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MANAGEMENT OF HEARING LOSS: A PROSPECTIVE RANDOMIZED OPEN-LABEL INTERVENTIONAL STUDY

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ABSTRACT
Hearing loss is one of the commonest problem in ear diseases due to sound pollution, over usage of earphones, cell phone, improper care in early stages of ear diseases etc. According to Ayurveda it is correlated with badirya. Acharya Susruta and Vagbhata described the disease badirya as an independent disease, which is manifests as hearing impairment, caused by vitiation of vata and kapha. According to vagbhata, vata in association with kapha is gradually produces badirya. This study was undertaken to determine the usefulness of *Asanabilvadi taila and Sarivadi vati* in the treatment of badirya. **Materials and Methods:** A prospective, randomized, open-label interventional study was conducted. The observational period was of 3 months. Outcome measured and data was analyzed using paired t-test and Wilcoxon signed rank tests. **Results:** Out of 31 enrolled participants, 29 completed the 3months follow up. Two subjects did not report after 1 month but were included under Intention-To-Treat (ITT). Though there were overall statistically significant results in hearing improvement, score ($P < 0.001$) but no effect was seen in old aged. **Conclusions:** *Asanabilvadi taila and Sarivadi vati* has a good role in early and short duration cases of badirya. Further study on a larger sample size is desirable.

KEYWORDS: Badirya, Hearing loss, Asanabilvadi taila, Sarivadi vati.

INTRODUCTION
Hearing loss is generally described as mild, moderate, severe, or profound, depending upon how well a person can hear the sound. Hearing loss can occur in either one or both ears. It can be either congenital or acquired. Sometimes deafness is similar in both ears or different in each ear. On onset of duration, hearing loss is presented as sudden and gradual.

Acharya Susruta and Vagbhata described the disease badirya as an independent disease, which is manifests as hearing impairment, caused by vitiation of vata and kapha.[1] According to vagbhata, vata in association with kapha gradually produces badirya. This study was undertaken to determine the usefulness of *Asanabilvadi taila and Sarivadi vati* in the treatment of badirya. Acharya Susruta mentions similar line of treatment for karnasula, pranadha, karnaksveda and badirya because of vata predominance.[2] There are several regimens are available regarding badirya in various samhitas and other literatures. We selected easily and abundantly available drugs. Common etiological factors of karnaroga are described in classics its include Avasyaya, Jalakrida, Karnakandu, Mithya yogensastrasya, Pratisyaya and also other causes.[3] Prolonged exposure to avasyaya leads to vitiation of kapha, vata and produces itching in external auditory canal. With this subjects are stimulated to clean the ear to relieve itching will lead to scratch in auditory canal and facilitates various ear infections. Jalakrida (swimming, bath in the river etc) lead to kapha, vata vitiation. It causes moistening of wax, derangement of the defence mechanism and may cause infection. Mithyayogena sastrasya (Improper introduction of instruments by unskilled person or doctors) may injure the external ear or tympanic membrane. Pratisyaya (Infection of nose and nasopharynx) can spread to eustachian tube and middle ear. Due to indulge in excessive intake of these nidana, vatha and kapha dosas are abnormally aggravated in and around the ears and will block the pathway of hearing and produce badirya.

MATERIALS AND METHODS
Aims and objectives of the study
To evaluate the efficacy of Asanabilvadi taila.
To evaluate the effect of Karnapoorana in Badirya.
To evaluate the efficacy of Sarivadhi vati.

Design overview
A prospective, randomized, open-label interventional study was conducted on human subjects from July 2015 to August 2016. The study was conducted at Ayurveda College Coimbatore, Tamilnadu, India. Subjects gave written consent before initiation of the study. The case of

each subject was recorded on a predesigned case taking questionnaire.

Sample size

31Patients of both sexes presenting the hearing impairment were screened as per the inclusion/ exclusion criteria mentioned below.

Inclusion and exclusion criteria

Subjects were Outpatient Department (O.P.D) patients of both sexes between 25 to 75 years, who had hearing impairment. Subjects who had any drug or alcohol addiction, suffering from any chronic systemic disease, cases with life threatening medical condition, mental retarded patients were excluded. Subjects who were taking any other medication for systemic diseases were excluded from the study. Patients who were aged than 75 were also excluded from the study.

Table 1. Age wise distribution

Age in years	No of patients	Percentage (%)
25 - 35	3	9.67
36- 45	7	22.58
46-55	9	29.03
56- 65	10	32.25
66- 75	2	6.45

Table 2. Sex wise distribution

Sex	No of Patients	Percentage
Male	18	58.06
Female	13	41.93

Table 3. Diet wise distribution

Diet	No of Patients	Percentage
Mixed	22	70.96
Veg	9	29.03

Intervention

On first visit *Asanabilvadi taila Karnapurana* was prescribed one time day for 7 days. After 7 days gap procedure was repeated. The subjects came for clinical evaluation every alternate week for monitoring the response to the medicine. Sarivadi vati given 1 tablet trice a day internally. The total regimen was given for 3 months. The medicines were procured from pharmacy. The subjects were not allowed to take any other medications during the study. Dietary restrictions and life style changes were advised. The primary outcome was the percentage change in hearing capacity in 3 months. Screening was done manually. The subjects were asked to fill the questionnaire both at the start and at end of treatment.

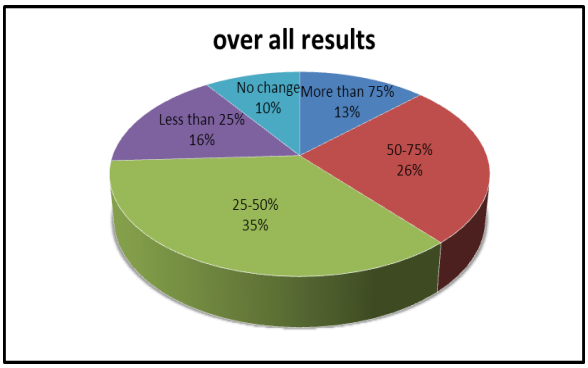
Procedure of Karnapoorana consists of three stages. In Preoperative stage, patient was lie down. Mrudhu abyanga and swedana was done around the ear with tila taila. Next in Operative stage, Asanabilvadi taila made in to lukewarm and filled full of auditory canal for 5 min. In Post operative stage, oil removed from the ear and again hot fomentation was done around the ear. Same procedure is done for another ear to prevent the bilateral hearing loss.

RESULTS

31 subjects were enrolled for the study. Two subjects did not report after 1 month of treatment but were considered under ITT and data analyzed. There were 18 male and 13 female subjects (n = 31). Duration of complaints was 1.9 + 1.2 years.

Table 4. Overall results

Percentage improvement	No. of subjects	Percentage
More than 75%	4	12.90
50-75%	8	25.08
25-50%	11	35.48
Less than 25%	5	16.12
No relief	3	9.67



The improvement was statistically significant $P < 0.001$. Out of the 31 subjects, 4 subjects showed >75% relief, 8 subjects showed 50–75% relief, 11 subjects showed 25 – 50% relief, 5 subjects showed less than 25%. There are three subjects were not improved with treatment. It was ineffective in old aged and it acted better in young subjects. The results are very good in short duration cases, younger and middle age group patients.

DISCUSSION

Hearing loss is generally described as mild, moderate, severe, or profound, depending upon how well a person can hear the sound. Disabling hearing loss refers to hearing loss greater than 40 dB in the better hearing ear in adults (15 years or older) and greater than 30 dB in the better hearing ear in children (0 to 14 years). (WHO global estimates on prevalence of hearing loss, 2012) Generally, only children whose hearing loss is greater than 90 decibels (dB) are considered as deaf. It can be either congenital (hearing loss was present at birth) and acquired (occurred after birth, due to illness or injury). Hearing loss can occur in either one or both ears. Systemic disease should produce bilateral rather than unilateral ear symptoms.[4]

Sometimes deafness is similar in both ears (symmetrical deafness) or different in each ear (asymmetrical deafness). On onset of duration, hearing loss is presented as sudden and gradual. Sudden Hearing Loss (SHL) is defined as a rapid-onset, occurring over a 72 hour period, of a subjective sensation of hearing impairment in one or both ears. The primary presenting symptom of SHL is a full or blocked ear.[5] Hearing loss of 30 dB or more over at least three contiguous audiometric frequencies that develops over a period of a few hours to 3 days' and whose etiology can be found only in 10% to 15% of patients.[6,7]

Causes of Hearing Loss

Congenital causes of hearing loss include a family history of hearing loss, infections during pregnancy (such as rubella), complications during pregnancy (such as the Rh factor, maternal diabetes, or toxicity). The most common causes of acquired hearing loss is exposure to noise, fluid in the middle ear, infections, childhood diseases, such as mumps, measles, or chicken pox and head trauma. Syndromes can leads to hearing loss include Down syndrome, Usher syndrome, Treacher Collins syndrome, Crouzon syndrome and Alport syndrome. In 85% to 90% cases of sudden sensori neural hearing loss (SSNHL), in spite of thorough evaluation, the underlying cause is unknown or uncertain at the time of presentation and treatment decisions are generally made without knowledge of the etiology.[8,9]

Bilateral Hearing Loss

Presbycusis is a symmetric, progressive deterioration of hearing in elderly patients. The etiology is a combination of inherited and environmental factors, including lifetime noise exposure and tobacco use. Noise trauma is the most common preventable cause of sensorineural hearing loss. Gunfire, explosions and loud music can cause irreversible hearing impairment. High frequencies are affected first, typically at 4,000 Hz, followed by middle and lower frequencies. A less common cause of hearing loss is ototoxin exposure, typically from diuretics, salicylates, aminoglycosides and many chemotheraupetic agents. Autoimmune hearing loss present with rapidly progressive bilateral sensorineural hearing loss and poor speech discrimination scores and they also may have vertigo or disequilibrium.

Unilateral Hearing Loss

Temporal bone fractures can cause unilateral sensorineural and conductive hearing loss. When the fracture line involves the bony labyrinth, sensorineural hearing loss occurs. Meniere's disease patients report unilateral fluctuating hearing loss with aural fullness, tinnitus and episodic vertigo.[10]

There are four types of hearing loss, as follows. Conductive hearing losses are caused by abnormality in the conductive apparatus (external or middle ear). Conductive hearing losses usually affect all frequencies of hearing evenly and do not result in severe losses. Sensori neural hearing losses result from damage to the delicate sensory hair cells of the inner ear or the nerves that supply it. These hearing losses can range from mild to profound. A mixed hearing loss refers to a combination of conductive and sensorineural loss and means that a problem occurs in both the outer or middle and the inner ear. A central hearing loss results from damage or impairment to the nerves or nuclei of the central nervous system, either in the pathways to the brain or in the brain itself.[11] Diagnosis can be done with otoscope (used to examine the external auditory canal, tympanic membrane), Paper test, Watch test, tuning fork test (Rinne's test and Weber's test). Hearing acuity can be measured with either objective or subjective tests in childrens. Objective examonation include brainstem auditory evoked response, otoacoustic emissions (OAE), auditory steady state response (ABR) and impedance testing (Tympanometry). Subjective tests include behavioural and pure-tone testing etc. Management includes aural toilet, cerumenolytics, antibiotics, myringotomy, stapedectomy, hearing aids, cochlear implantation, counseling to subjects and parents etc.

Asana bilvadi taila contains asana (Pterocarpus marsupeum), Bilva (aegle marmelos), Bala (sida cardifolia), Amrutha (Tinospora cardifolia), Madhuka (Glycyrrhiza glabra), nagara (zingiber officinale), Amalaki (emblica officinale), Haritaki (Terminalia chebula), Vibitaki (Terminalia bellarica), Kshera (Milk) and Taila (Oil). Sarivadi vati contains Sariva (Hemidismus indicus), madhuka (Glycyrrhiza glabra), Kusta (Sassurea lappa), Twak (Cinnamon), Patra (Cinnamomum tamala), Ela(Cardamom), Nagakeasara (Mesua ferra), Priyangu (Callicarpa macrophylla), Nilotpala (Nymphaea stellata), Guduchi (Tenospora cardifolia), Devapuspa (Syzigium aromaticum), Amalaki (Emblica officinale), Haritaki (Terminalia chebula), Vibitaki (Terminalia bellarica), Abraka basma (Basma of silica), Loha basma (Basma of Iron) done bhavana with Brungaraja decoction (Eclepta alba), Partha (Terminalia arjuna), Yava (Hordeum vulgare), Kakamachi (Solanum nigrum), Gunjamula (Root of Abrus precatorius). *Asanabilvadi taila and Sarivadi vati* lead to statistically significant response in hearing impairment. Asana and vibetaki having kapha pitta hara property, bilva and nagara contains vata kapha hara property, bala having vata pitta hara property and guduchi, amalaki, haretaki, madhuka having tridosa hara property. overall Asana bilvadi taila having kasaya, tikta and madhura rasa, laghu and ruksha guna, ushna verya, madhura vipaka and tridosa hara property. Most of the ingredients of both drugs are having rasayana and vatahara, anti inflammatory, antioxidant property etc.

CONCLUSION

Asanabilvadi taila and Sarivadi vati has shown positive results in hearing loss. The sample size being small, further trials with a larger sample may be conducted for verification of results. Though certain prescribing symptoms of this medicines in relation to hearing loss

have been elucidated but the likelihood ratio of these symptoms may be worked out in future studies for confirming their relevance.

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