Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 13 (4), 2022; 1004-1012

Evaluation of comparative efficacy of Guduchyadi Leha Versus Kalyanaka Leha as a standard control in the management of Gadgada (Stuttering) in children: A Randomized double-blind clinical study

Research Article

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Abstract

Background- Speech is a unique characteristic of a human being that helps to convey his/her thoughts, and ideas to others. Stuttering is a speech disability in which a person is unable to speak with a normal fluency of speech. Ayurveda portrays a disease named '*Gadgada'*, which shows the same clinical features as 'Stuttering' in conventional science. The present study aimed to compare the efficacy of '*Guduchyadi Leha*' and '*Kalyanaka Leha*' as local applications on the tongue and same as internal administration also for the management of *Gadgada* in children. Material and Method- This Clinical trial was a parallel-arm, randomized double-blind study. A total of 30 patients were enrolled in this study after fulfilling the inclusion criteria, 15 patients were in each group. In Group A- *Kalyanaka Leha* (Standard control (drug selected on the basis of previous work done in 2012)) and in Group B- *Guduchyadi Leha* (Trial drug) was given for local application over the tongue (*Jivha Pratisarana* and *Prashan*) same as for internal administration also for 45 days. Assessment of stuttering was done by using the parameters of the SSI-4 scale fortnightly. Results- Positive results were seen in both groups. On the 90th day, follow-up showed both the group was reduced stuttering and there was an improvement in the fluency of speech. Conclusion- Significant results were noted in both the interventions with less % of regression of stuttering after treatment.

Key Words: *Guduchyadi Leha, Gadgada*, Stuttering, *Jivha Pratisarana, Kalyanaka Leha*, SSI-4.

Introduction

Humans have a unique structure of mouth and tongue which are evolved to facilitate the production of speech. Along with this, humans also have a unique brain mechanism that permits them to automatically produce multifaceted skillful and careful movements of the tongue, lips, palate, and other structures.

Speech is a unique characteristic of human beings. It is an aptitude to express his or her judgments, opinions, philosophies, concept, ideas, designs or any other evidence with the help of articulation of sound into meaningful words. Fluency in speech is needful in the psychosocial development of the child and also plays important role in the transfer of thoughts from one person to another (1) the problem in fluency of speech is the reason of disruption in the development of emotional and social behavior of children such as stuttering, which is being a most disturbing and severe problem in the age of childhood (2). Classic textbooks of Ayurveda contribute to significance of speech and its associated diseases. *Vak Indriya* is one of the *Karmendriya* recognized for speech.

Ayurvedic classics give importance to speech and its related disorders. *Vak Indriyas* is one of the *Karmendriya* attributed to speech. Concepts of *Mooka, Minmina, Gadgadatwa, Vaksanga* are also explained in science which indicates pathological aspects of speech disorders. The approach of Ayurveda towards the production of sound or speech is denoted as *Vak Pravrutti*. It is a major function of *Vata Dosha* and a specific function of *Udana Vata*, which is a subtype of *Vata Dosha* (4). *Vak* enables human beings to express his or their opinions, concepts, thoughts, etc. (5) which is the important role of *Vak-indriya* (6).

Gadgada is a universally encountered speech disability in day to the practice of Pediatrics. In the present era of life, it is a burning ailment in the childhood age group. India is the second-largest populated country all over the world (7) and children are the pillar of developing countries Prevalence of Stuttering in preschool age is nearly about 9% and approximately 21% of older children are suffering delayed speech milestones (8). In India, the incidence rate of speech disorders is near about 11% in the age group of 5 – 12 years of children.

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Disorders of speech can make the child physiologically, psychologically, emotionally and socially handicapped. In medical sciences, there is no specific treatment protocol for stuttering to get relieved from its symptoms, speech therapy takes a big hand in the treatment of stuttering (9) but in the results of speech therapy, variations have been observed according to speech therapists. Therefore, there was a need to check the effectiveness of Ayurvedic drug compositions over stuttering, which will reduce the symptoms of stuttering in a short period of time, with negligible side effects and financially affordable for all economical classes. Hence this study was carried out to evaluate the efficacy of *Guduchyadi leha* in comparison with *Kalyanaka Leha* in the management of *Gadgada.* The reason behind the selection of *Guduchyadi Leha*, the ingredients of *Guduchyadi leha* are mentioned in *Vangsen Samhita* which is indicated for *Gadgada*. *Kalyanaka Leha*, showed proven result for the treatment of *Gadgada* in 2012)

Till today, studies on stuttering including local application of medicated formulated *Leha* on the tongue have not been carried out else. In this study, *Leha* was directly applied over the tongue to determine how both the intervention i.e., *Guduchyadi Leha* and *Kalyanaka Leha* will show results in stuttering.

This study aimed to analyze and compare the efficacy of *Guduchyadi Leha* and *Kalyanaka Leha* in the management of *Gadgada*, with a focus on stuttering. The objectives of the study were to check the efficacy of *Guduchyadi Leha* and *Kalyanaka Leha* individually by using SSI-4 in the management of stuttering.

Ethical Clearance

The research work was approved by Institutional Ethical Committee of Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha (MGACHRC/IEC/ August-2020/96) and C.T.R.I. registration (CTRI/ 2020/09/027751).

Objectives of the study

- To assess the efficacy of *Guduchyai Leha* in the management of *Gadgada* using Stuttering Severity Instrument – 4.
- To assess the efficacy of *Kalyanaka Leha* in the management of *Gadgada* using Stuttering Severity Instrument – 4.
- To evaluate the comparative efficacy of *Guduchyadi Leha* and *Kalyanaka Leha* in *Gadgada* using Stuttering Severity Instrument - 4

Materials and Methods

The trial drug *Guduchyadi Leha* is a modified form of *Guduchyadi Ghrita*, the modification of the drug was done because it is very difficult to administer *Ghrita* in children, to enhance its palatability and easy acceptability *Guduchyadi Ghrita* was modified as *Guduchyadi Leha* (10). The required raw materials for the preparation of Guduchyadi Leha and Kalyanaka Leha were procured from reliable sources and were authenticated by the department of Dravyaguna MGACH&RC. The trial and standard drug both were prepared in Dattatray Rasashala, Salod (H).

Guduchyadi Leha and *Kalyananka Leha* was prepared by author in institutional Rasashala. The ingredients of Formulation are cited in table 1. The formed *Leha* was applied over the tongue (*Jivha Pratisarana*) as per the decided dosage given below. After application, the *Leha* was left as it is on the tongue. As both formulations were sweet in taste, no difficulty in the administration was noticed.

Table 1: Contents of *Guduchyadi Leha and Kalyananka Leha*

Sr No	Drug Name	Botanical name / English name	Part used	Ratio
Contents of *Guduchyadi Leha*				
1	*Guduchi*	*Tinospora cordifolia* Willd	Stem	250 g
2	*Apamarga*	*Achyranthus aspera* Linn	Leaf	250 g
3	*Vidanga*	*Embelia ribes* Burm F	Fruit	250 g
4	*Shankhapushpi*	*Convolvulus pluricualis* Chois	*Panchang*	250 g
5	*Vacha*	*Acorus calamus* Linn	Roots	250 g
6	*Shatavari*	*Asparagus racemosus* Willd	*Kanda*	250 g
7	*Haritaki*	*Terminalia chebula* Retz	Fruit	250 g
8	*Shunthi*	*Zingiber officinale* Roscoe	Rhizome	250 g
9	*Sita/Sharkara*	Sugar	-	250 g
10	*Ghrita*	Clarified butter	-	50 ml
11	*Madhu*	Honey	-	50 ml
Contents of *Kalyanaka Leha*				
Sr	**Drug Name**	**Botanical name**	**Part used**	**Ratio**
1	*Haridra*	*Curcuma longa* Linn	Rhizome	250 g
2	*Vacha*	*Acorus calamus* Linn	Rhizome	250 g
3	*Kushta*	*Saussurea lappa* C. B.	Root	250 g
4	*Ajmoda*	*Apium graveolens* Semen	Fruit	250 g
5	*Jirak*	*Cuminum cyminum* Linn	Fruits	250 g
6	*Pippali*	*Piper longum* Linn	Fruit	250 g
7	*Shunthi*	*Zingiber officinale* Roscoe	Rhizome	250 g

8	*Yashtimadhu*	*Glycerrhiza glabra* Linn	Root	250 g
9	*Saindhav*	Sodium chloride	-	250 g
10	*Sita/ Sharkara*	Sugar	-	250 g
11	*Ghrita*	Clarified butter	-	50 ml
12	*Madhu*	Honey	-	50 ml

Selection of subjects

A total of 30 patients were enrolled in the trial after getting ethical approval from IEC and C.T.R.I. This clinical trial was carried out in children age group of 2-12 years with complaints of stuttering, patients were selected from OPD, IPD and Specialty Camps.

Type of Study

The present clinical trial was a parallel-arm, randomized double-blind study.

Randomization

Randomization was done by using a computerized generated randomized table and divided into two groups. Group A was treated with *Kalyanaka Leha* (Standard drug) and Group B was treated with *Guduchyadi Leha* (Trial drug). The coding of the trial drug and standard drug was done by another person who was not involved in any part of the study trial. The Coded document was sealed in an envelope and kept safe in custody to avoid bias for the same. Envelop was opened after completion of the study to reveal the drug for interpretation of the result. Assessed observations were documented during follow-ups were analyzed and findings were evaluated by using statistical analysis to compare and establish the effectiveness.

Inclusion Criteria

- Patients in the age group of 2 years to 12 years affected children were taken.
- Children with clinical manifestations of speech impairment i.e. stuttering were included in the study.
- Patients were selected irrespective of gender, religion, or socioeconomic status.
- Patients with diagnosed cases of delayed development of speech due to the sequel of cured neurological disorder which is cured.

Exclusion Criteria

- Deaf children were excluded.
- Children with severe infection, brain trauma
- Patients suffering from cleft palate & cleft lip or conditions where surgical intervention is required
- Patient suffering from stomatitis.
- Children do not speak small sentences.
- Children suffering from autism spectrum disorder.

Criteria for Withdrawal

- If any side effects were observed during the research.
- If symptoms get aggravated.
- If the patient refuses to continue with treatment.

Assessment Criteria

For the assessment of the efficacy of both the interventional drug, following the Stuttering Severity Instrument – 4 (SSI-4) Scale were opted.(11)

Table 2: Interventions of both groups with posology

Objectives	Group A	Group B
Drug	*Kalyanaka Leha*	*Guduchyadi Leha*
Dose	2-5 years – 1.5 gram/ day in 3 divided doses 6-12 years- 5 gram/day in 2 divided doses	2-5 years – 1.5 gram/ day in 3 divided doses 6-12 years- 5 gram/day in 2 divided doses
Route of administration	Local application over tongue and same internal administration	Local application over tongue and same internal administration
Duration	90 days	90 days
Follow-up	Fortnightly	Fortnightly

Follow-up and Monitoring

All the enrolled children were called for follow-up after every 15 days. Every follow-up, re-assessment was done by using the same scale and observed values were noted in proforma.

Observation and Result

Table 3: Gender wise distribution of patients in Group A and B

Study Variables		Group		Chi-Square Test Statistic
		A	B	
Gender	**Male**	8 (53.3%)	12 (80.0%)	Chi Square = 2.400 P = 0.121
	Female	7 (46.7%)	3 (20.0%)	

Table 3 shows gender-wise distribution of patients in both groups. In Group Sample A, Male to Female ratio is 8:7 and in Group Sample B, Male to Female ratio is 12:3. There are 15 participants was enrolled in each group with a non-significant mean difference in the Male and Female ratio.

Table 4: Religion wise distribution of patients in Group A and B

Study Variables		Group		Chi Square Test Statistic
		A	B	
Religion	Hindu	15 (100.0%)	15 (100.0%)	--

Table 4 showed that in Group A and Group B both groups were having 15 (100.0%) Hindu patients

Table 5: Distribution of patients in Group A and B according to Socioeconomic status

Study Variables		Group		Chi Square Test Statistic
		A	B	
Socio Economic Status	**Middle Class**	11 (73.3%)	12 (80.0%)	Chi Square = 0.186 P = 0.666
	Poor	4 (26.7%)	3 (20.0%)	

In table 5, it has been observed that Group A were having 11 (73.3%) patients from the middle class and 4 (26.7%) patients from the poor category. Group B having 12 (80.0%) patients from the middle class and 3 (20.0%) patients were from poor category.

Table 6: Distribution of patients according to Appetite

Study Variables		Group		Chi Square Test Statistic
		A	B	
Appet-ite	**Average**	5 (33.3%)	5 (33.3%)	Chi Square =3.377 P = 0.337
	Good	6 (40.0%)	5 (33.3%)	
	Moderate	2 (13.3%)	5 (33.3%)	
	Poor	2 (13.3%)	0 (0.0%)	

In table 6 it has been observed that 14 (93.3%) patients of Group A were having sound sleep and 1 (6.7%) patient was having disturbed sleep. In Group B, all 15 (100.0%) patients were having sound sleep.

Table 7: Distribution of patients according to Bowel Habits

Study Variables		Group		Chi Square Test Statistic
		A	B	
Bowel Habits	**Irregular**	2 (13.3%)	3 (20.0%)	Chi Square =0.240 P = 0.624
	Regular	13 (86.7%)	12 (80.0%)	

Table 7 showed that in Group A, 2 (13.3%) patients had irregular bowel habit and 13 (86.7%) patients had regular bowel habit. In Group B, 3 (20.0%) patients had irregular bowel habit and 12 (80.0%) patient had regular bowel habit.

Table 8: Distribution of patients according to Sequel of Developmental Delay

Study Variables		Group		Chi Square Test Statistic
		A	B	
Sequel of Developmental Delay	**No**	15 (100.0%)	15 (100.0%)	--

Table 8 showed that among Group A and B, there was no patient who suffering from developmental delay in past and having stuttering as sequel.

Table 9: Distribution of patients according to Delivery

Study Variables		Group		Chi Square Test Statistic
		A	B	
Delivery	**Preterm**	5 (33.3%)	4 (26.7%)	Chi Square = 0.144 P = 0.705
	Term	10 (66.7%)	11 (73.3%)	

Table 9 shows that in Group A, 5 (33.3%) patients were born preterm, 10 (66.7%) patients were born term and in Group B, 4 (26.7%) patients were born newborn and 11 (73.3%) patients born term.

Table 10: Distribution of patients according to history of NICU stay

Study Variables		Group		Chi Square Test Statistic
		A	B	
H/O NICU Stay	**Yes**	6 (40.0%)	7 (46.7%)	Chi Square = 0.136 P = 0.713
	No	9 (60.0%)	8 (53.3%)	

In table 10 it is observed that in Group A out of 15, 6 (40.0%) patients required NICU stay and in Group B out of 15, 7 (46.7%) patients required NICU stay.

Table 11: Distribution of patients according to schooling

Study Variables		Group		Chi Square Test Statistic
		A	B	
Pre-schooler/ School going	Pre-schooler	5 (33.3%)	7 (46.7%)	Chi Square = 0.556 P = 0.456
	School going	10 (66.7%)	8 (53.3%)	

Table 11 showed that in Group A 5 (33.3%) patients were of preschooler and 10 (66.7%) patients were school going and in Group B 7 (46.7%) patients were of preschooler and 8 (53.3%) patients were school going.

Table 12: Distribution of patients according to infective history

Study Variables		Group		Chi Square Test Statistic
		A	B	
Infective History	Recurrent Tonsillitis	1 (6.7%)	1 (6.7%)	Chi-Square=2.000 P=0.572
	Tonsillitis	1 (6.7%)	1 (6.7%)	
	No	13 (86.7%)	13 (86.7%)	

In table 12 it has been observed that in both the group A and B 1 (6.7%) patient was suffering with recurrent tonsillitis, 1 (6.7%) patient was having tonsillitis and 13 (86.7%) patients wasn't having any infective history.

Table 13: Distribution of patients according to probable cause of Stuttering

Study Variables		Group		Chi Square Test Statistic
		A	B	
Probable cause of stuttering	Fear	3 (20.0%)	4 (26.7%)	Chi-Square = 3.700 P = 0.717
	Anxiety	3 (20.0%)	2 (13.3%)	
	Fear & Anxiety	4 (26.7%)	4 (26.7%)	
	Fall from bed	0 (0.0%)	1 (6.7%)	
	Vacuum Delivery	0 (0.0%)	1 (6.7%)	
	Unknown	5 (33.3%)	3 (20.0%)	

In table 13, it has been observed that in Group A, the probable cause of stuttering may be fear for 3 (20.0%), anxiety for 3 (20.0%), fear and anxiety for 4 (26.7%), unknown cause for 5 (33.3%) patients. In Group B, probable cause of stuttering was fear for 4 (26.7%), anxiety for 2 (13.3%), fear and anxiety for 4 (26.7%) and history of fall from bed for 1 (6.7%), vacuum delivery for 1 (6.7%) and unknown cause for 3 (20.0%) patients.

Table 14: Distribution of patients as per the type of stuttering

Study Variables		Group		Chi Square Test Statistic
		A	B	
Type of Stuttering	Primary	10 (66.7%)	11 (73.3%)	Chi-Square = 0.159 P = 0.690
	Secondary	5 (33.3%)	4 (26.7%)	

Table 14 showed that in Group A, 10 (66.7%) patients were suffering from primary stuttering, 5 (33.3%) patients were suffering from secondary stuttering. In Group B, 11 (73.3%) patients were suffering from primary stuttering and 4 (26.7%) patients were suffering from secondary stuttering.

Table 15: Distribution of patients according delay in sentence articulation

Study Variables		Group		Chi Square Test Statistic
		A	B	
Delay in Sentence articulation	Yes	8 (53.3%)	6 (40.0%)	Chi-Square = 1.327 P = 0.515
	No	7 (46.7%)	9 (60.0%)	

In table 15 it has been observed that 8 (53.3%) patients were suffered from delay in speech making and 7 (46.7%) patients were had normal sentence making in Group A. In Group B, 6 (40.0%) patients were suffered from delay in speech making and 9 (60.0%) patients were had normal sentence making.

Table 16: Distribution of patients as per the previous speech therapy course taken

Study Variables		Group		Chi Square Test Statistic
		A	B	
Speech Therapy	Yes	3 (20.0%)	5 (33.3%)	Chi-Square = 0.682 P = 0.409
	No	12 (80.0%)	10 (667%)	

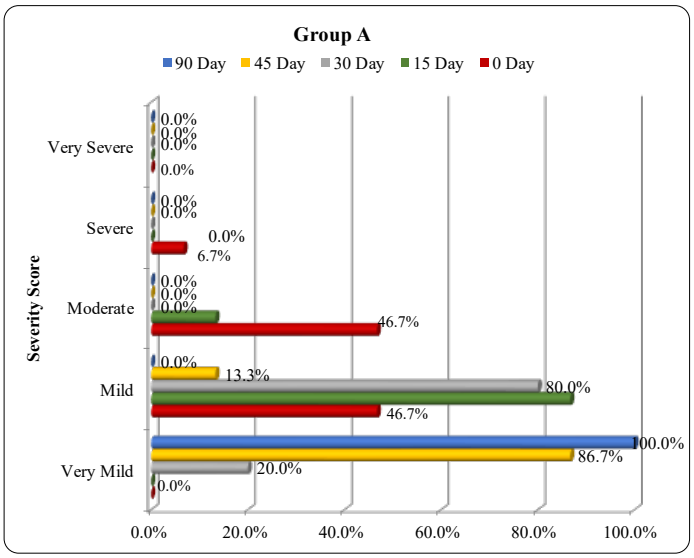
Table 16 showed that in Group A, out of 15 patients 3 (20.0%) patients took speech therapy and Group B, out of 15 patients 5 (33.3%) patients took speech therapy previously.

Table 17: Distribution of patients as per disturbed frequency of speech on daily basis

Study Variables		Group		Chi Square Test Statistic
		A	B	
Disturbed Frequency of speech	Always	9 (60.0%)	7 (46.7%)	Chi-Square= 1.250 P=0.535
	Rarely	1 (6.7%)	3 (20.0%)	
	Sometimes	5 (33.3%)	5 (33.3%)	

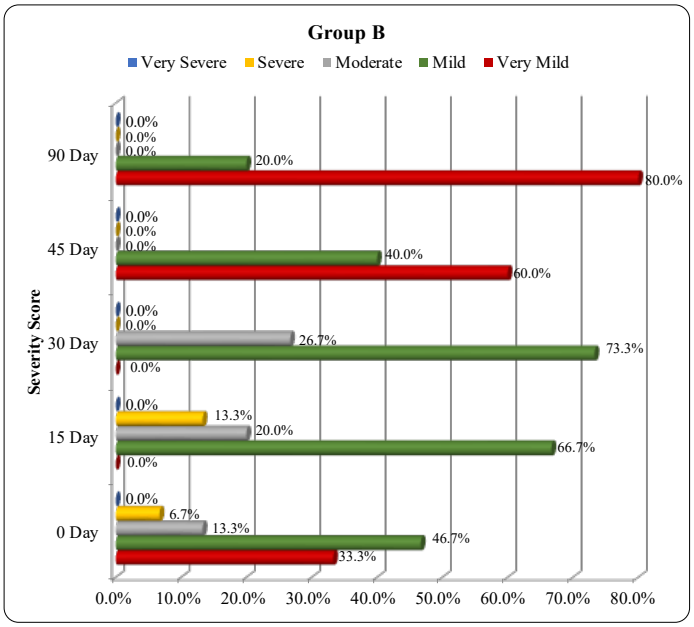
In table 17 it has been observed that in Group A, 9 (60.0%) patients were always disturbed frequency of speech, 1 (6.7%) patient was having rarely disturbed frequency, 5 (33.3%) patients were having sometimes disturbed frequency. In Group B, 7 (46.7%) patients were always disturbed frequency of speech, 3 (20.0%) patient was having rarely disturbed frequency, 5 (33.3%) patients were having sometimes disturbed frequency.

Graph 1: Graph showing distribution of participants according to severity score of Group A



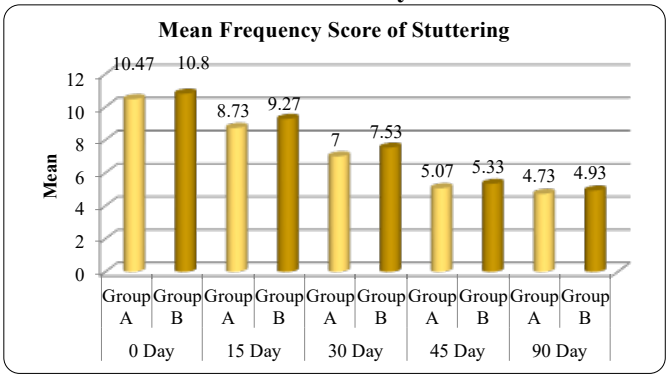
In graph 1 of participants severity score in Group A, it has been observed that before treatment on 0th day 0.0% patient were having very mild severity score. On 15th, 30th, 45th and 90th day of follow-up very mild severity score were 0.0%, and 20.0 %, 86.7%, 100.0% respectively. Before treatment 46.7% patient were having mild severity score. On 15th, 30th, 45th and 90th day of follow-up mild severity score were 86.7%, and 80.0 %, 13.3%, 0.0% respectively. Before starting treatment 46.7% patient was having moderate severity score. On follow-up of 15th, 30th, 45th, 90th day moderate severity score reduced to 13.3%, 0.0%, 0.0%, and 0.0% respectively. Before treatment on 0th day 6.7% patient was having severe severity score which reduced to 0.0% for 15th, 30th, 45th and 90th day of follow-up. In group A, no patient were enrolled under very severe severity score. Kruskal-Wallis Test was used to show significance of data, observations found to be Chi Square = 56.302 (P=0.001,S)

Graph 2: Graph showing the distribution of participants according to severity score of Group B



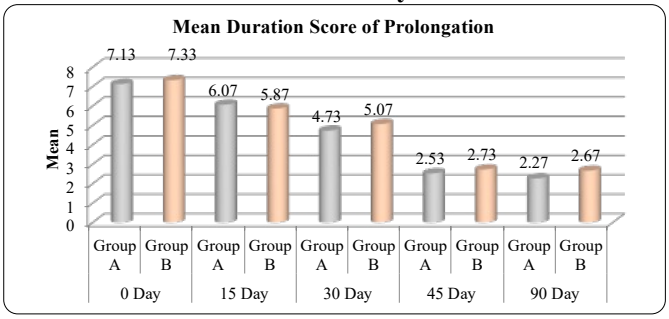
In graph 2 showed distribution of participant's according to severity score in Group B, it has been observed that before treatment on 0th day 33.3% patient were having very mild severity score. On 15th, 30th, 45th and 90th day of follow-up very mild severity score were 0.0%, and 0.0 %, 60.0%, 80.0% respectively. Before treatment 46.7% patient were having mild severity score. On 15th, 30th, 45th and 90th day of follow-up mild severity score were 86.7%, 73.3 %, 40.0%, 20.0% respectively. Before starting treatment 13.3% patient was having moderate severity score. On follow-up of 15th, 30th, 45th, 90th day moderate severity score reduced to 20.0%, 26.7%, 0.0%, and 0.0% respectively. Before treatment on 0th day 6.7% patient was having severe severity score which increased to 13.3% for 15thday and then reduced to 0.0% on 30th, 45th and 90th day of follow-up. In group A, no patient were enrolled under very severe severity score. Kruskal-Wallis Test was used to show significance of data, observations found to be Chi Square = 45.170 (P=0.001, S)

Graph 3: Comparison of mean frequency score of stuttering of Group A and B on 0th, 15th, 30th, 45th and 90th day



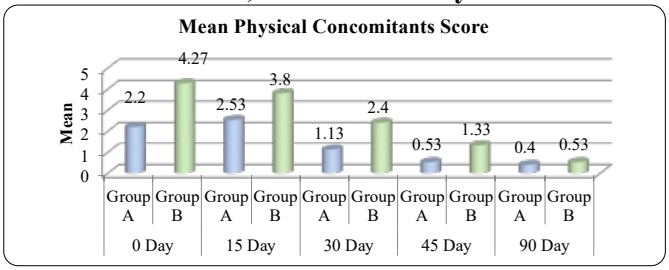
In graph 3 it has been observed that before initiating treatment on 0th day mean frequency score of stuttering in Group A and B was found to be 10.47 and 10.80. Mean difference on 0th day was -0.33 (p=0.678, NS) which reduced to 4.73 and 4.93 for Group A and B respectively on 90th day of treatment with mean difference of -0.20 (P=0.285,NS).

Graph 4: Comparisons of mean duration score of prolongation of Group A and B on 0th, 15th, 30th, 45th and 90th day



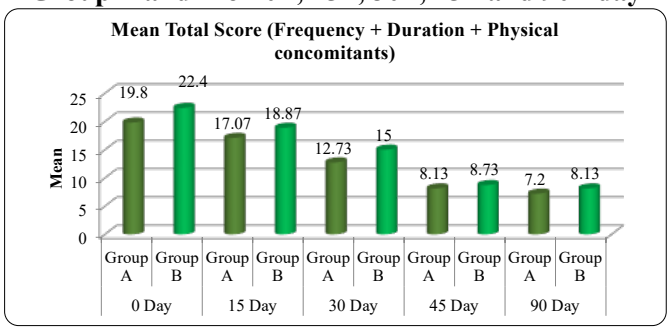
In graph 4 it has been observed that before initiating treatment on 0th day mean duration score of prolongation in Group A and B was 7.13 and 7.33. Mean difference on 0th day was -0.20 (p=0.753, NS) which reduced to 2.27 and 2.67 for Group A and B respectively on 90th day of treatment with mean difference of -0.40 (P=0.285, NS)

Graph 5: Comparison of mean physical concomitants score of Group A and B on 0th, 15th, 30th, 45th and 90th day



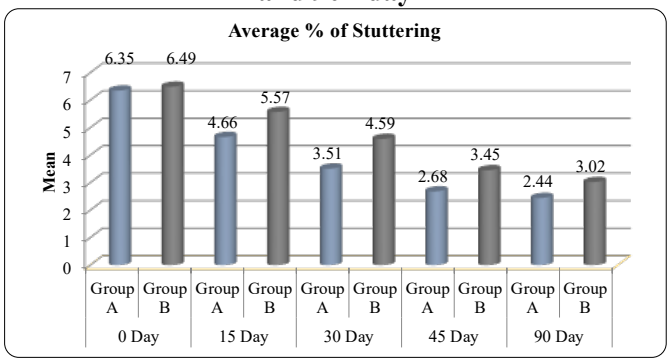
In graph 5 it has been observed that before initiating treatment on 0th day mean physical concomitants in Group A and B was found to be 2.20 and 4.27. Mean difference on 0th day was -2.06 (p=0.009,S) which reduced to 0.40 and 0.53 for Group A and B respectively on 90th day with mean difference of -0.13 (P=0.571, NS).

Graph 6: Comparison of mean total score (Frequency+ Duration+ Physical concomitants) of Group A and B on 0th, 15th, 30th, 45th and 90th day



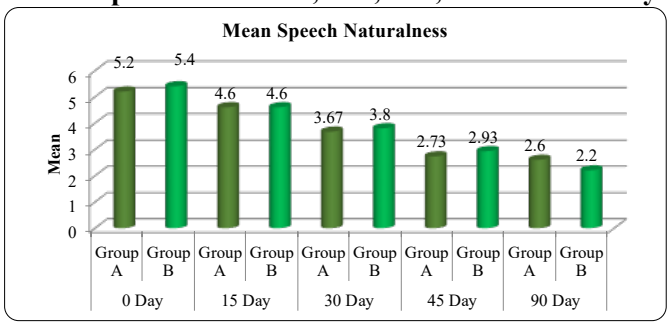
In graph 6 it has been observed that before initiating treatment on 0th day mean total score in Group A and B was found to be 19.80 and 22.40. Mean difference on 0th day was -2.60 (p=0.118,NS) which reduced to 7.20 and 8.13 for Group A and B respectively on 90th day of treatment with mean difference of -0.93 (P=0.276, NS)

Graph 7: Comparisons of mean average % of stuttering of Group A and B on 0th, 15th, 30th, 45th and 90th day



In graph 7 it has been observed that before initiating treatment on 0th day mean average % in stuttering in Group A and B was found to be 6.35 and 6.49. Mean difference on 0th day was -0.13 (p=0.863,NS) which reduced to 2.44 and 3.02 for Group A and B respectively on 90th day of treatment with mean difference of -0.58 (P=0.031,S).

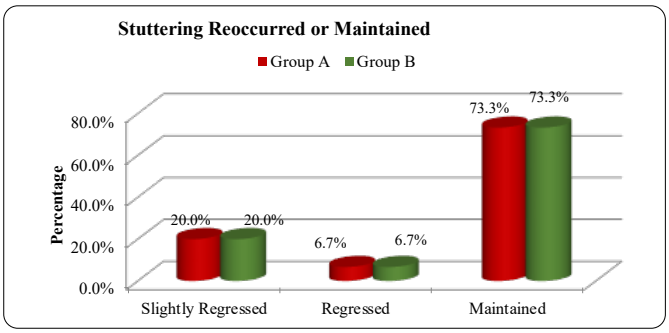
Graph 8: Comparisons of mean speech naturalness of Group A and B on 0th, 15th, 30th, 45th and 90th day



In graph 8 it has been observed that before initiating treatment on 0th day mean speech naturalness in stuttering in Group A and B was found to be 5.20 and 5.40. Mean difference on 0th day was -0.20 (p=0.542,NS) which reduced to 2.60 and 2.20 for Group

A and B respectively on 90th day of treatment with mean difference of 0.40 (P=0.077,NS).

Graph 9: Graph showing distribution of participants according to events of stuttering reoccurred or maintained



Graph 9 shows the post follow-up event on stuttering on 90th day. 20.0% of patients in each group showed slightly regression of stuttering. 6.7% of patients both groups showed regressed of stuttering and 73.3% of patients maintained the speech fluency and naturalness. Chi square test was applied for assessment, chi square-0.00 (P=1.00, NS)

Discussion

This clinical trial study was planned as a double-blind randomized, parallel-arm interventional study. In this present study, randomization was done by using a computerized generated randomization table to distribute patients in two groups to reduce bias between both groups. The interventional drug was packed in sealed containers and labeled as Sample A and Sample B. Interventional trial and control medication is given was double-blinded to all the patients of both the groups for treatment. Allocation concealment was done by third person by blinding both the drugs and documentation was sealed after coding. The coded document was sealed envelope and kept safe in custody to avoid bias for the same. Envelop was opened after completion of enrollment and analysis of data of both the groups to reveal the drug for interpretation of results.

In this clinical trial, 30 patients were enrolled, where each 15 patients were enrolled in Group A and Group B, and both groups received Sample A and Sample B drugs respectively. Written and verbal consent was taken from the parents about the study criteria, intervention, benefits as they were made aware of the study and drug administered for their benefits, dose, duration and recommendation of exercises. After the completion of the study and statistical interpretation of both groups, the coded document was opened and the formulation of groups were revealed. Group A was having *Kalyanaka Leha* (control drug) and Group B (trial drug) was having *Guduchyadi Leha* in it and further conclusion were made.

Severity score of stuttering

The effect of Group A and Group B on the severity score of stuttering was analyzed statistically by using ANOVA test and the result was found highly significant (P-value= 0.001) in both the groups.

Frequency score of stuttering

When effect of Group A and Group B on frequency score of stuttering was analysed statistically by using the ANOVA test and results were found highly significant (P value-0.0001) in the patients of both the groups. To justify the day-wise significant difference, Post Hoc Tukey test was applied after ANOVA test which was found significant in group A and B at the level of 0.05.

Duration score of prolongation

When the effect of Group A and Group B on the duration score of prolongation was evaluated by using ANOVA test was found highly significant (P value: 0.0001). For the justified difference of mean in duration score of prolongation Post Hoc Tukey test was applied after ANOVA test which found significant at the level of 0.05 level.

Physical concomitants score

When the efficacy of group A and Group B on physical concomitants was evaluated by using ANOVA test was found to be highly significant (P value-0.0001). After ANOVA test, Post Hoc Tukey was applied to get justified mean difference in both the group which was not significant. From this, it was concluded that Group A and Group B was equally significant in reducing physical concomitants score.

Total score (Frequency + Duration + Physical concomitants)

The effect of Group A and Group B on total score (Frequency + Duration + Physical concomitants) was analyzed by using ANOVA test which was found highly significant (P value- 0.0001). Post Hoc Tukey was applied to analyse mean difference in both the groups which was found significant. But on application of student's unpaired t-test, results were found non-significant. From the above, it was concluded that Group A and Group B were effective and equally significant in total score (Frequency + Duration + Physical concomitants) but if compared with one another then it has been found that in spite of individual significance, comparison shown non-significance owing to less sample size.

Average % of stuttering

The effect of Group A and Group B on the average % of stuttering was evaluated by using ANOVA test, the result of both the groups was found highly significant (P value- 0.0001). By the application of students unpaired t-test was also found highly significant with P value of 0.031. Groups A and B both were found to be highly significant in the reduction of average % of stuttering

Speech naturalness

Efficacy of Group A and Group B on speech naturalness was evaluated by using ANOVA test, the results of both groups were found highly significant (P value- 0.0001) Both groups were found highly significant.

Regression or maintenance of stuttering

On the post treatment follow-up, 73.3% patients from each group A and B maintained fluency of speech post follow-up without treatment which shows that both the interventions are having good residual efficacy. After analysing the data by using Chi-square test, result of both the groups were found non-significant with P value = 1.00.

Probable mode of action of medication

Both the interventions have *Aampahak*, *Kaphahara*, *Deepana*, *Medhya*, *Swarya* and *Rasayana* properties, subsequently showed effective outcomes in the treatment of *Gadgada*. *Guduchyadi Leha* having *Kapha-Vatahar* property, acted as *Swarya* and *Medhya* in turn, facilitating to breaking the etiopathogenesis. *Swarya* property is needful to initiate the uttering of words and *Medhya* property helps in the articulation of sentences. Some of the drugs in *Guduchyadi Leha* have the property of *Rasayana* which helps to reduce the anxiety and stress caused due to un-cleared speech and hesitation while speaking and vice versa anxiety is an important causative factor in stuttering, need to break this vicious cycle (13). *Vacha* has the property of *Swarya*, which helps in speech-related problems (14).

Conclusion

Stuttering is a health-related problem, the child may suffer from depression and may feel hesitation, and low esteem while speaking. There is no medicinal treatment is available to treat this condition in modern sciences. Speech therapy is a helpful hand for people suffering from stuttering, but the results may vary from one therapist to another. This study was piloted to compare the efficacy of *Guduchyadi Leha* and *Kalyanaka Leha* for the treatment of *Gadgada*. In comparative assessment of both groups, this showed significant results in stuttering after assessment of speech fluency by using SSI-4 scale, no adverse drug reaction where noted.

Consent

As per the IEC and CONSORT protocol, written consent was taken from the parents of patients and collected and preserved by the author.

Acknowledgment

DMIMS, Deemed to be University, Wardha, MH, India for intramural funding to conduct the research.

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