

Effect of Amritadi Lozenges in the Treatment of Kaphaja Kasa in Children

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Abstract

In the present clinical study 30 patients were treated by dividing them into trial & control group each containing 15 patients. The drugs were administered in the Lozenge (Rasakriya) form for its easy palatability in both the groups. Amritadi Lozenges (Rasakriya) is one such herbal combination mentioned in Bhaishajya Ratnavali, the efficacy of which is still to be proved by modern research methods. It is explained specially in the context of Kasa in children and said to be very effective in curing all the five types of kasa. The present study has shown significant relief by Amritadi Lozenges in children of Kaphaja kasa in comparison to Placebo lozenges in the signs & symptoms of Kaphaja Kasa. Moreover results are encouraging, cost effective, palatable & can be an alternative choice in patients of respiratory tract infection.

Keywords: Kasa; cough; lozenges; pranavaha srotas; children.

Introduction

The abnormality of respiration indicates disease, and its cessation marks death. This unique sign of life is affected in the disease Kasa i.e., cough. Cough is the fifth most common symptom for which patients seek care & prevalence rate of which is 25% in children worldwide. Cough usually occurs in association with acute upper respiratory infection, acute pharyngitis and acute bronchitis as well as in chronic sinusitis, all rank among the top 10 reasons for visiting pediatrician.[2] The cough is considered as a symptom in the modern medicine. The attack rate of cough in children is very high leading to morbidity and mortality. Sequential

administration of the Snehana, Swedana, Shodhana, Dhoopana, Shamana and Rasayana line of treatment forms the complete treatment of kasa expounded in the Ayurvedic literature.[3] Among these procedures, the Shamana line of treatment that includes oral administration of medicine is of utmost importance as the administration is very easy and also effective compared to shodhana in children. By looking at the individual herbal constituents of Amrutadi Lozenges, it appears that this combination should be very effective in combating the signs and symptoms associated with kasa. Therefore, the present research work was planned to evaluate the relative merit of the oral administration of Amritadi Lozenges carried out with following aims and objectives.

- To evaluate the effect of Amritadi Lozenges in curing Kaphaja Kasa.

Ingredients of Amritadi Lozenges:

Name of the drug	Latin name	Parts used
1.	Amrita	Tinospora cardifolia Stem
2.	Vacha	Acorus calamus Root
3.	Vaasa	Adathoda vasika Leaves
4.	Yashtimadhu	Glycyrhiza glabra Root
5.	Shirisha	Albezzia lebbeck Twak
6.	Shati	Hedychium spicatum Root
7.	Arka	Calotropis procera Leaves

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Method of preparation of drug

- After thorough cleaning and drying of raw drug in a shade, each drug was finely powdered separately.
- Equal quantity of all the seven finely powdered drugs were mixed together after weighing.
- Double quantity of guda (Jagary) was taken and guda paka was prepared.
- To this finely powdered (mixed) drugs were added and mixed well.
- Vati was prepared each weighing about 2 gms .
- It was used in the form of lozenges as a chewable tablet (vati).

For the purpose of controlled study Lozenges prepared out of wheat powder in guda paka, each weighing about 2 gm were used.

Materials & Methods*Source of data*

Diagnosed cases of Kaphaja Kasa were selected randomly from IPD and OPD of Kaumarabhrthya, S.D.M college of Ayurveda, and Hospital, Hassan and included in the study.

Method of collection of data

Patients who fulfilled the diagnosis and inclusion criteria were selected for the study. Selected children were thoroughly examined; both objective and subjective manifestations were recorded in a specially designed clinical Performa.

Diagnostic criteria

The diagnosis was made as per clinical signs and symptoms mentioned in Ayurvedic classics.

Inclusion criteria

Children belonging to the age group of 3-10 years and presenting with signs and symptoms of Kaphaja Kasa.

Exclusion criteria

1. Kshataja kasa
2. Kshayaja kasa
3. Kasa as an Anubandha lakshana in other systemic disease, ex. pneumonia
4. Kasa with sub-acute condition of more than thirty days of chronic history.

Dosage & Groups of the treatment

33 patients of Kaphaja Kasa were randomly divided into following 2 groups. Group A comprised of 16 patients & Group B comprised of 17 patients. Out of 33 patients 1 patient from group A & 2 patients from group B were dropped out & the study was completed on 30 patients.

Group-A

Children in the Trial group were given 4 Amritadi lozenges per day once in 4 hour to chew for a period of 10 days.

Group-B

Children in this group were given 4 placebo prepared out of wheat flour per day once in 4 hour to chew for a period of 10 days.

Duration of study

The treatment period was for 10 days and the total period of study was done for two months. Progress during treatment was recorded periodically once in 5 days. After the treatment the child was called for follow up once in a month. Both the groups were assessed before and after study as per the

graded clinical parameters of Kasa and relevant investigations. The variations in severity of Kaphaja Kasa and its re-occurrence were recorded.

Assessment criteria

1. Assessment was analyzed on the basis of improvement in the clinical features.
2. The assessment was based on the gradation of both Subjective and Objective clinical features before and after treatment.

Subjective criteria

1. *Number of bouts of cough:* The number of bouts of cough in one hour was noted in each patient and graded as follows:
 - More than 8 bouts of cough03
 - 3 to 7 bouts of cough02
 - Less than 3 bouts of cough01
 - Absence of bouts of cough00
2. *Duration of bout of cough:* The duration of each bout of cough in seconds was observed and the duration of 10 such bouts were counted and mean time of cough was calculated.
 - Duration of cough more than 10 secs03
 - Duration of cough in between 5 - 10 secs02
 - Duration of cough less than 5 secs01
 - Absence of cough00

Objective criteria

1. *Added sounds:* Added sounds like wheeze and crepitations were observed and graded as follows:
 - (a) *Wheeze*
 - Polyphonic wheezing all over the lung field.....03
 - Polyphonic wheezing limited to

- zones.....02
- Mild monophonic wheeze present.....01
- Wheezing absent.....00

(b) *Crepitations*

- Scattered all over the lung field03
- Distributed here and there in all the zones02
- Present in one or two zones01
- Absent crepitations.....00

2. *Sputum:*

- The quantity and consistency of sputum was observed and graded as follows:
 - Thick large quantity of solid sputum03
 - Moderately thick solid sputum02
 - Serous expectoration with traces of thick sputum.....01
 - No productive cough.....00

Laboratory investigations

Improvement in laboratory investigation report was observed before and after treatment to assess the improvement of the condition of the patient.

Assessment of overall effects of therapy

Overall effect of the therapy was assessed in terms of complete relief, marked relief, moderate relief, mild relief and unchanged is observed by adopting the following criteria.

- *Complete relief:* 100% relief in Chief complaints and no recurrence during follow up study were considered as complete relief.
- *Marked relief:* 75 - 100% improvement in chief complaints is recorded as marked relief.

	BT	AT	Mean Diff	% of improvement	SD	SE	t	P
Group A	2.6	0.9	1.66	64.10%	0.47	0.12	6.34	<0.001
Group B	2.6	2.2	0.3	12.8%	0.47	0.12	2.90	<0.01

	Group A		Group B	
	No. of Pts	%	No. of Pts	%
Unchanged	0	0	9	60
Mild	5	33.33	6	40
Moderate	10	66.66	0	0
Marked	0	0	0	0

- *Moderate relief*: 50 - 75% improvement in chief complaints is recorded as moderate relief.
- *Mild relief*: 25 - 50% improvement in chief complaints is considered as mild relief.
- *Unchanged*: Less than 25% reduction in chief complaints or recurrence of the symptoms to the similar extent of severity is noted as recurrence.

Effects of the Therapies

The results obtained and the effects of both the therapies on the each parameter of assessment are being explained here under a single heading.

1. Number of bouts of cough

It was found that there was a reduction of 64.10% in number of bouts of cough in Group-A which is statically significant as the 'p' value is <0.001 while Group-B showed a reduction

	Group A		Group B	
	No. of Pts	%	No. of Pts	%
Unchanged	6	40	10	66.66
Mild	4	26.66	2	13.33
Moderate	5	33.33	2	13.33
Marked	0	0	1	6.66

of 12.8 % in number of bouts of cough and was not significant with the 'p' value <0.001.

It was found that in Group-A around 33.33 % of patients got mild improvements & 66.66 % of patients got moderate improvements. In Group -B around 40 % of patients got mild improvement whereas 60 % of patients remained unchanged.

2. Duration of bout of cough

It was found that there was a reduction of 55.55 % in duration of bout of cough in Group- A which is statically significant as the 'p' value is <0.001 while Group-B showed a reduction of 11.4 % in duration of bout of cough and was not significant with the 'p' value <0.001.

It was found that in Group-A around 60 % of patients got mild improvements & 40 % of

	BT	AT	Mean Diff	% of improvement	SD	SE	t	P
Group A	2.4	1.06	1.33	55.55%	0.47	0.12	5.61	<0.001
Group B	2.3	2.0	0.2	11.4%	0.11	0.11	2.59	

	Group A		Group B	
	No. of Pts	%	No. of Pts	%
Unchanged	0	0	11	73.33
Mild	9	60	3	20
Moderate	6	40	1	6.66
Marked	0	0	0	0

	BT	AT	Mean Diff	% of improvement	SD	SE	t	P
Group A	1.8	0.55	1.33	70.58%	0.74	0.19	5.71	<0.001
Group B	1.26	0.86	0.4	31.57%	0.4	0.12	3.07	

Table 7: Showing the statistical analysis of Ronchi

	BT	AT	Mean Diff	% of improvement	SD	SE	t	P
Group A	2	0.6	1.4	70%	0.71	0.18	5.55	<0.001
Group B	1.2	0.8	0.33	27.27%	0.7	0.2	2.2361	

Table 8: Improvement in Ronchi of 30 Patients of Kaphaja Kasa

	Group A		Group B	
	No. of Pts	%	No. of Pts	%
Unchanged	12	80	12	80
Mild	2	13.33	3	20
Moderate	1	6.66	0	0
Marked	0	0	0	0

Table 10: Improvement in Quality of Sputum in 30 Patients of Kaphaja Kasaa

	Group A		Group B	
	No. of Pts	%	No. of Pts	%
Unchanged	0	0	4	26.66
Mild	2	13.33	10	66.66
Moderate	8	53.33	1	6.66
Marked	5	33.33	0	0

patients got moderate improvements. In Group -B around 20 % of patients got mild improvement & 6.66 % of patients got moderate improvement whereas 73.33 % of patients remained unchanged.

% of patients got mild improvements & 6.66 % of patients got moderate improvements & 80 % got unchanged. In Group -B around 20 % of patients got mild improvement whereas 80 % of patients remained unchanged.

3. Crepitation

It was found that there was a reduction of 70.58 % crepitation in Group- A which is statically significant as the 'p' value is <0.001 while Group-B showed a reduction of 31.57 % in crepitation and was not significant with the 'p' value <0.001.

5. Quality of Sputum

It was found that there was a reduction of 66.66% in quality of sputum in Group- A which is statically significant as the 'p' value is <0.001 while Group-B showed a reduction of 12.5 % in bouts of cough and was not significant with the 'p' value <0.001.

It was found that in Group-A around 26.66 % of patients got mild improvements & 33.33 % of patients got moderate improvements & 40 % of patients remained unchanged. In Group -B around 13.33 % of patients got improvement & 13.33 % of patients got moderate improvement, 6.6% of patients got marked improvement whereas 66.66 % of patients remained unchanged.

It was found that in Group-A around 13.33 % of patients got mild improvements & 53.33 % of patients got moderate improvement & 33.33 % patients got marked improvement. In Group -B around 66.66 % of patients got mild improvement & 6.66 % patients got moderate improvements whereas 26 .66% of patients remained unchanged.

4. Ronchi

It was found that there was a reduction of 70% Ronchi in Group- A which is statically significant as the 'p' value is <0.001 while Group-B showed a reduction of 27.27% in Ronchi and was not significant with the 'p' value <0.001.

6. Laboratory Investigation Values of AEC

The present study showed, Increase in AEC count in Group-A with mean reduction value of 32.22 % and it was not significant, where as 2.70 % reduction in mean score of AEC was observed in Group-B, which is statistically significant with the p value of <. 001.

It was found that in Group-A around 13.33

Table 9: Showing the statistical analysis of Quality of Sputum

	BT	AT	Mean Diff	% of improvement	SD	SE	t	P
Group A	2.8	0.9	1.86	66.66%	0.95	0.24	6.68	<0.001
Group B	2.6	2.3	0.33	12.5%	0.47	0.12	2.89	<0.001

Discussion

In Kaphaja Kasa the predominant dosha is Kapha & the main feature is cough with expectoration. Having kapha predominant body & indulging in kaphakara ahara -vihara dominantly increased the incidence of kaphaja kasa in children. By looking into the individual herbal constituents of the drug compound ie, Amrutadi Lozenges taken for present study. It was found that drugs are having both kasaghna & kaphaghna properties along with deepana, pachana, vatahara properties which is needed to bring back normalcy in respiratory tract. Moreover in the present study administration of drug in the form of lozenge is palatable along with local & systemic effects. In the present study, the disease kasa was more prevalent in male children (66.66%) in both the age group of 3-5 years (54.54%) and 6-8 yrs (45.45 %,) hailing from middle class (69.69%) and most probably because of cold living place (66.66%) or lack of knowledge about health (57.57%). Gradual onset (57.57%) with irregular time of occurrence (48.48%) and productive cough (100%) was observed. Comparison of the effects of both the groups showed that Amritadi lozenges provided significantly better relief in comparison to placebo lozenges in number of bouts of cough (54.4%), duration of cough bout (38.15%), crepitations (60.08%), rhonchi (59%) & bad quality of sputum (54.2%) of kaphaja kasa. In the study, high significant results were observed in reducing the bouts of cough, duration of bout of cough, added sounds and quantity of sputum in Group A patients. Whereas no significant results were noticed in the Group B. Hence it can be claimed that, Amritadi Lozenge is palatable, effective, safe and cheap remedy for the treatment of Kaphaja kasa in children.

Conclusion

Based on the observations and results of the study, the following conclusions were made. Among 30 patients in maximum 11patients

Snigdhaahara was the cause for Kaphaja Kasa. Next to this Madhura and Abhishyandi ahara was found as a cause in each 5 patients. Whereas it was not significant in 8 patients, which might be because of some seasonal variations. Maximum patients (22) of Kaphaja Kasa were from Anupa desha. Gala talu lepa (11 patients), Kante kandoo (9 patients) and Swashabdha vaishamya (7 patients) was predominantly observed as poorava roopa of Kaphaja kasa in the present study. Hot water and Kapha nishtivana has been found good in relieving Kasa for some moments. AEC was found moderately elevated in 16 patients where as it was within normal limits in 17 patients. Children of Trial group who has been administered Amritadi Lozenges showed good relief compared to children of Placebo group shows the efficacy of drug.

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