.19 p=0.84,* |
| Lymphocyte              | 35.40| 38.13 | 12.90 | 2.35 | 2.73±8.50 (7.71%) | 1.75 p=0.089,* |
| Eosinophil              | 2.26 | 2.30 | 1.14 | 0.20 | 0.03±1.09 (1.76%) | 6.16 p=0.86,* |
| Monocyte                | 3.70 | 4.26 | 2.13 | 0.38 | 0.56±2.14 (15.13%) | 1.44 p=0.15,* |
| ESR                     | 25.73| 21.66 | 16.51 | 3.01 | 4.06±11.95 (15.81%) | 1.86 p=0.073, |

Table No 9: Over All Result on Assessment Criteria (Z test)

| SL No | Assessment Criteria | Fully Cured | Partially Relief | No Effect | Overall Improvement in % |
|-------|---------------------|-------------|------------------|-----------|--------------------------|
| 1     | Kasa Nature         | 66.66%      | 33.33%           | 0%        | 45.26%                   |
| 2     | Kasa (Frequency)    | 66.66%      | 33.33%           | 0%        | 57.91%                   |
| 3     | Kantha Kandu        | 92.85%      | 0%               | 7.14%     | 93.45%                   |
| 4     | Peenasa(Nasal Discharge) | 90.90%   | 9.09%            | 0%        | 51.98%                   |
| 5     | Kapha Nistivanam(Sputum) | 91.30% | 8.69%            | 0%        | 52.71%                   |
| 6     | Adventitious Sounds | 100%        | 0%               | 0%        | 53.70%                   |
| **Total Result**       | 14.07%      | 1.09%          |                  | 59.16%     |

The assessment shows that all the subjective parameters have a highly significant association with the p value obtained. In objective criteria, in Adventitious Sound shows highly significant result Lymphocyte counts which showed significant results, all the others have an insignificant association with the p value obtained. Overall Improvement seen in Kasa Assessment criteria is 59.16% which shows Moderate improvement as Improvement is in between 50% to 75%. Comparing the overall results, the percentage of fully cured children is far more as compared to partial relief children. Maximum children enrolled in the study had shown mild sign and symptoms only and very few were affected with moderate sign symptoms so after treatment there is moderate overall improvement i.e. 59.16% was found in final result. The individual and overall effect of therapy was tested for statistical significance by using Wilcoxon sign rank test and
Student’s ‘t’ test including mean %. Shwasa Kasadi Gutika provided relief in all symptoms of Kasa irrespective of Dosha involvement. The total remission was statistically highly significant (i.e. P<0.001).

Discussion

In the present study, school going age group was more likely to suffer from the cough which might be due to exposure to external environment and contact with infected group of children. Male children were more in the study since they have smaller air ways for a given lung size, which is independently inherited in addition to the fact that boys have a higher incidences of respiratory infections during childhood(15). With respect to religion, it was observed that maximum number of children belonged to Hindu community, followed by Buddhist. This may be due to the geographical distribution of the particular set in the place of study. Prevalence of Kasa belonging to lower middle and lower class family can be considered as a reasonable finding due to the surrounding in which they live, poor personal as well as social hygiene and negligence towards health which provokes respiratory infections. The same was observed in the study. All participants were accurately immunized up to their age by routine vaccines, suggesting the lack of relation between the disease and immunization. As vaccines only stimulate specific immunity to disease specific (16) and they are not directly associated in preventing routine infections.

Regarding nature of Kasa (Cough), 46.66% subjects revealed history of gradual onset of Kasa while sudden onset was found in 43.33% in whom specific allergic substances had a key role. 10% children had sudden onset was found in 43.33% in whom specific allergic substances had a key role. 10% children had sudden onset of cough which is a classical sign of Kapha dominance. Wet cough exhibits surface action on the pharyngo-laryngeal mucosa and modulate them to decrease exudation (34). Thus, in the present study dominance of Kapha dosha was seen in maximum children. It is during the change of season which is called as Rutusandhi kala (duration between two seasons) in Ayurveda wherein observing Rutucharya (Seasonal Regimen) is said to be very vital. Children generally do not follow these guidelines and thus, suffer from various seasonal diseases. 63.33% participants had white color of sputum which is due to kapha dominance and it is a classical sign of Kapha dosha dominant Kasa.

Discussion on Kasa nature and frequency

The trial drug with its vata Kaphahara properties might have modified the disease-causing properties of Kapha and reduced obstruction of channel of the body also facilitating normal movements of Vata which has reduced Kasa Vega /frequency. Haritaki is having Immune modulatory activity (18) and Antitussive action of Shunthi (19) Haritaki (20) is helpful in treating Kasa.

Kantha Kandu

Pharmacological Activity of drug Swasa Kasadi Gutika was proved as Anti-bacterial activity (21) Anti-viral activity (22) of Haritaki and it shows direct effect on chronic cough and sore throat (23), Z. officinale has been reported to exhibit antibacterial properties and exerts anti-inflammatory and relaxant effects on airway lumen(24), Antimicrobial (25), Antibacterial (26), Anti-Inflammatory (27), Tranquilizing (28) effect of Musta collectively shows significant effects in Kantha kandu.

Peenasa (Nasal Discharge)

Anti-viral, Anti-Bacterial effect of all drugs Haritaki is having immune-modulatory activity(18) Anti-allergic activity of Haritaki (29) and Tranquilizing activity(28) of Musta which helps in sedating the child which is useful in case of peenasa thus, all collective effect of trial drug has shown significant effect on Peenasa.

Kapha Nistivanam (Sputum)

All the drugs are having Vata-kaphahara properties and Ushnaguna (Hot potency) (30) which help in expectoration by resolving reduced obstruction of channel because of this drug- Swasa Kasadi Gutika collectively showed significant improvement.

Adventitious Sounds

Adventitious sounds were reduced because of ushanaguna and Vatkaphahara property of drugs (30) which resolve the strotorodha and maintain the natural flow of Vata in the chest region. Antibacterial (21), Anti-viral (22) Anti-microbial (25,31) activity of drugs helped to reduce adventitious sound like crepitation and rhonchi.

Hematological parameters

Total lymphocyte counts also showed significant results. All the other blood investigations have an insignificant association with the p value obtained. DLC and ESR value had not shown significant results. All the other blood investigations had Madhura-Kashaya katu Rasa.

Probable Mode of Action of Drug- Shwasa Kasadi Gutika

The drug had Madhura-Kashaya and katu Rasa (sweet-astringent taste). Jaggery was the ingredient for the sweet taste and as per Ayurveda considers jaggery to be beneficial in treating throat and lung infections(32,33), Haritaki is having abundant tannins which exhibit surface action on the pharyngo-laryngeal mucosa and modulate them to decrease exudation (34). Also Haritaki is having Antibacterial (21), Antiviral.
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