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EVALUATION OF EFFICACY OF DASHAMOOLA KASHAYA KAVALA IN THE MANAGEMENT OF CHRONIC NON-SPECIFIC PHARYNGITIS: A RANDAMIZED CONTROLLED CLINICAL STUDY."

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Abstract

Ayurveda is the science of life, which has 8 Specality branches. Shalakya Tantra is an important branch of Astanga Ayurveda which deals with the diseases of Eyes, Ears, Nose, Throat and Head. Throat is the common passage for air and food that is taken, so it is the site which is frequently exposed to infections from bacteria, Virus…Pharyngitis i.e the inflammation of Pharynx is very commonly occurring disease of Throat. This is a comparative study to evaluate the efficacy of Dashamoola Kashaya Kavala and Triphala Kwatha Kavala in the management of chronic non-specific pharyngitis.

Introduction

Shalakya Tantra is an important branch of Ashtanga Ayurveda which deals with the diseases of Eyes, Ears, Nose, Throat and Head[1]. Throat is the common passage for air and food that is taken, so it is the site which is frequently exposed to infections from bacteria, Virus or other organisms. Pharyngitis i.e the inflammation of Pharynx is very commonly occurring disease of Throat. It is characterized by sore throat, cough, and runny nose, harshness of voice, headache and fever[2]. It is typically a type of respiratory tract infection caused by virus, bacteria or allergy[3].

Pharyngitis occurring frequently and of long duration is termed as chronic Pharyngitis. It can cause a significant problem in day-to-day activities starting from throat discomfort in the morning to alteration of voice, which affects both their personal life and professional life. Chronic inflammatory condition of the pharynx if left untreated Leeds to hypertrophy of mucosa, seromucinous glands, sub epithelial lymphoid follicles and muscular coat of the pharynx[4].

In India around 36-40% of people suffer from chronic Pharyngitis. Every fourth patient attending ENT OPD will have the symptoms of chronic pharyngitis[5] and administration of anti-inflammatory drugs and antibiotics is the choice of treatment in contemporary science[6]. In spite of administering these drugs repeatedly, the reoccurrence of the symptoms are seen as many patients are becoming resistance to antibiotics.

In Ayurveda classics these symptoms can be seen in Galashotha,Galagraha, swarabheda and vataja kasa[7].The drug Dashamoola kashaya is mentioned in all classical texts having shothahara activity. Gada Nigraha specifically mentions Dashamoola kashaya in Shotha, sleepada, galagandarogachikitsa[8, 9].

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Triphala is a combination of three drugs – Haritaki, Vibhitaki and Amalaki which are known very well for their Tridoshahara, Shothahara, Kasahara along with Rasayana properties. A previous study done on the efficacy of Triphala Kashaya Kawala in the management of Pharyngitis[10] has given satisfactory results and so this study is taken up to compare its efficacy with the trial drug – Dashamoola Kashaya Kavala.

Aims & Objectives

- To evaluate the effect of Dashamoola Kashaya kavala in the management of Chronic Non-Specific Pharyngitis
- To compare the efficacy of both Dashamoola Kashaya kavala and Triphala Kashaya Kavala in the management of Chronic Non-Specific Pharyngitis

MATERIALS AND METHODS:

RESEARCH DESIGN – Controlled double arm open label Prospective, Interventional study with pre hoc and post hoc test design.

SOURCE OF DATA:

Participant source: Patients with the clinical features of Chronic Pharyngitis coming under the inclusion criteria through screening approaching the OPD and IPD of Shalakya Tantra, JSS Ayurveda Hospital, Mysuru were selected for the study.

Drug source: The raw drugs required for Dashamoola Kashaya and Triphala Kashaya were procured from the identified vendor and were prepared in GMP Certified Pharmacy of JSS AYURVEDA PHARMACY, MYSURU.

Screening the patients: Screening form which contains the Questionnaire to fulfil the inclusion criteria along with a detail Case sheet were used to recruit the patients presenting with signs and symptoms of Chronic Pharyngitis.

Sampling technique: Purposive sampling

Sample size : It is a comparative clinical study where in 40 subjects diagnosed as Chronic Pharyngitis were randomly assigned into two groups i.e., Group A (Trial Group) and Group B(Control Group) , each comprising minimum of 20 patients who completed the study.

Sampling – Two groups comparative interventional study of 40 Patients of Chronic Pharyngitis where random allocation method was used.

DIAGNOSTIC CRITERIA:

Diagnosis will be done on the basis of signs and symptoms of chronic pharyngitis, like

□ Sore throat & discomfort

□ Change in voice

□ Cough

□ Headache

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□ Congestion of pharynx,

□ Inflamed and Enlarged uvula.

□ Tonsilitis

Inclusion criteria:

1. Subjects diagnosed with Chronic non-specific pharyngitis with three or more than three attacks in a year.

2. Patients of either sex.

3. Patients aged between 10-40 yrs.

4. Haematological and biochemical parameters within normal limits.

5. Willing to sign inform consent document.

Exclusion criteria

1. Patients with cardiovascular, cerebrovascular, respiratory, liver or renal diseases or any other systemic disease.

2. Patients with h/o tuberculosis, leprosy, syphilis, rhinoscleroma, untreated dental caries, chronic tonsillitis, diabetes, ischemic heart disease and patients on steroid therapy.

3. Patients under antenatal and postnatal care.

4. Patients unwilling to provide informed consent or abide by the requirements of the study

INVESTIGATIONS PERFORMED-

- Blood investigations: Haemoglobin percentage, Total count, Differential count, Platelet count, Erythrocyte sedimentation rate.
- Throat Swab for culture and Sensitivity

INTERVENTION

It is a randomized comparative clinical study having two groups – A and B, of 20 patients each.

Sl No	Group	Drug	Duration
1	Group A	Dashamoola Kwatha	30 days
2	Group B	Triphala Kwatha	30 days

Group – A, in this group, 20 patients of Chronic Pharyngitis will be given Dashamoola Kashaya Kavala for one month.

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Dosage: Subjects who are included in the Group –A will be advised to do Kavala of 100ml of Sukoshna Dashamoola Kashaya for 1min, twice daily in morning and at night for a period of 30days, from day1.

Group – B, in this group, 20 patients of Chronic Pharyngitis will be given Triphala Kasaya Kavala for one month.

Subjects who are included in the Group –B will be advised to do Kavala of 100ml of Sukoshna Triphala Kashaya for 1min, twice daily in morning and at night for a period of 30days, from day1.

In this study 40 pts with mild to moderate Pharyngitis were enrolled. The pts are assessed during the follow-up visits (day1, day15, day30 and follow up on day 45, day 60) through clinical examination & lab parameters.

STUDY PERIOD: 2 months- 60 days

Table 6: Assessment Schedule of Clinical Study

Assessment	Stage	Day
1st	BT (Before Treatment)	Day 0
2nd	(During Treatment)	Day 15
3rd	(After Treatment)	Day 30
4th	(At Follow-Up)	Day 45
5th	(At Follow-Up)	Day 60

ASSESSMENT CRITERIA –

- □ Sore throat & discomfort
- □ Change in voice
- □ Cough
- □ Headache
- □ Congestion of pharynx,
- □ Inflamed and Enlarged uvula.

Gradation index: For the purpose of statistical analysis the parameters considered for assessment will be scored on a scale from 0 to 3. (0-No symptom, 1-Mild, 2-Moderate, 3-Severe)

STATISTICAL ANALYSIS:

For statistical analysis, the data was obtained using Case Report form (CRF) designed by incorporating all aspects for the study and was compiled on to a MS office excel sheet. Data is presented in tabulations and drawings and using SPSS (Statistical package for social sciences) version 20 and analysis is done.

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Descriptive Statistics: Demographic data and other relevant descriptive information was analysed with descriptive statistics expressing in frequency (f), Percentage (%), Range. Continuous data is expressed in Mean, Standard deviation (SD), Standard error of Mean (SEM), Standard error of difference between two means (SE). Nominal and Ordinal data will be expressed in Median and Percentages.

Inferential Statistics: To infer the clinical study and to draw conclusions Non-Parametric tests was applied accordingly as all the parameters falls under ordinal data.

Level of significance: Keeping alpha error at 5% and beta error at 20%, power at 80%, Changes in One tailed test with $P<0.05$ was considered as statistically significant

Non-parametric test:

For intra comparison of data (Within the group analysis) **Friedman's test with Wilcoxon-signed rank test** as post hoc after applying Bonferroni correction was applied.

For inter comparison of Data (Between the group analysis) **Mann-Whitney U test** was employed for Ordinal data.

Observation:

In the present study total 46 patients were enrolled and they were divided into 2 groups i.e GROUP A – 20 Subjects, GROUP B – 20 subjects, and 06 subjects are droupouts.

Age of the participants in group A ranges from 18 years to 38years with mean (SD) age 31.25(6.302) years and of group B ranges from 13 years to 39 years with mean (SD) age 29.05(8.87) years.

Table 1. Gender wise distribution of participants

Group		Frequency	Percentage
A	Male	7	35.0
	Female	13	65.0
	Total	20	100.0
B	Male	9	45.0
	Female	11	55.0
	Total	20	100.0

Comparison between Day 0 and Day 60 within group A and group B

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Group A

Symptom	Day 0 Median (IQR)	Day 60 Median (IQR)	Z-value	p-value
SORE THROAT	2(2-3)	0	-4.008	0.001
CHANGE IN VOICE	2(1-2)	0	-3.852	0.001
COUGH	2(1-2)	0	-3.839	0.001
HEADACHE	0(0-1_	0	-2.646	0.008
PHARYNGEAL CONGESTION	2	0	-4.089	0.001
UVULAL INFLAMMATION	1(1-2)	0	-4.134	0.001
TONSILLITIS	1(0-1)	0	-3.557	0.001

Group B

Symptom	Day 0 Median (IQR)	Day 60 Median (IQR)	Z-value	p-value
SORE THROAT	3(2-3)	0	-4.030	0.001
CHANGE IN VOICE	2(2-3)	0	-4.011	0.001
COUGH	2(1-2)	0	-3.905	0.001
HEADACHE	1	0	-3.448	0.001
PHARYNGEAL CONGESTION	2(1-2)	0	-3.919	0.001
UVULAL INFLAMMATION	2	0	-3.919	0.001
TONSILLITIS	1(1-2)	0	-3.874	0.001

Comparison of objective parameters between BT and AT within group A and group B

Group A

Objective parameters	Day 0 Mean (SD)	Day 60 Mean (SD)	t-value	p-value*
Hb	13.16(2.11)	13.36(2.17)	-5.037	.000
TC	7866.5(1130.57)	7719.5(1014.08)	.972	.343
DC-N	49.5(6.58)	50.15(6.62)	-1.216	.239
DC-L	31.35(5.18)	32.4(4.044)	-1.961	.065
DC-M	4.4(1.46)	4.35(1.09)	.160	.874
DC-E	3.75(1.89)	2.75(1.25)	2.874	.010
DC-B	0.95(0.76)	0.65(0.49)	1.674	.110

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PLAT	3.47(0.55)	3.5(0.48)	-.924	.367
ESR	25.55(10.13)	23.2(7.25)	2.669	.015
THROAT-SWAB	Median-0	Median-0	-1.414	0.157**

*Paired t test**Wilcoxon signed rank test

Group B

Objective parameters	Day 0 Mean (SD)	Day 60 Mean (SD)	t-value	p-value*
Hb	13.31(1.93)	13.42(1.97)	-2.465	.023
TC	8130.5(1036.25)	8225.5(1016.42)	-4.708	.000
DC-N	50.25(4.81)	50.85(4.36)	-1.580	.131
DC-L	27.65(5.78)	28.4(6.01)	-1.702	.105
DC-M	3.6(1.53)	3.25(1.21)	1.677	.110
DC-E	3.1(2.81)	2.25(1.58)	2.429	.025
DC-B	1.35(1.18)	1.1(0.91)	1.561	.135
PLAT	3.22(0.64)	3.3(0.55)	-2.491	.022
ESR	29(5.84)	26.25(4.92)	3.684	.002
THROAT-SWAB	Median-0	Median-0	-1.414	0.157**

*Paired t test

Comparison of AT between group A and group B

Objective parameters	Group A Mean(SD)	Group B Mean(SD)	t-value	p-value*
Hb	13.36(2.16)	13.42(1.97)	-.092	.927
TC	7719.5(1014.08)	8225.5(1016.42)	-1.576	.123
DC-N	50.15(6.62)	50.85(4.36)	-.395	.695
DC-L	32.4(4.04)	28.4(6.01)	2.469	.018
DC-M	4.35(1.09)	3.25(1.21)	3.023	.004
DC-E	2.75(1.25)	2.25(1.58)	1.107	.275
DC-B	0.65(0.49)	1.10(0.91)	1.107	.059
PLAT	3.51(0.48)	3.30(0.55)	-1.945	.219
ESR	23.20(7.25)	26.25(4.92)	1.249	.128
THROAT-SWAB	Median-0	Median-0	0	1.0**

*t test for independent samples**Mann-Whitney U test

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DISCUSSION

In the present study 46 subjects were selected randomly irrespective of sex , age, and religion for the clinical trial, who have mild to moderate signs and symptoms of Pharyngitis. They were divided into 2 groups as Group – A and Group – B OF 20 subjects each and 06 subjects didn't complete the study and were considered as dropouts.

GROUP A

Among 20 subjects, 07 were males and 13 were females, and subjects in the age group of 30-40 yrs, were more. Majority of them belong to urban population and they are engaged in outdoor work i.e exposed to Dust and infection. Most of the subjects were having Allergic Rhinitis as the associated symptoms(pratisyaya). Symptoms such as Sore Throat, Change in voice, Cough, Headache, Pharyngeal Congestion, Uveal inflammation, Tonsilitis were reduced considerably with in 15 days of treatment. Diet restriction such as avoidance of cold and oily, fried items were advised. Hence Dashamoola Kwatha Kavala showed good result in the management of Chronic Pharyngitis.

GROUP B

Among 20 subjects, 09 were males and 11 were females, and subjects in the age group of 30-40 yrs, were more. Majority of them belong to urban population and they are engaged in outdoor work i.e exposed to Dust and infection. Most of the subjects were having Allergic Rhinitis as the associated symptoms(pratisyaya). Symptoms such as Sore Throat, change in voice, Cough, Headache, Pharyngeal Congestion, Uveal inflammation, Tonsilitis were reduced considerably within 30 days of treatment. Diet restriction such as avoidance of cold and oily, fried items were advised. Hence Triphala Kwatha Kavala showed Moderate result in the management of Chronic Pharyngitis.

Throat swab was not positive for any type of organism in majority of cases. This may be due to Chronicity or may be the symptoms due to Allergy to dust etc…Hence it is not significant in this study.

Overall, in both clinical and objective evaluations, results were encouraging in both the groups. Clinical assessment of Pharyngitis was found statistically significant with Dashamoola Kwatha Kavala than Triphala Kwatha Kavala in Clinical features of Chronic Pharyngitis like Sore Throat, Change in voice, Cough, Headache, Pharyngeal Congestion, Uveal inflammation, Tonsilitis.

Conclusion

Pharyngitis is the most commen disease that comes to ENT opd, which affects all age group people and both genders.

Pharyngitis occurs very frequently, as the Pharynx is a common passage for nasal and oralcavity.

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In Ayurveda - Galagraha and Galashotha/Kantashotha is compared to chronic Pharyngitis depending on the signs and symptoms.

Repeated administration of antibiotics and anti-inflammatory drugs leeds to antibiotic resistance in many individuals leading to reoccurrence of the disease.

In the present research, the trial drug Dashamoola Kwatha Kavala has given excellent results in comparison with Triphala Kwatha Kavala in Chronic Pharyngitis.

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