



**CLINICAL EVALUATION OF EFFECT OF KAPIKACCHHU GHAN VATI IN BHRAMA
(VERTIGO) RELATED TO SENILE DEAFNESS**

***Dr. Gajanan Balkrishn Patil M.S. Ph.D. (ENT) (Shalakyatantra)**

Assistant Professor, Deptment of Shalaky Tantr (ENT), Bharati Vidyapeeth Deemed To Be University, College of Ayurved, Pune India.

***Corresponding Author: Dr. Gajanan Balkrishn Patil**

Assistant Professor, Deptment of Shalaky Tantr (ENT), Bharati Vidyapeeth Deemed To Be University, College of Ayurved, Pune India.

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ABSTRACT

Vertigo associated with senile deafness occurs usually after 45 years age. The spinning sensation or disturbance in equilibrium experienced by a patient causing one to lose balance or fall to the ground so there were mild, moderate or severe restriction in life style of patient. Bhrama (Vertigo) originally was not considered a separate disease but rather a symptom of other diseases. According to Ayurveda Badhirya and bhrama is mainly related with Vata dosha which is predominant in old age. hence, 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 vertigo related to senile deafness, mainly vitiated vata dosha alone or along with Kapha goes in Shabdavaha sira / strotas beacuse of that margavrodh occurs and leads to Badhirya and vertigo. So with help of Vatagnata the balya property of Kapikachhu it is useful in treatment of Badhirya and vertigo. This study is the view of ancient and modern science concerning with conceptual understanding of its etiology, diagnosis of Bhrama (vertigo) associated with senile deafness and its Ayurvedic treatment. The present study has shown that the kapikachhu Ghana vati is highly significant in the management of the vertigo associated with senile deafness.

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

INTRODUCTION

The spinning sensation or disturbance in equilibrium experienced by a patient causing one to lose balance or fall to the ground so there were mild, moderate or severe restriction in life style of patient. Bhrama (Vertigo) originally was not considered a separate disease but rather a symptom of other diseases. Here we are going to consider bhrama (Vertigo) related to age and ear diseases only. According to Ayurveda bhrama can occur due to vitiated Vata and Pitta doshas and Rajas guna. Ear related bhrama mainly occur due to vitiated Vata dosha because ear is one of the sthana of Vata dosha. Vata Prakopa lakshanas, an increase in intensity of sancaya signs, sour taste in the mouth Sour fragrance of the perspiration, Increased dryness causing increased thirst, Slight burning in the throat, stomach. Nidana consists of five considerations: Nidana (etiology), Purvarupa (prodromal signs), Rupa (main symptoms), Upashay-anupashaya (therapeutics), and Samprapti (course). Nidana can be understood as four aspects—Aharaja, Viharaja, panchakarmjanya, and anyaja Vata prakopak nidana Teekshna, laghu, ruksha, sheeta guna aharas can cause vata prakopa Anashana, adyashana, vishamashana, vishamopacharam, vruddahara, sevana can also cause vata prakopa Sushkashaka, vallura, varakoddalaka, koradoosha, shyamaka, neevara, mudgara, masura,

adhaki, harenu, kalaya. Vihara Ativyayama, vegasandharana (suppression of BM), vyayava, jagarana Bharaharana (over-exertion) Gataturagaradha, padhaticharya (standing), prapatana (flying), bhagnam (amorous pleasure) Abhighata, unmada, shoka, vishama, sharirasya Chinta, rogitakarshana Marma gatam (gatam=related) Excessive movement Kama shoka bhayam (kama=desire; bhaya- fear) The particular causative factors responsible for the Pitta component of bhrama are: excessive intake of sour, pungent, salty, or alkaline foods, alcoholic beverages, excessive exposure to sun and fire, excessive competitiveness, judgment, jealousy, and covetousness.

Purvarupa

Bhrama itself is not always a discreet disease according to Ayurveda. It is also considered a possible purvarupa for the following diseases: Jvara, apasmara, arsha, raktapitta, grahani, kustha, masurika.

Rupa

Rupa refers to a collection of symptoms which are recognized as a discrete disease (synonyms: lakshanam, samstanam). They too can be either the samanya or vishishta type.

Bhrama is mentioned as a rupa of many diseases including various forms of jvaras, udavartha, murcha, chardi, arsha, kundalika, udara, pandu, halimakam, vishagni vyadi, krimi, marmagat, masurika, Rakta pradaram, and many others.

Samprapti

Due to uncorrected exposure for a period of time to the causative forces described above, the doshas can become aggravated and begin a sequence of pathological steps culminating in the creation of a disease state. The term "samprapti" refers to this sequence of dosh-related pathology triggered by one or more nidana (cause). Before we describe this sequence in detail let us consider a brief explanation of this sequence.

First, one or more doshas begins to accumulate in the body and soon becomes vitiated (aggravated). Next, the aggravated dosha spills over and begins to spread. When it reaches a vulnerable or somewhat weakened area or organ of the body, it will stagnate there and begin to mix with and disturb the structure and function of the local tissues. The tissues of the body, when spoken of in their healthy state are of course called the dhatus; however when we speak of these same tissues with regard to their mixing with vitiated doshas, we always refer to the tissues as dushyas.

This dosha-dusyas sammurcchana is the actual disease process (sammurcchana means "interaction"). The interaction of the doshas and dushyas, together with the specific effect from the site or organ involved (adhithana) leads to the development first of specific prodromal features, and then of the main symptomatology, of a disease. Left untreated the disease will evolve its unique set of complications and reach a stage where it is no longer curable by any means.

Ayurveda, in one of its seminal contributions to medical thought, precisely describes this sequence of pathogenesis in terms of six specific stages. This has become known as the satkriyakala. Literally, this translates to "six times for action" but is also more commonly referred to as "the six stages of disease". Either translation is suitable.

The satkriyakala gives a view of the entire natural course of the disease from its early, reversible, pre-organic stages through its stage of manifestation and symptoms, to its late advanced stage with its irreversible complications. Knowledge of which stage of the satkriyakala a particular disease is in guides us toward the appropriate therapeutic intervention for that stage. The legacy left behind by this brilliant and profound set of observations into the nature of the disease process is the vital importance and practical relevance of the early identification of the incipient disease process, so that the disease can be precluded while in one of its early stages dosha Today in Western medicine we give the name Vertigo to that disease (from Latin: vertere, to turn.

AIM AND OBJECTIVES

Aim

1. To Evaluate the effect of Kapikachhu Ghana Vati in Vertigo associated with age related sensory neural hearing loss.

Objectives

1. To study in detail about Kapikachhu Ghana Vati.
2. To study in detail about Vertigo associated with age related sensory neural hearing loss.
3. Understanding the effect of Kapikachhu Ghana Vati in Vertigo associated with age related sensory neural hearing loss.
4. To establish the role of Ayurvedic line of treatment according to etiopathology of Vertigo associated with age related sensory neural hearing loss.

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 Ghan 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.: BVDU COA/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.

STUDY DESINE

First screening done as per inclusion criteria – counseling and informed consent - Randomization and Grouping – all these process comes under screening after that collection of data – in this study I made to groups – group A no treatment given to this group – Group B which is trail group where the Kapikachhu Gana vati given to this group – initial assessment done on 0 day

with Audiometry – follow ups on 15th, 30th, 45th, and 60th days – Audiometry done on 0, 30th, and 60th days only- total duration was 60 days –all the processes comes under collection of data - after that data analysis and reporting done.

Inclusion criteria

- Individuals of 45 years and above age were included.
- Individuals having complaints of Vertigo associated with age related sensory neural hearing loss.
- 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.
- Congenital deformity.

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

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

Vertigo (Bhrama)

| GRADATION | SYMPTOMS |
|-----------|---|
| 0 | No Vertigo |
| 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 |

GRADATION CHART

| | |
|---|----------|
| 0 | NORMAL |
| 1 | MILD |
| 2 | MODERATE |
| 3 | SEVERE |

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 |

In the Control group, No treatment was given, only Audiometry done for study and questioner asked and observations done.

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

Subjective Criteria

The effect of treatment would be assessed by observing following symptoms from the patients:-

Primary endpoint

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

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

Secondary outcome

Kapikacchu Ghana Vati is beneficial in Vertigo associated with age related sensory neural hearing loss.

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

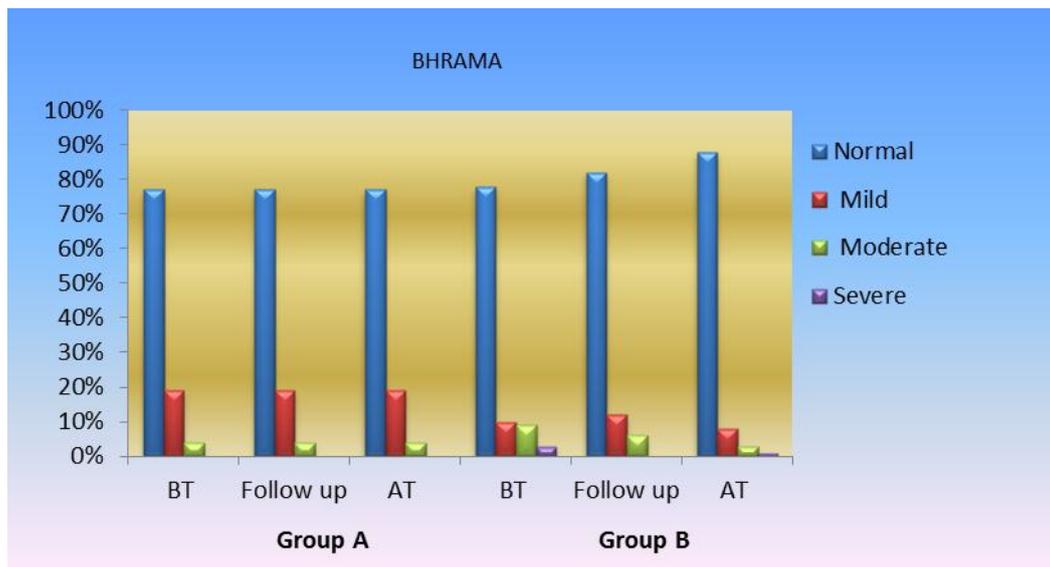
The data collected from the study was compiled, tabulated and analyzed using Wilcoxon Signed Rank test for the efficacy of Trial Drug and Control Drug and Mann Whitney U test for comparison; this was in accordance with the aim and objectives of the study.

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.

EFFECT OF GROUP A AND GROUP B ON BHRAMA

| BHRAMA | | | | | | | | | | | | |
|--------|-----------------|-----|-----------------|------------|-----------------|-----|-----------------|-----|-----------------|------------|-----------------|-----|
| Grade | Group A | | | | | | Group B | | | | | |
| | BT | | Follow up | | AT | | BT | | Follow up | | AT | |
| | No. of patients | BT | No. of patients | Follo w up | No. of patients | AT | No. of patients | BT | No. of patients | Follo w up | No. of patients | AT |
| 0 | 77 | 77% | 77 | 77% | 77 | 77% | 78 | 78% | 82 | 82% | 88 | 88% |
| 1 | 19 | 19% | 19 | 19% | 19 | 19% | 10 | 10% | 12 | 12% | 8 | 8% |
| 2 | 4 | 4% | 4 | 4% | 4 | 4% | 9 | 9% | 6 | 6% | 3 | 3% |
| 3 | 0 | 0% | 0 | 0% | 0 | 0% | 3 | 3% | 0 | 0% | 1 | 1% |



| BHRAMA | Mean Rank | Chi sq | df | P value |
|---------------------------|-----------|---------|----|----------|
| Pre | 2.13 | 15.2328 | 2 | 0.000492 |
| 2 nd Follow up | 1.97 | | | |
| Post | 1.9 | | | |

p value<0.05 hence Reject Ho)

I.e. Results of this analysis indicated that there, were highly significant in improvement observed in Group B on bhrma in sensori-neural deafness.

However there was significant difference in follow up and post treatment in sensori-neural deafness, for improvement observed in Group A.

Comparison of Group A and Group B on BHRAMA in sensory-neural deafness.

| BHRAMA | N | Mean of ranks | Sum of Ranks | Mann Whitney U test | Z value | p value |
|---------|-----|---------------|--------------|---------------------|---------|---------|
| Group A | 100 | 104.82 | 10482 | 4568 | -1.5638 | 0.1178 |
| Group B | 100 | 96.18 | 9618 | | | |

There, was not statistically significant difference in improvement on bhrama found in sensori-neural deafness. i.e. effect of Group A was same as effect of Group B on bhrama in sensori-neural deafness.

(p value<0.05 hence Reject Ho) i.e. results of this analysis indicated that there, were highly significant in improvement observed in Group B on bhrama in sensory-neural deafness.

However there was significant difference in follow up and post treatment in in sensory-neural deafness, for improvement observed in Group A.

DISSCUSION

Kapikacchhu 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 were analyzed. Total 14 patients were dropouts. The reason for dropout was, due to lack of or 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 60-70years. Means from age 50-70 years of age, age related hearing loss is most commonly found it indicate that degeneration of cochlear nerve accure in this age. Above 70 years of age difficulty in hearing increases but number of participants was less, because number of patients of this age group was unable to come in 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 Bhrama (Vertigo) results of this analysis indicated that there were highly significant in improvement observed in Group B on bhrama in age related sensory-neural deafness, after treatment of *Kapikacchhu Ghana Vati*. However there were, no significant differences observed, before and after follow up in Group A because no treatment given to this group.

DISCUSSION ON LITERATURE REVIEW

- Acharya Sushrutacharya and vagbhatachary mentioned badhirya, in which Vata dosha vitiated along with Kapha goes in Shabdavaha sira / Strotas because of that Margavrodh occurs and leads to Badhirya
- According to Bhavaprakash Nighantu *Kapikacchhu* have **Vatashamak, Vajikar and Balya properties**. So, by taking into consideration these properties, *Kapikacchhu* worked in the management of Badhirya.(sensory -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 *Kapikacchhu*. *Kapikacchhu* is *vajikar* because of that it is *Saptadhatu* poshak, so it gives nourishment to *Majjadhatu* (neuro protective and neuro regenerating) and *Balya* property gives *bala* (strength) to *Majja dhatu* 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 *Kapikacchhu* contains many phyto chemicals. Among them Following are useful in treatment of hearing loss.

CONCLUSION

- Oral administration of *Kapikacchhu Ghana vati* reduces difficulty in hearing of whispering sound and difficulty in hearing in noisy area.
- *Kapikacchhu Ghana vati* reduces bhrama and karnanada
- *Kapikacchhu Ghana vati* gives significant changes in Audiogram.
- No any toxic effects of '*Kapikacchhu Ghana vati*' were noted in this present study.

Hence “Kapikacchhu Ghana Vati” is effective in age related sensory neural deafness as prescribed in hypothesis [H₁].

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