



CLINICAL EVALUATION OF THE EFFECT OF KAPIKACHHU GHANA VATI ON AGE RELATED SENSORI-NEURAL DEFFNESS

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ABSTRACT

Age related sensory neural deafness occurs usually after 45 years age. It is unilateral or bilateral progressive sensori neural deafness. In the world more than 250 millions peoples suffering from Age related sensory neural deafness. But there is no assured treatment for Age related sensory neural deafness only hearing aid can be useful. According to Ayurveda Badhirya (deafens) is mainly related with Vata dosha which is predominant in old age. So, as the age increases, Badhirya also increases. Kapikachhu (*Mucuna pruriens* bek) seeds are Ayurvedic medicine, Acharya Bhavprakash has mentioned that Kapikachhu have Vatghna, Balya and Vajikar properties. In the disease development process of Badhirya mainly vitiated vata dosha alone or along with Kapha goes in Shabdavaha sira / strotas beacuse of that margavrodh occurs and leads to Badhirya. So with help of Vataghnata the balya property of Kapikachhu it is useful in treatment of Badhirya. This study is the view of ancient and modern science concerning with conceptual understanding of its etiology, diagnosis of age related sensory neural hearing loss and its Ayurvedic treatment. The present study has shown that the kapikachhu Ghana vati is highly significant in the management of the age related sensory neural deafness.

KEYWORDS: Ayurveda, Karna, Badhirya, deafness, Vatghna, Kapikachhu.

INTRODUCTION

Ayurved is a science of life, it is widely accepted by the world, for its relevance and adaptability to the modern times. In modern time every person is running to achieve their life's goal, hence does not have time to think, act for healthy life and not able to follow proper Dincharya, Rutucharya, Dietary Rules and Regulations which are necessary for maintaining the proper health. Now a days due to environmental hazards like noise pollution, air pollution, industrial pollution etc. due to this many geriatric problems are seen, which disturbs our day to day life, which are the most relaxing or resting times of life. Among them 'Deafness' is one of the big problem observed in old age particularly after 50 years of life. Age related hearing impairment is very troublesome, which not only affects the physical health of a person but also affects his state of mind. Patient feels awkward to communicate and express himself in a society.

Need for Research

Hearing impairment is the most frequent sensory deficit in human population, affecting more than 250 million people in the world. Consequences of hearing impairment include inability to interpret speech, often

producing a reduced ability to communicate, economical and educational disadvantage, social isolation and stigmatisation. In the Version 1 which estimates the Global Burden of Disease 2000 study, published in the World Health Report 2001-2002, adult-onset hearing loss was the 2nd leading cause of (Years lived disability) YLDs at global level, accounting for 4.6% of total global YLDs. So there is a need of research for deafness (Badhirya). Age related hearing loss is defined as middle to late adult age onset, unilateral or bilateral progressive sensory neural hearing loss. Factors involving inner ear were described by Dr. Schuknecht & colleagues

- (1) **Sensory** – loss of hair cells (sustentacular cells) at basal end of organ of corti
- (2) **Neural** – Due to the cochlear ganglionic cell loss the degeneration of neurons of cochlear nerve occurs.

Now a days there is no effective treatment for Badhirya specially Badhirya due to the old age. Karna is one of the important sense organ and it is the sthana of Vata dosha as mentioned in Ayurvedic text. According to Ayurveda, Badhirya is Karnagata Vyadhi. In Badhirya mainly Vata Dosha is vitiated.

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Vata dosha vitiated along with Kapha goes in Shabdavaha sira / Srotas and because of that Margavrodh occurs which leads to Badhira. According to Acharya Bhavaprakash, Kapikachhu is Vatghna, Balya and Vajikar

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So, by taking under consideration, Vatashamak property of Kapikachhu will work in management of Badhira. It also has a Balya property which will work in age related Badhira. (Sensori- neural deafness).

AIM AND OBJECTIVES

Aim

1. To Evaluate the effect of Kapikachhu Ghana Vati in age related sensori-neural deafness

Objectives

1. To study in detail about Kapikachhu Ghana Vati.
2. To study in detail about age related sensori-neural deafness.
3. Understanding the effect of Kapikachhu Ghana Vati in age related sensori-neural deafness.

MATERIALS AND METHOD

1) Materials

A. Patient

Selected as per the eligibility criteria.

B. Drugs / Medications

KAPIKACHHU GHAN VATI

Raw drugs required for preparation was collected and authentication done from "Agharkar Research Institute" Pune.

Kpikachhu Ghana Vati was prepared as per standard Ghana vati preparation method and the same was used for the clinical study.

METHODOLOGY

a. Type of study: Randomized Controlled Clinical Trial.

b. Place of study: Bharati Vidyapeeth Medical Foundation's Ayurved Hospital and Research centre, Pune - 411043.OPD & IPD of *Shalakyatantra* department.

c. Ethics Committee approval

d. Approval of ethical committee was taken on 13/08/2015

Ref.: BVDUCOA/EC/1168/2015 - 16

d. Study methodology

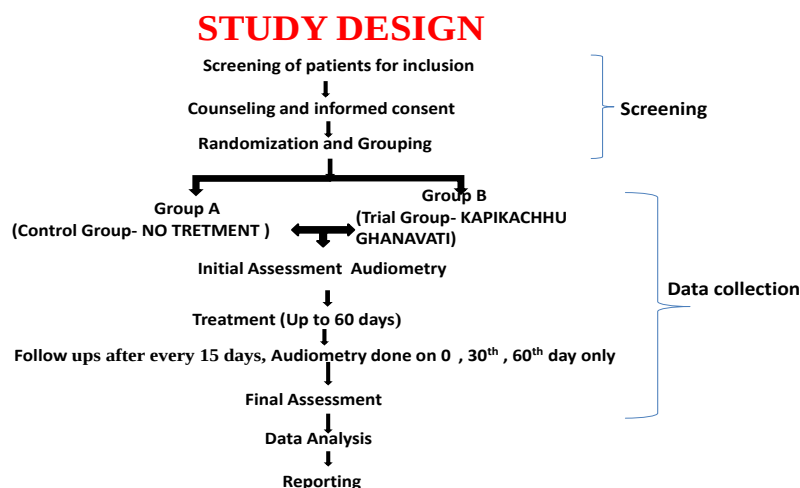
✚ Randomization technique –randomization done by container method selection of patients after inclusion criteria.

✚ Grouping-

‘A’ group - Control group-No treatment

‘B’ group - Trial group – Kapikachhu Ghana Vati - .

✚ 100 patients were studied in each group.



Inclusion criteria

- Individuals of 50 years and above age were included.
- Individuals having complaints of Sensory-neural Deafness
- Individuals of both the gender were included.

Exclusion Criteria

- Individuals having conductive deafness.
- Individuals of SN loss due to traumatic injury.
- Mentally retarded patients.
- Individuals of SN loss secondary to other diseases like Carcinoma, Tuberculosis etc.

iii) Dropout patients

- ❖ Patients who were irregular in follow-ups, who failed to follow the instructions or those who exited the study for personal reasons were considered as dropouts.

1. Drug Administration**Subjective Criteria**

Sr no	Criteria	Gradation
1	Difficulty in hearing in noisy area	0-no difficulty in hearing in noisy area 1- mild difficulty in hearing in noisy area 2- moderate difficulty in hearing in noisy area 3- severe difficulty in hearing in noisy area
2	Difficulty in hearing of whispering sound	0-no difficulty in hearing of whispering sound 1- mild difficulty in hearing of whispering sound 2- moderate difficulty in hearing of whispering sound 3- severe difficulty in hearing of whispering sound

Normal - No perceptible difficulty.

Mild 26–40 dB - Difficulty hearing soft speech and conversations, but can understand in quiet environment.

Trial drug Kapikachhu Ghana Vati, was given to the patient with Godugdha (cow milk), two times a day (morning and evening).

In the Control group, No treatment was given, only Audiometry done for study.

2. Duration of Study

A selected patient was observed for 60 days in both the groups, screened on day 0 for inclusion in study fulfilling inclusion criteria was randomized into either group and test Audiometry was performed on 0, 30th, 60th and follow up on 15th, 30th, 45th, 60th day to assess the progress. From day 1 drug was started.

3. Parameters of Assessment**❖ Objective Parameter****Objective Criteria**

Audiometry – was done on Pure Tone Audiometer

0- Normal- up to 25db

1- Mild- 25db to 40db

2- Moderate-40db to 60db

3- Severe- above 60db

Moderate - 41–60 dB- Difficulty understanding speech, especially in the presence of background noise. Higher volume levels are needed for hearing TV or radio.

Severe -Above 60 dB -Normal speech is inaudible, only amplified speech may be audible.

Vertigo (Bhrama)	0-No symptoms 1-Mild symptoms leading to some restriction in life style, but not interfering with day to day lifestyle of the patient. 2- Moderate symptoms that significantly restrict life style and prevent totally independent existence. 3- Severe symptoms leading to total dependence requiring constant attention during day and night.
Tinnitus (Karnanada)	0-No symptoms 1-Audible in silent environment only 2-Audible in ordinary acoustic environment but masked by loud environmental sounds, can disturb falling asleep but not a sleep in general. 3-Audible in all acoustic environment, disturbs falling asleep, can disturb a sleep in general and it is a dominating problem that affects the quality of life.

WHO grades of hearing impairment

Grade of Impairment	Audiometric ISO value (average of 500, 1000, 2000, 4000 Hz)	Impairment description
0 (no impairment)	25 dBHL or less (better ear)	No or very slight hearing problems. Able to hear whispers
1 (Slight impairment)	26-40 dBHL (better ear)	Able to hear and repeat words spoken in normal voice at 1 metre
2 (Moderate impairment)	41-60 dBHL (better ear)	Able to hear and repeat words using raised voice at 1 metre
3 (severe impairment)	61-80 dBHL (better ear)	Able to hear some words when shouted into better ear
4 (Profound impairment including deafness)	81 dBHL or greater (better ear)	Unable to hear and understand even a shouted voice

Primary endpoint

Use of Kapikachhu Ghana Vati is beneficial in age related sensory neural deafness.

The progress of SN loss can be effectively controlled with Kapikachhu Ghana Vati.

Secondary outcome

Kapikachhu Ghana Vati is beneficial in vertigo and tinnitus.

4. Sample Size

It was calculated considering 6.6% Prevalence rate of disease at BVMF's Ayurved hospital Department of Shalakyatantra.

Total number of patients studied was 100 in each group, who completed treatment excluding the dropouts.

6. Method of data analysis

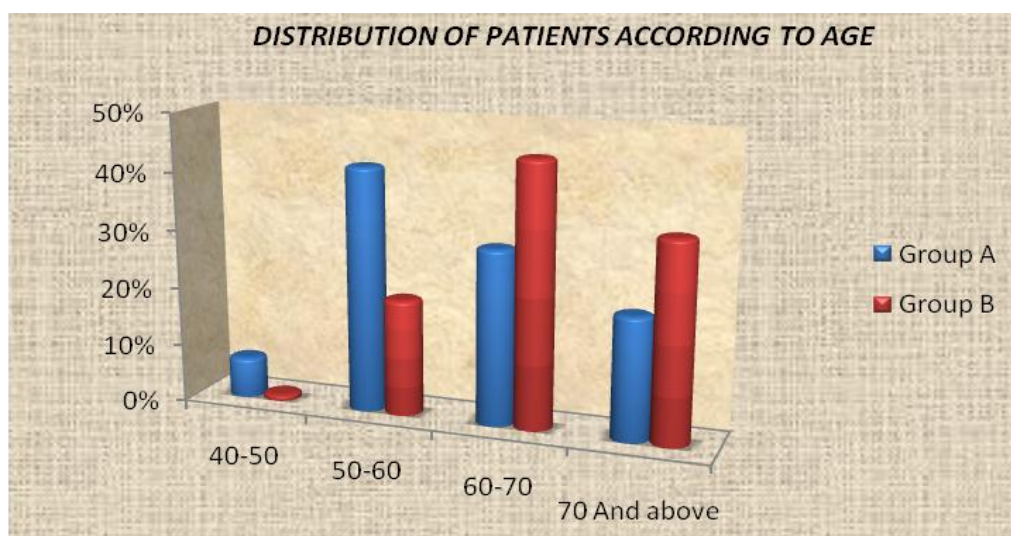
The data collected from the study was compiled, tabulated and analyzed using Wilcoxon Signed Rank test for the efficacy of Trial Drug and Control Drug and Mann Whitney U test for comparison; this was in accordance with the aim and objectives of the study.

OBSERVATIONS, RESULTS AND ANALYSIS

After completing the clinical study, observations, results and analysis were noted. The data was divided into three group's i.e. demographical, subjective and objective data.

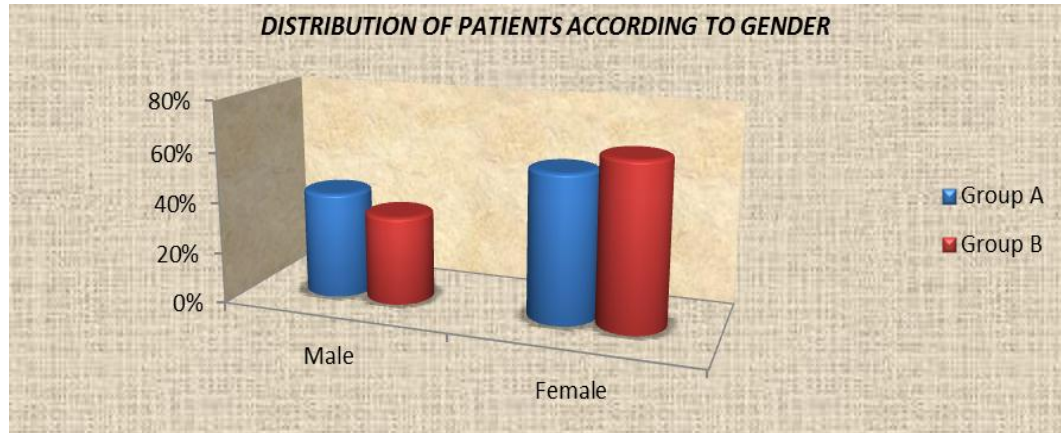
a) Age: Total patients – 100 in each group

Age	Group A		Group B	
	No.Of Patients	Percentage	No.Of Patients	Percentage
50-60	42	42%	20	20%
60-70	34	34%	45	45%
70 And above	24	24%	35	35%
Grand Total	100	100%	100	100%



Gender wise distribution

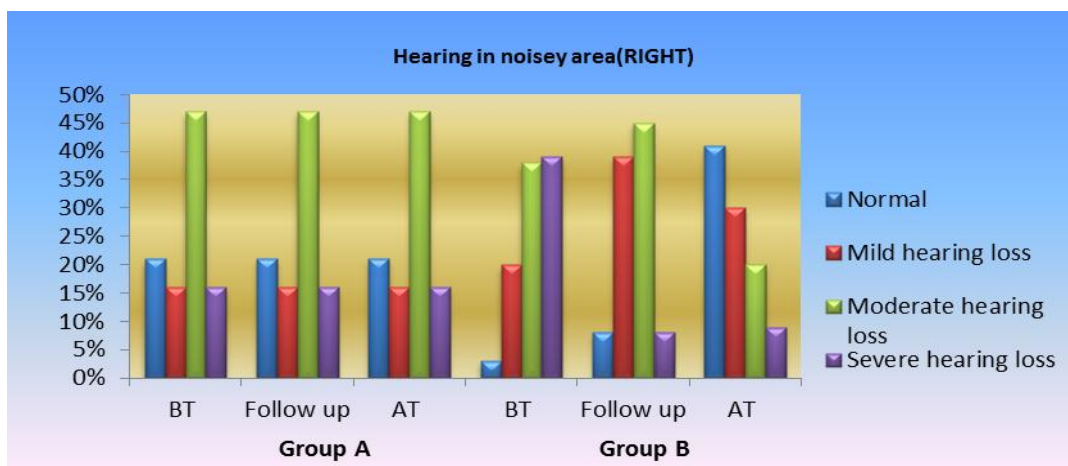
Gender	Group A		Group B	
	No. Of Patients	Percentage	No. Of Patients	Percentage
Male	42	42%	35	35%
Female	58	58%	65	65%
Grand Total	100	100%	100	100%

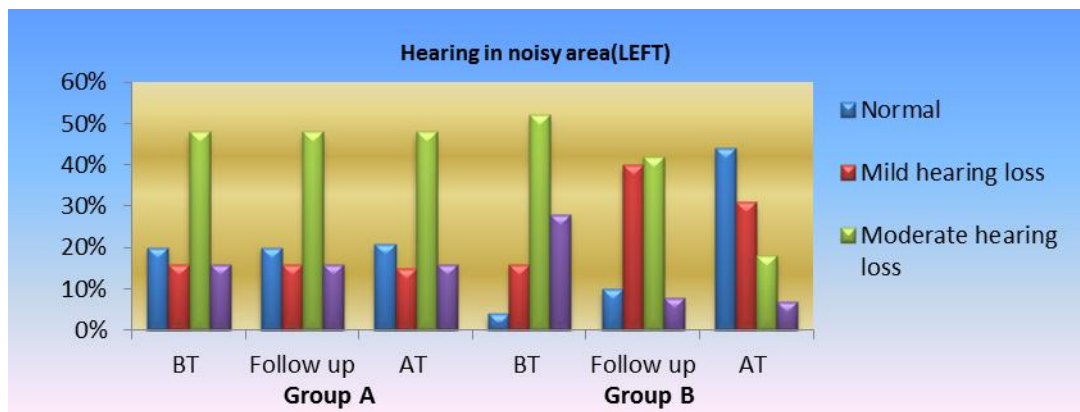
**Effect of Group B on Audiometry**

Audiometry		Mean Rank	Chi sq	Df	P value
Right	Pre	2.32	128	2	1.60E-28
	2 nd Follow up	2.32			
	Post	1.36			
Left	Pre	2.345	116.3474	2	5.44E-26
	2 nd Follow up	2.26			
	Post	1.395			

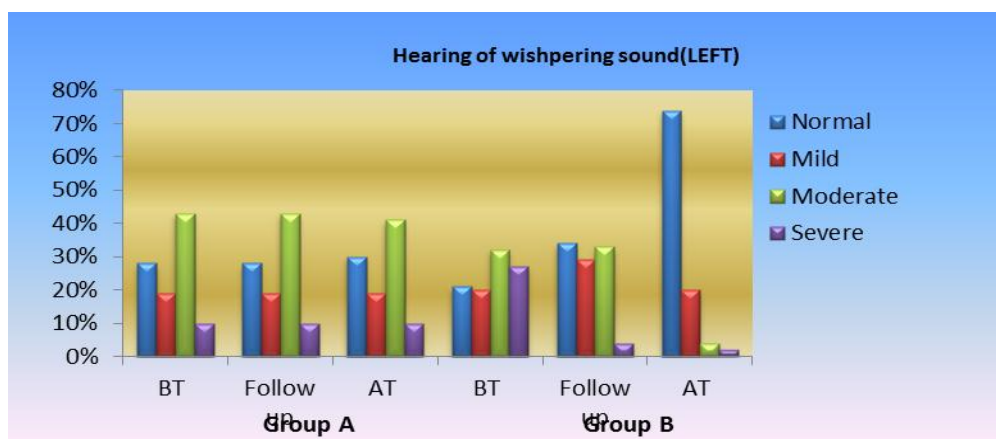
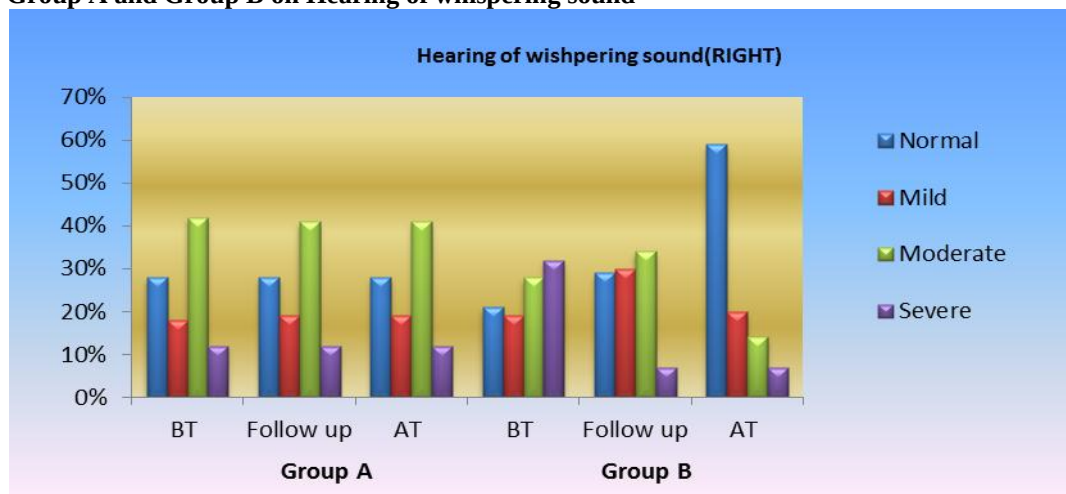
Effect of Group A Group B on Hearing in noisy area

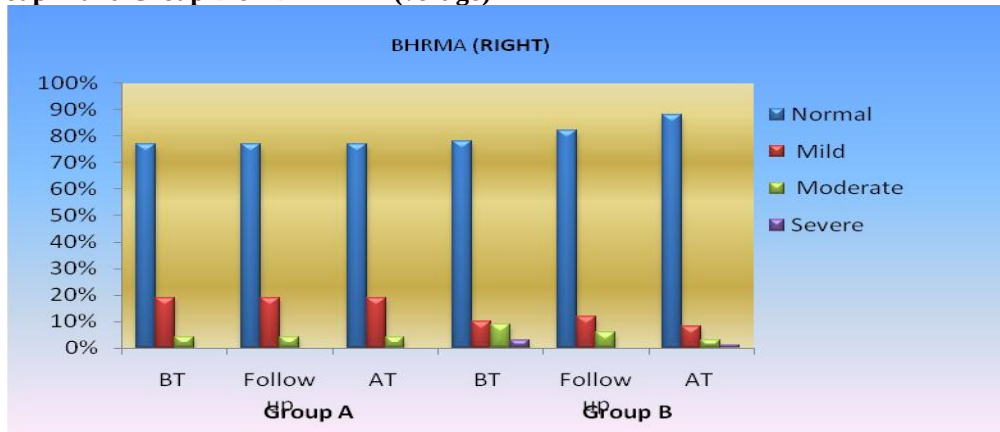
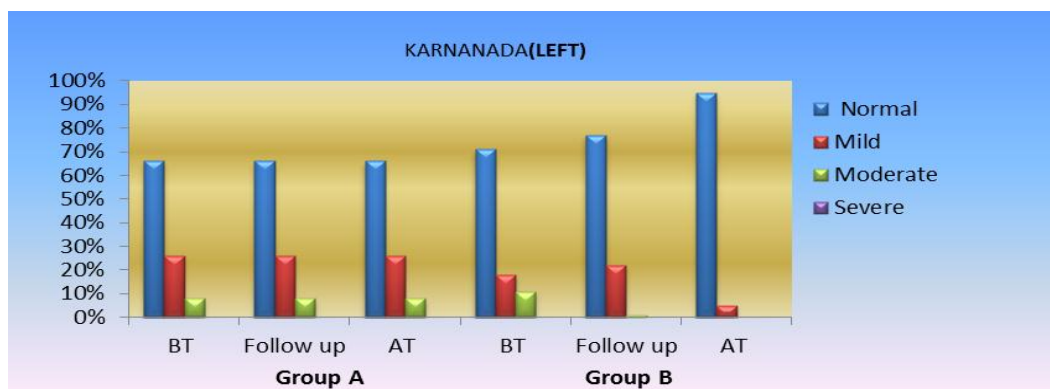
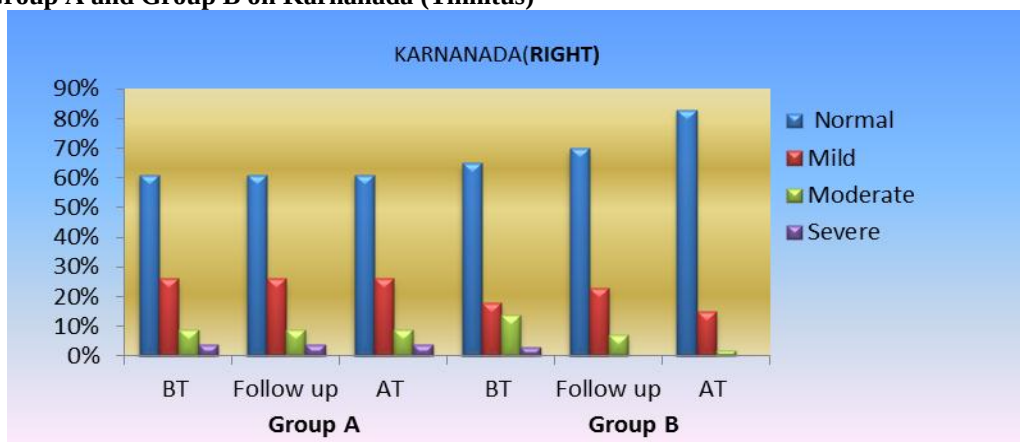
Effect of group A and effect of group B on symptom hearing in noisy both left and right ear.



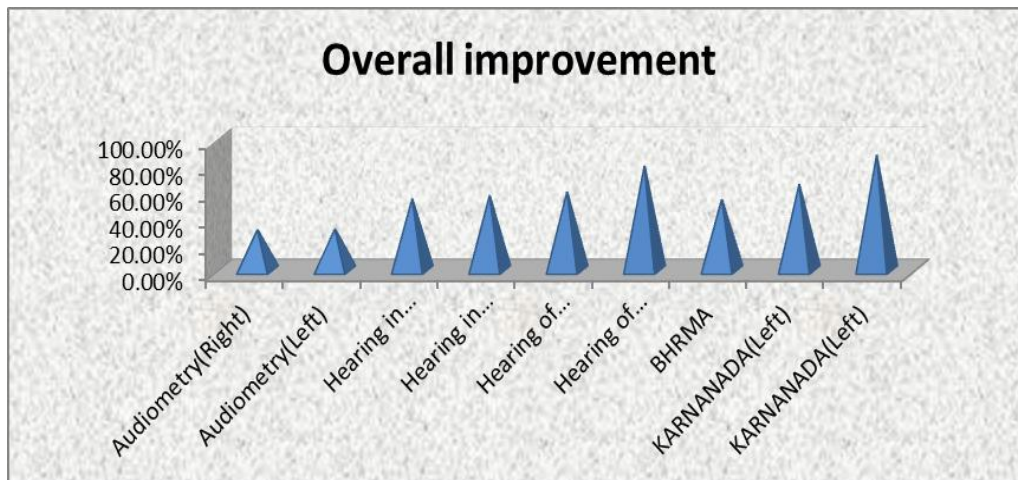


Effect of Group A and Group B on Hearing of whispering sound



Effect of Group A and Group B on BHRAMA(vertigo)**Effect of Group A and Group B on Karnanada (Tinnitus)****Overall improvement of Kpikachhu Ghana Vati**

Parameters	Improvement
Audiometry(Right)	30.88%
Audiometry(Left)	31.43%
Hearing in noisy area(Right)	54.46%
Hearing in noisy area(Left)	56.86%
Hearing of whispering sound(Right)	59.65%
Hearing of whispering sound(Left)	79.39%
Bhrama (vertigo)	54.05%
Karnanada (Left)	65.45%
Karnanada (Left)	87.50%



IMPROVEMENT AS PER GEDATION

GRADE	BT	AT
Normal hearing problem	34.10%	58.70%
Mild hearing problem	17.20%	22.30%
Moderate hearing problem	28.60%	15.20%
Severe hearing problem	20.10%	3.80%

(Ref. W. H.O. Gradation of hearing loss)



Before trial normal sensory neural deafness patients were more than 34% and after trial it improved up to 58% similarly mild sensory neural deafness patients improved from 17.20% to 22.30%.

Moderate and severe sensory neural deafness patients were decreased from 28.60% to 15.20% and 20.10% to 3.80% respectively.

DISCUSSION

Kapikachhu Ghana Vati was authenticated and standardized prior to trials. Clinical trials were conducted and selected patients were randomly allotted to Trial and Control groups. Regular follow-ups at an interval of 15

days that was 0, 15th, 30th, 45th, 60th day, were conducted for a maximum of 60 days.

Total 222 patients were assessed. From which 8 patients were excluded. Then 214 patients were allocated randomly in both groups. 10 patients in Group A and 4 patients in Group B were lost follow-ups. Finally 100 patients in each group was analyzed. Total 14 patients were dropouts. The reason for dropout was, due to irregular follow-up.

On the basis of 'AGE', In Present study all patients are above 50 years of age. In group A maximum no of patient's i.e. 42%. in age group 50-60years. Similarly, in Group B it was found that maximum i.e. 45% in age

group 60-70 years. Means from age 50-70 years of age, age related hearing loss is most commonly found, which indicates that degeneration of cochlear nerve occurs in this age. Above 70 years of age, difficulty in hearing increases but number of participants were less, because numbers of patients of this age group were unable to come to hospital or negligence towards age related deafness is more in this age group.

As per the '**GENDER**', the maximum numbers of cases were seen in females (58% and 65% respectively in A and B Group). Although no such rule exists, this is just an observation that the probable causes could be attributed to their occupations and habits thus making them more prone to the condition. On the other hand, ignorance towards health by the females in our society could be an influencing factor.

Effect of Group A and Group B on Audiometry Results of this analysis indicated that there, were highly significant improvements observed in Group B on Audiometry in sensori-neural deafness after treatment of Kapikachhu Ghana Vati. However there were no significant differences observed, before and after follow up in Group A because no treatment was given to this group.

Effect of Group A and Group B on Hearing in noisy area, Results of this analysis indicated that, there were highly significant improvements observed in Group B on Hearing in noisy area in age related sensori-neural deafness, after treatment of Kapikachhu Ghana Vati. However there were no significant differences observed before and after follow up in Group A because no treatment given to this group.

Effect of Group A and Group B on Hearing of whispering sound, Results of this analysis indicated that, there were highly significant improvement observed in Group B on Hearing of whispering sound in age related sensori-neural deafness after treatment of Kapikachhu Ghana Vati. However there were, no significant differences observed before and after follow up in Group A because no treatment was given to this group.

Effect of Group A and Group B on Bhrama (vertigo), Results of this analysis indicated that there, were highly significant improvement observed in Group B on bhrama in age related sensori-neural deafness, after treatment of Kapikachhu Ghana Vati. However there were no significant differences observed, before and after follow up in Group A because no treatment was given to this group.

Effect of Group A and Group B on karnanada Results of this analysis indicated that there, were highly significant improvement observed in Group B on karnanada in sensori-neural deafness, after treatment of Kapikachhu Ghana Vati. However there were no significant

differences observed before and after follow up in Group A because no treatment was given to this group.

Before treatment of Kapikachhu Ghana Vati normal sensory neural deafness patients were more than 34% and after trial it improved up to 58%, Similarly mild sensory neural deafness patients improved from 17.20% to 22.30%, Moderate and severe sensory neural deafness patients were decreased from 28.60% to 15.20% and 20.10% to 3.80% respectively. It indicates that there were significant improvements observed after the treatment of Kapikachhu Ghana Vati.

DISCUSSION ON LITERATURE REVIEW

- Sushrutacharya and vagbhatachary mentioned badhirya, in which Vata dosha vitiated along with Kapha goes in Shabdavaha sira / Strotas because of that Margavrodh occurs that leads to Badhirya
- According to Bhavaprakash Nighantu Kapikachhu have **Vatashamak, Vajikar and Balya properties**. So, by considering these properties, Kapikachhu worked in the management of Badhirya.(sensori - neural deafness).
- In this study associated symptoms like, difficulty in hearing in noisy area, whispering sound, bhrama and karnanada are because of vitiated vata dosha and Kapha dosha. Which were reduced due to vatashamak and ushna virya properties of Kapikachhu. The drug Kapikachhu is vajikar, madhur rasatmak and balya because of that it is saptadhatu poshak, so it gives nourishment to majjadhātu (neuro protective and neuro regenerating) and balya property gives bala(strength) to majja dhātu which reduces degeneration of neurons.

The concept of Badhirya according to the modern science, there is degeneration of neurons of cochlear Nerve, loss of hair cells and loss of cochlear ganglionic cells.

- It is tested & proved that the drug Kapikachhu contains many phyto chemicals. e.g. Alanine, Glycine, Cystine, histidine, Dopa,, these ingredients are very useful in regeneration of neurons and neuro protection, hence it works in age related S.N. deafness. The concept of badhirya according to the modern science, there is degeneration of neurons of cochlear Nerve, loss of hair cells and loss of cochlear ganglionic cells.
- Properties of Godugdha also increase effect of kapikachhu which use as Anupana.
- It is tested & proved that the drug Kapikachhu contains many phyto chemicals. Among them Following are useful in treatment of hearing loss and their functions are as follows-
(ref 13-24)
- Dopamine helps in prevention of hearing loss in old age.
- N-Acetyl L-cysteine is capable of preventing age related hearing loss

- N- N-Acetyl L-cysteine can stop damage to the inner ear, which helps to reduce age related hearing loss.
- Linoleic acid helps to improve brain stem function in old age in rats.
- When the arachidonic acid decreases in old age, it leads to neurodegenerative disorders.
- L- arginine successfully works in angina, strokes and is also studied on 12 patients with profound hearing loss.
- Calcium can prevent and even reverse age related hearing loss.
- Decreased calcium level leads to memory loss and age related hearing loss in older people.
- Lopic acid has also been found to reduce age related hearing loss and tinnitus.
- Age related and noise induced hearing loss in mammalian cochlea shows that melanin and L DOPA can prevent these hearing loss.
- Omega-3 fatty acids leads to slow the gradual loss of hearing associated with age.
- Fatty acid intake was associated with lower risk of hearing loss in the old age. Amazing benefits of Gallic acid in age related vision and hearing loss was observed.
- Two months use of gallic acid leads to delay the progression of age related hearing loss.
- Glutamic acid is useful in sensory neural hearing loss.
- Several animal models have been used to study the presbycusis, the glycine is neuroreactive and receptor binding in the cochlear nucleus which helps to reduce age related sensory neural deafness.
- Histadine is useful in sudden and age related hearing loss by preventing macular degeneration.
- methocondria take centar stage in aging and neurodegeneration the methionine helps to reduce neurdegeneration in age related hearing loss
- Decrease in level of amino acid ie. Tyrosine leads to hearing loss in old age.
- -isoleucine is useful in age related hearing loss
- Lecithin reduces age related hearing loss.
- Glycine is the essential inhibitory neurotransmitter in mammals, it helps in age related hearing loss.
- linolenic acid deficiency causes age related hearing loss.
- lysine helps to reduce oxidative damage and prevention of age related hearing loss.
- Oleic acids regular use leads to preventon in age related hearing loss.
- Phenylalanine and thyrosine is useful in age related hearing loss in dogs.
- Magnesium is usefui in age related hearing loss. It is also involved in homocystine metabolism which is also helpful in noise induc ed hearing loss
- Proline has neuroprotective effects which help in preventing of age related hearing loss.
- Proteins help to improve the function of hair cells in inner ear and thus leads to prevent and reduce age related hearing loss.
- Valine is useful in age related sensory neural hearing loss.
- These ingredients are very useful in regeneration of neurons and neuro protection; hence it works in age related S.N. deafness
- **MODE OF ACTION OF DRUG ACCORDING TO AYURVEDA**

MADHUR, TIKTA RASA	• VATASHAMAK AND KAPHAGHNA
USHNA VIRYA	• REDUSES VATADOSHA AND KAPHADOSHA
MADHUR VIPAK	• REDUSES VISHIATED VATADOSH
GURU AND SIGDHA GUNA	• VATASHAMAK, AND PROMOTES HEARING .
BALYA	• VATASHAMAK, NURISMENT TO COCLIAR NERVE AND PROMOTES HEARING .

DISCUSSION ON CLINICAL STUDY

- Age related hearing loss is commonly found after 50 years of age.
- Both male and female are sufferers, but females are more in number.
- There are significant changes in audiogram of trial group after treatment of Kapikachhu Ghana Vati. In control group, no treatment was given to the patients, only Audiometry was done but there were no significant changes noticed in sixty days.
- In present study Hearing loss is found in all patients but the associated symptoms like difficulty of hearing in noisy area, difficulty in hearing of whispering sound, bhrama, karnanada was not found in each and every patient, it indicates that age related deafness occurs only with, difficulty in hearing or associated with one or more symptoms.
- After doing the comparison between trial and control group, no significant changes were found in control group because no treatment was given to this group.
- But in trial group, the results are encouraging after the treatment of Kapikachhu Ghan Vati.
- Associated symptoms like difficulty in hearing in noisy area and difficulty in hearing of whispering sound improves significantly.
- Bhrama and karnanada also improves significantly after treating with Kapikachhu Ghana vati.

CONCLUSION

- Oral administration of Kapikachhu Ghana vati reduces difficulty in hearing of whispering sound and difficulty in hearing in noisy area.
- Kapikachhu Ghana vati reduces bhrama (Vertigo) and karnanada (Tinnitus).
- Kapikachhu Ghana vati gives significant changes in audiogram.
- No other toxic effects of 'Kapikachhu Ghana vati' were noted in this present study.
- Hence "Kapikachhu Ghana Vati" is effective in age related sensory neural deafness as prescribed in hypothesis [H₁].

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19. By Kelvin DiDonato- Omega-3 fatty acids leads to slow the gradual loss of hearing associated with age www.gateprogarde.com/omega-3-hearing loss.html
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