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A comparative study of *Guduchyadi Leha* and *Kalyanak Leha* in management of *Gadgada* (Stuttering): A Study Protocol

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Abstract:

Background: Stuttering is distinctive defect in speech mechanism, which is characterized by hesitation while speaking or spasmodic repetition of some syllables with pauses in speech. Difficulty in pronouncing the initial consonants causes due to spasm of lingual and palatal muscles while speaking. Now a day, stuttering is being common and one of the burning problems of speech disorder in day to day practice in Paediatrics. This clinical condition of stuttering closely resembles to *Gadagad* thus, the management of Stuttering can be done on the line of treatment of *Gadagad.*

Aim-The present study is aimed at comparing*Guduchyadi Leha* and *Kalyanaka Leha* in management of *Gadgada* (Stuttering) and thereby assessing improvement in stuttered speech.

Materials and Methods- The present study is designed as Parallel arm, randomized double blind study in which minimum 15 patients will be enrolled in each group. In Group G(Experimental)-*Guduchyadi Leha* and in Group K(Standard Control)-*Kalyanaka Leha* will be administeredfor2-5 years, the dose will be: 0.5 gm TDS and for 6-12 years: 2.5 gm BD.Assessment will be recorded on 15^{th}, 30^{th} and 45^{th} day.

Results: Changes will be noted, by using Stuttering Severity Instrument-4 (SSI-4).

Conclusion: Suitable conclusion will be drawn at post completion of trial based on quantitative and qualitative statistical tests.

Keywords:*Gadgada, Guduchyadi Leha, Kalyanaka Leha,* SSI-4, Stuttering, Speech disorder.

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BACKGROUND:

Unique characteristic of human being is Speech. To convey thoughts, ideas and other words by means of articulating sound into meaning full words is only done by the help of Speech. Fluency in the speech is necessary for psychological development of childand for expressing thoughts. It empowers the person to express knowledge and his thoughts to convey other people[1]. Any kind of problem in speech fluency can create trouble in emotional and social behavior of children like stuttering, which is burning problem in child age group which can leads to disability in adult hood[2]. According to World Health Organisation,stuttering is a condition of rhythm of speech fluency in which the person suffering from stuttering knows accurately what he or she wants to say but while speaking suffers with the difficulty because of cessation of sound, involuntary repetition or prolongation, which may be the pointer reason of frustration and may he or she starts avoidance of situation of talk. [3]

Generally, speech development occurs more rapidly in the age group of 2–5 years and vocabulary development increases from 50-100 words to more than 2000. By the thumb rule of speech, between the age from 2 to 5 year, number of words coming in sentence are directly proportional to the age of the child (2 words by age 2 year, 3 words by age 3 year, and so on) [4]. As per Ayurved literature, expression of thoughts and ideas of person occurs with the help of *Vaka* which is the *karma* of *Vagindriya.*[5]Dysfluency of speech in which fluency of speech is interrupted by repetition of syllable or word, pause, prolongation, hard contact and hesitation are the specification commonly occurs in stuttering[6]. Even the *Manasika karanas* similar to *Shoka*(grief), *Bhaya*(fear), *Udvega*(temper) can affect speech of person because of improper functioning of mind, which is essential for *Indriya* to work physiologically [7]. *Dhatukshaya* and *Avarana* arebeing responsible for *Vatavyadhi* and the same principle should be applied in case of *Gadgada* [8].

In preschool children, prevalence rate of speech disorders is up to 8 % and nearly 20% old children of 2 years are thought to have delayed speech development in them [9]. Among various types of developmental disabilities, the incidence of speech disorders in India is 9.6 % which occurs mostly in between the ages of 5-12 years in school age children.In District Hospital Wardha, till the date 23rdApril 2020, 139 paediatric patients were enrolled under stuttering. During the learning period of speech, generally child starts repetition of consonants frequently and often followed by repetition of words, if such condition occurs continuously, child suffers from speech disability; can make the child physically, psychologically, emotionally and socially handicapped. In current system of medicine, Speech therapy takes the upper hand in the management of Stuttering [10].Incidences of Stuttering are increasing recently with no satisfactory treatment in any science up till now.

This clinical condition of *Gadgada* closely resembles to stuttering thus, the management of *Gadgada* can be done on the line of treatment of stuttering.Causative factors of stuttering are mentioned as multifactorial like genetics influence, familial inheritance, adaptive behaviours, psychological causes, CNS injury and primary to secondary as developmental and unknown cause. *Dhatukshaya* and *Avarana* arebeing responsible for *Vatavyadhi* and the same principle should be applied in case of *Gadgada* [11]. Prior cause is evident in *Garbhini Vataja Ahara Vihara*, *Garbhopaghatakara Nidana*, and leading *Garbha Shoshana* whichleads to

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Dhatukshayaja Vatavriddhi. Avarana of *Vata* as a cause of *Gadgada* is seen in vitiation of *Vata* and *Kapha* as explained *Kaphavrita vata*. *Abhighata* to *Shiras* leading to *Achaya poorvaka prakopa* of *Vata* also cause *Gadgada*. [12]

In *Gadagad*, main cause due to vitiation and aggravation of *Vata Dosha* and *Kapha Dosha* is by analyzing the *Rasa* present in the individual drugs of *Guduchyadi Leha*[13], reveals that maximum drugs have *Katu, Tikta* and *Madhura Rasa* combination. Most of the drugs are having property to pacify *Kaphavata*. The ingredients of *Guduchyadi Leha* have predominantly *Laghu, Tikshana*, and *Snigdha Guna*. These will lead to *Anulomana* and *Strotoshodhana. Ruksha* and *Tikshna Guna*dispels the obstruction by *Kapha* leads to clarity of sense organs (*Indriyaprasada*). Pharmacological evaluation of *Veerya* of drugs shows that *Ushna Veerya* is dominating. *Ushna Veerya* by virtue of its *Vata* alleviating property pacifies the vitiated *Vata dosha* in the condition of speech impairment. Hence, this study is planned to determine the action of "*Guduchyadi Leha*" in comparison with *"Kalyanaka Leha*[14]*"* in children with stuttering.

METHODOLOGY:

Trial Design: This study is designed asParallel arm, Randomized double blind study. The randomization will be done on the basis of computerized generated table. Allocation of concealment will be done by coding of both the drugs with the help of third person. In these clinical trial 30 patients (15 patients will be in each group) will be taken in trial study.

Study Setting: The participants will be selected after informed consent by informers from OPD and IPD of *Kaumarbhritya*, Mahatma Gandhi Ayurved College, Hospital and Research Center, Salod (H) and from Specialty Camps and nearby schools of Salod, Sawangi, Wardha.

CTRI Registration Number:REF/2020/08/036053

IEC Number: MGACHRC/IEC/August-2020/96

Eligibility Criteria:

a. Patients with age group of 2 years to 12 years will be taken suffering from *Gadgada*.
b. Children with clinical manifestations of speech impairment i.e. stuttering will include in the study.
c. Patients will be selected irrespective of gender, religion, socioeconomic status.
d. Patients with diagnosed delayed development of speech as sequel of neurological disorder which is cured.

Exclusion criteria:

a. Deaf children will be excluded
b. Children with severe infection, brain trauma
c. Patients suffering from cleft palate & cleft lip or the conditions where the surgical intervention is required
d. Patient suffering from*Mukhpaka* (Stomatitis)
e. Children not speaking small sentence

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f. Children suffering from Autism Spectrum disorder

Criteria for discontinuing or modifying allocated interventions: Participant will be withdrawn from the study if there is no improvement in speech will occur, features of drugs or any sensitivity or any other disease or problem arises, the participant will be offered free treatment till the problem subsides.

Sample Size: 30 Patients (15 Patients in each group G and Group K)

Time schedule of enrolment, interventions: Diagnosed patients of *Gadgada*will be enrolled in the present study after fulfilling the inclusion criteria.

Interventions:

Group G – In Group G, 15 Patients, having complaints of *Gadgada* will be selected and *Guduchyadi Leha* will be given as intervention with dose of 0.5 gm thrice a day for age group of 2 to 5 years and for 6 to 12 years the intervention drug will be given in 2.5 gm in twice a day frequency for *Jivha Pratisarana*, up to 2 minutes for 45 days and follow up will be taken on 15^{th}, 30^{th} and 45^{th} day of treatment.

Group K – In Group K, 15 Patients, having complaints of *Gadgada* will be selected and to them *Kalyanaka Leha* will be given as intervention with dose of 0.5 gm thrice a day for age group of 2 to 5 years and for 6 to 12 years the intervention drug will be given in 2.5 gm in twice a day frequency for *Jivha Pratisarana*(application on tongue), up to 2 minutes for 45 days and follow up will be taken on 15^{th}, 30^{th} and 45^{th} day of treatment.

Screening Scale: Stuttering Severity Instrument – 4 (SSI - 4)[15]

Assessment Criteria:

Patient's response will be assessed on following parameters.

1. Repetition of syllables, words.
2. Prolongation
3. Silent pause
4. Hard contact
5. Hesitation
6. Physical concomitants

Investigations:

1. Assessment of difficulty/ease in speech by checking time in seconds for uttering words.
2. Pitch, intensity of voice, hesitation reduction, tongue movements, other sounds.

Follow up period after treatment: Follow up will be taken on 15^{th}, 30^{th}, 45^{th} day of on going treatment.

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Primary outcomes: Improvement in the speech fluency along with reduction of pitch, frequency and duration of the stuttered words and loudness of the stuttered word or the tone of the stutterer is expected in this trial study.

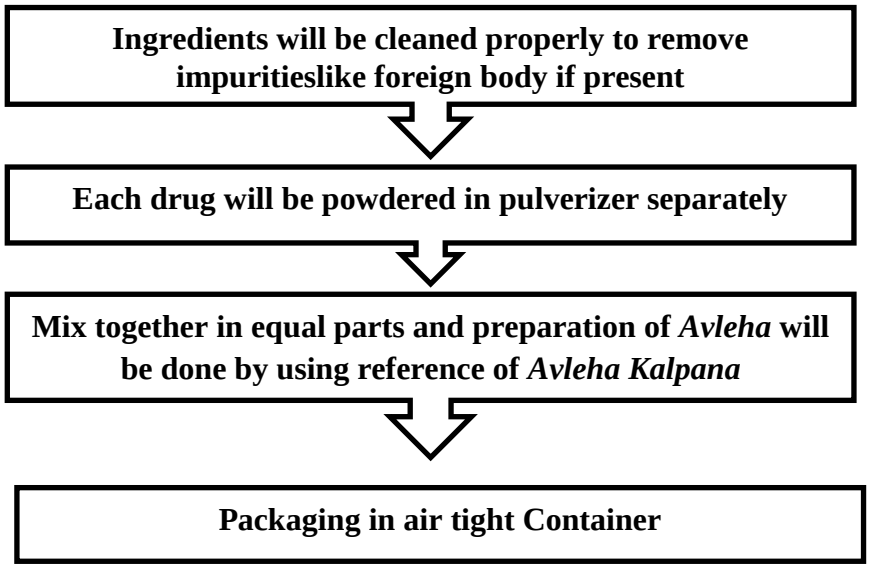
Secondary outcome: The effect of interventional drug *Guduchyadi Leha*which have contents *Guduchi, Apamarga, Vidanga, Shankhpushpi, Vacha, Shatavari, Haritaki, Shunthi, Mishri*, Ghrita and Honey.Occurrence of any side effect of interventional drug on *Gadgada*will be noted.

Analysis Plan:

Drug analysis:

Raw drug analysis - Crude material of *Guduchyadi Leha* and *Kalyanaka Leha* will be procured from local shop and will be authenticated by Department of Dravyaguna and standardized by analytical lab of Dattatraya Rasashala (GMP certified and FDA approved) MGACH&RC, Salod (Hi), Wardha.

Formulation analysis - *Guduchyadi Leha* and *Kalyanaka Leha* will be prepared in Dattatray Rasashala of MGAC&RC Salod(H), Wardhaas per *Avleha kalpana* explained in *Sharangdhar samhita*[16]and will be analytically tested byDepartment of Rasa Shastra and Bhaishajya Kalpana, MGACH&RC, Salod (Hi), Wardha.



Data Analysis (statistical methods): The data will be analysed by using Paired t-test, Wilcoxon Rank sum and sign rank test by drawing percentage in tabular format, pie or bar diagrams

Implementation: Primary investigator will enroll the patient and allocate intervention.

Data Management: The data entry coding will be done by primary investigator.

Ethics and dissemination: Research ethics approval; approval from research ethics committee of institute has been taken. IEC approval Number of this trial isMGACHRC/IEC/August-2020/96

Consent or assent: The written consent will be taken before starting clinical trial from each patient(assent) and from parents whose child is not willing to give consent. Confidentiality of each patient will be maintained during the clinical trial. The consent will be taken in their own language.

Dissemination policy: The data will be disseminated in future clinical work and also paper publication.Authorship eligibility guidelines and any intended use of professional writers.

Informed consent materials: Model consent form of this clinical trial and other related documentation will be given to participants and authorized informants with all the information.

Scope and Implications of the proposed study:

Scope: Scope of the proposed study will help to plan more research studies to increase the fluency in speech in subjects, suffering from stuttering.

Implications: This study will improve memory of child and concentration along with this it will clear the nasal passage obstruction, will smoothen the throat and calms mind.

1. This study will show reductive effect in hesitation on uttering the words.
2. It will help in reduction of pitch and loudness of the stuttered word or the tone of the stutterer.

EXPECTED RESULT:

At the time of protocol writing analysis was not complete and study is yet to start. The expected result of this clinical trial is that group G with intervention is potentially equal to group K with intervention. It is effective in subsiding symptom of hoarseness of pitch and loudness of the stuttered word or the tone of the stutterer will be noted. Patient who will take all follow up will have fluency in speech without stuttering.

DISCUSSION:

The main reason behind selecting this trial drug was the easily availability of ingredients. The reason for selecting this trial drug was as its indication against *Gadgada*which has a close similarity with that of Stuttering.Most of the drugs of "*Guduchyadi Leha*" are having property to pacify *Kaphavata*. The ingredients of *Guduchyadi Leha* have predominantly *Laghu, Tikshana,* and *Snigdha Guna*. These will lead to *Anulomana* and *Strotoshodhana. Ruksha*&*Tikshna Guna* dispels the obstruction by *Kapha* leads to clarity of sense organs (*Indriyaprasada*). Pharmacological evaluation of *Veerya* of drugs shows that *Ushna Veerya* is dominating. Hence, this study is planned to determine the action of "*Guduchyadi Leha*" for the patients of stuttering in children.

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CONCLUSION:

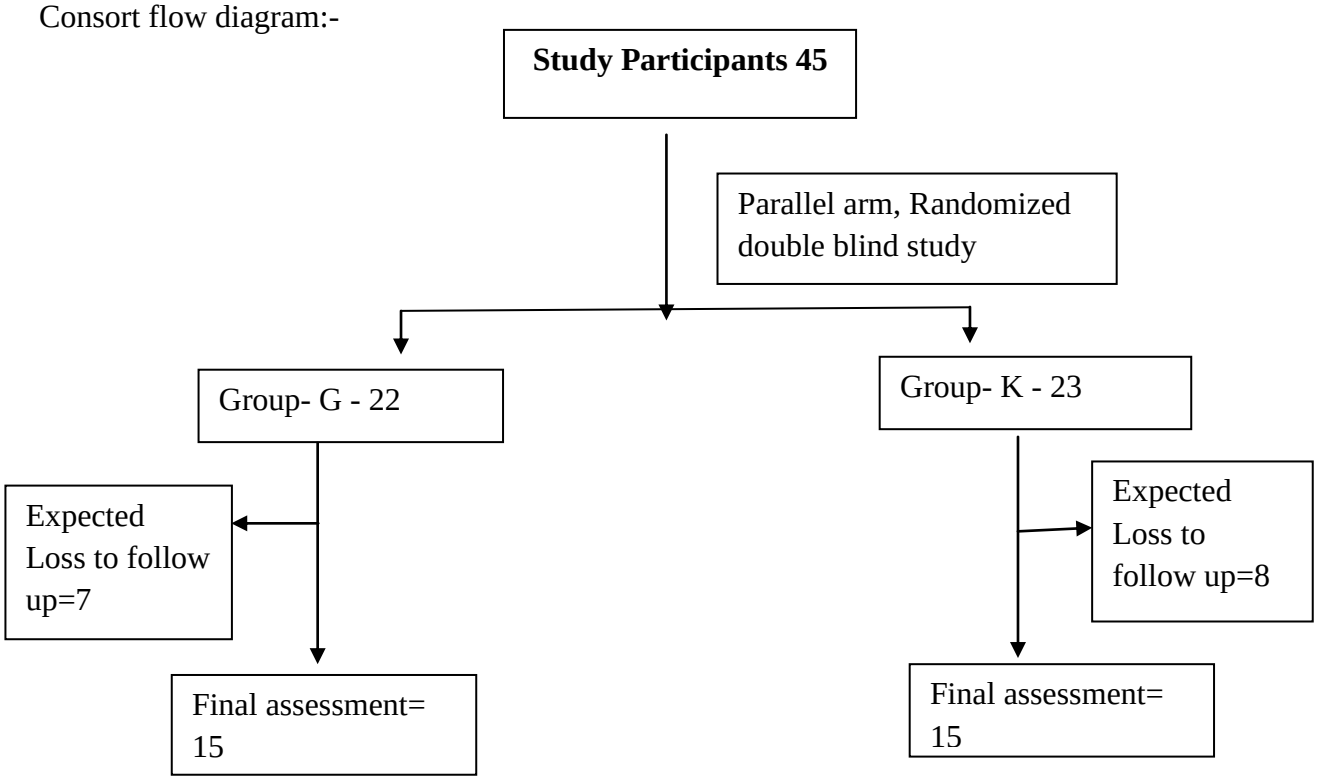
The interventional drug group G is equal effective as group K with least side effects in paediatric age group.

Conflict of Interest – None

Funding – Intramural funding

Figure (1)-

Consort flow diagram:-



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