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Efficacy of oral *Musalyapamarga churna* in improving hearing threshold: A randomized controlled clinical trial in *Badhirya* w.s.r. to Sensory neural hearing loss (SNHL)

Research Article

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Abstract

Introduction: The sense of hearing plays a crucial role in daily life, yet it is often taken for granted. Hearing loss, whether partial or complete, in one or both ears, can significantly affect social interactions, professional engagements, and personal well-being. While modern interventions like hearing aids and cochlear implants provide effective solutions, they can be costly and may not be accessible to all, particularly in underdeveloped regions. In such areas, traditional *Ayurvedic* treatments like *Musalyapamarga Churna*, which is known for its *Vata-hara* (balancing Vata) and *Rasayana* (rejuvenating) properties, may offer a more affordable and accessible alternative. This study aims to investigate the effectiveness of *Musalyapamarga Churna* in treating sensory neural hearing loss (*Badhirya*), applying *Ayurveda's* holistic approach to improve hearing health outcomes. Methods: The study involved 30 patients diagnosed with *Badhirya*, who were randomly assigned into two treatment groups. Group A received *Musalyapamarga Churna*, while Group B was treated with *Sarivadi Vati*, a standard *Ayurvedic* formulation. Both groups consisted of 15 patients. Results: Statistical analysis revealed significant improvement within both groups, as evidenced by paired t-tests (p=0.001). However, there was no significant difference between the two groups when analyzed with unpaired t-tests. Conclusion: The study concluded that *Musalyapamarga Churna* was effective in managing *Badhirya*, showing comparable efficacy to *Sarivadi Vati*. Both treatments demonstrated similar effectiveness, suggesting that *Musalyapamarga Churna* could be a viable alternative for managing sensory neural hearing loss, particularly in resource-limited settings.

Keywords: *Badhirya, Musalyapamarga churna*, *Sarivadi Vati*, Sensorineural hearing loss.

Introduction

Hearing loss is a significant societal and medical issue, often termed a hidden disability. The World Health Organization defines hearing loss as the inability to hear as well as someone with normal hearing and hearing thresholds of 20 dB. Hearing loss of more than 35 decibels (dB) in the better-hearing ear is called "disabling" hearing loss. According to a poll conducted by the World Health Organization on April 1, 2021, over 5% of the world's population - 430 million people - need rehabilitation to treat their "disabling" hearing loss. Over 700 million individuals, or roughly one in ten, are predicted to have debilitating hearing loss by 2050 (1,2). In India, the prevalence of hearing loss is around 6.3% of people are suffering from hearing loss (3). Compared to people without hearing loss, people with hearing loss are more likely to be unemployed, work part-time jobs (underemployed), and earn poor wages, according to population-based studies (4). By using hearing aids, vitamin supplementation hearing loss can be improved however it is not the complete solution to treat deafness. Hearing aids are inaccessible to everyone because of low custom designs, incorrect amplification adjustment, and economic constraints.

Ancient *Ayurvedic* texts, although not specifically describing the disease, correlate hearing loss with *Badhirya*. *Sushruta* categorized it among 28 *Karna rogas*, *Charaka* under 80 *Nanatmaja Vata Vikara*, and *Vagbhata* among 25 *Karna rogas* (5). Modern science classifies hearing loss into conductive, sensorineural, and mixed deafness, reflecting various auditory dysfunctions (6).

Ayurveda distinguishes two types of *Badhirya: Vataja* and *Vatakaphaja*, aligning with modern classifications. Causes may be congenital, acquired, or hereditary. Treatment options include medicinal therapies, surgeries, and hearing aids, each yielding good outcomes when appropriately diagnosed and treated. However, prolonged use of nasal decongestants and antibiotics can alter manifestations rather than address underlying causes, and surgical interventions are not without risks.

Despite advancements, finding effective treatments for *Badhirya* remains a challenge. Traditional Indian systems of medicine, like *Ayurveda*, offer potential solutions. *Musalyapamarga Churna* mentioned for *Karna Badhirya* (7), holds promise for treating Sensory Neural Hearing Loss. Further research

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aims to evaluate its efficacy compared to *Sarivadi vati* in managing *Badhirya*, highlighting ongoing efforts to explore *Ayurvedic* interventions for hearing impairment.

Materials and methods

Study drug details

KLE Ayurveda Pharmacy, Khasbag, Belagavi, provided *Krishna Musali* and *Apamarga moola was* collected from natural habitat. *Krishna Musali* and *Apamarga moola* were identified, authenticated, and analyzed for preliminary phytochemical and physico-chemical tests at AYUSH Government of Karnataka recognized ASU Drug Testing Central Research Facility of KAHER's Shri B M K Ayurveda Mahavidyalaya, Belagavi (Ref: BMK/CRF/244/2022-23). The study drug was manufactured (Table no 1) and packaged at GMP-certified KLE Ayurveda Pharmacy in Belagavi, Karnataka. It was then stored in the Medical Research Center of B.M.K. Ayurveda Mahavidyalaya, Belagavi, Karnataka for further dispensing the study drug to study subjects.

Table 1: Drug review of *Musali* and *Apamarga*

Sanskrit Name	Latin Name	Official Part	Proportion	*Karma*
Musali	*Curculigo orchioides* gaertn	Rhizome	1 part	*Rasayana, Brmhana, Vrushya, Arshohara*
Apamarga	*Achyranthes aspera* Linn	Root	1 part	*Dipana, Pachana, Kandughna, Medhya, Hridya, Vranaropana*

Clinical study

The study was initiated after ethical clearance (Protocol no: BMK/21/PG/SKT/2) and registered at CTRI (CTRI/2022/09/046044).

Patients were chosen from the outpatient department of the *Shalakya Tantra* department at KAHER's KLE Ayurveda Hospital in Belagavi, Karnataka, if they had been diagnosed with Sensory Neural Hearing Loss, met the diagnostic criteria, and were willing to give their consent. The inclusion criteria for *Badhirya* were (i) mild to moderate hearing loss (26 to 55 dB) and (ii) age group 18 to 70 years. Chronic Suppurative Otitis Media (CSOM), perforation of the tympanic membrane, infectious disorders such as encephalitis, herpes, mumps, etc., known cases of aural tumors, polyps, etc., and patients with uncontrolled diabetes and hypertension are among the exclusion criteria.

Grouping and treatment schedule

The study was carried out in ENT OPD at KLE Shri B.M.K. Ayurveda Hospital. 54 patients were screened, amongst whom 30 were included in a Randomized Controlled Clinical Trial and were randomized into two groups (Trial and Control group) by using an online software random number generator. Thirty patients were divided into 15 groups. Group A patients were given *Musalyapamarga Churna* with honey 4 grams thrice daily. Group B patients were given *Sarivadi Vati* with warm water one tablet thrice daily for 30 days.

Table 2: Group treatment intervention of *Musalyapamarga Churna* and *Sarivadi Vati*

Groups	Sample Size	Drugs	Dose and Duration	Assessment	
				Before treatment	After treatment
Group A -Trial	15	*Musalyapamarga Churna*	4gms three times a day with honey for 30 days after food	0th day	31st day
Group B - Control	15	*Sarivadi Vati*	1 tablet three times a day with warm water for 30 days after food	0th day	31st day

Assessment Criteria

Subjective Parameter: Reduced hearing
Objective Parameter: Pure Tone Audiometry BT and AT
Statistical Analysis:
Statistical analysis was done by using paired and unpaired t-tests.

Results

Table 3 shows the descriptive analysis of the sociodemographic variable of 30 hearing-impaired subjects. The average gender of the sample was 56.67% female. 36.67% were homemakers, 70% had irregular food habits and 53.33% had irregular *malapravrutti*.

Table no 4 shows the comparison of before and after treatment with audiometry (in dB) scores in the Right ear where the p-value of both groups is 0.0001* which is significant. Table no 5 shows the comparison of before and after treatment with audiometry (in dB) scores in the Left ear where the p-value of both groups is 0.0001* which is significant. Table no 6 shows the comparison of both the groups with audiometry (in dB) scores in the Right ear with the p-value 0.4112 before treatment which is non-significant and 0.9062 after treatment which is non-significant. Table no 7 shows the comparison of both the groups with audiometry (in dB) scores in the Left ear with the p-value 0.4666 before treatment which is non-significant and 0.6797 after treatment which is non-significant.

Objective parameter analysis

Table 4: Comparison of before treatment and after treatment with Audiometry (in dB) scores in the Right ear in Group A and Group B by paired t-test

Groups	Times	Mean	SD	% of change	t-value	p-value
Group A	BT	35.40	6.73	29.94	7.8841	0.0001*
	AT	24.80	4.69			
Group B	BT	33.33	6.84	25.00	7.1491	0.0001*
	AT	25.00	4.52			

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Table 3: Demographic Data					
	Group A		Group B		Average
	n	%	n	%	%
Gender					
Male	7	46.67	6	40.00	43.33
Female	8	53.33	9	60.00	56.67
Occupation					
Homemaker	6	40.00	5	33.33	36.67
Business	4	26.67	1	6.67	16.67
Doctor	2	13.33	2	13.33	13.33
Student	0	0.00	4	26.67	13.33
Others	3	20.00	3	20.00	20.00
Food Habits					
Regular	6	40.00	3	20.00	30.00
Irregular	9	60.00	12	80.00	70.00
Malapravrutti					
Regular	3	20.00	2	13.33	16.67
Constipation	3	20.00	6	40.00	30.00
Irregular	9	60.00	7	46.67	53.33

Table 5: Comparison of before treatment and after treatment with Audiometry (in dB) scores in the Left ear in Group A and Group B by paired t-test

Groups	Times	Mean	SD	% of change	t-value	p-value
Group A	BT	35.07	7.31	28.52	7.7906	0.0001*
	AT	25.07	5.20			
Group B	BT	33.20	6.52	26.91	5.9403	0.0001*
	AT	24.27	5.30			

Table 6: Comparison of Group A and Group B with Audiometry (in dB) scores in the Right ear before treatment and after treatment by unpaired t-test

Times	Group A		Group B		Mean Diff.	t-value	p-value
	Mean	SD	Mean	SD			
Before treatment	35.40	6.73	33.33	6.84	2.07	0.8342	0.4112
After treatment	24.80	4.69	25.00	4.52	-0.20	-0.1189	0.9062
Difference	10.60	5.21	8.33	4.51	2.27	1.2738	0.2132

Table 7: Comparison of Group A and Group B with Audiometry (in dB) scores in the Left ear before treatment and after treatment by unpaired t-test

Times	Group A		Group B		Mean Diff.	t-value	p-value
	Mean	SD	Mean	SD			
Before treatment	35.07	7.31	33.20	6.52	1.87	0.7380	0.4666
After treatment	25.07	5.20	24.27	5.30	0.80	0.4173	0.6797
Difference	10.00	4.97	8.93	5.82	1.07	0.5395	0.5938

Discussion

Musalyapamarga Churna is an herbal preparation that is explained in the context of *Badhirya*. It is a condition in which there is vitiation of *Vata dosha* alone or along with the *kapha dosha* leads to impairment in hearing i.e., reduced hearing. The *nidana* which is explained for *Karnagata roga* as *Avashyaya* is *sheeta* and *apya dravya* so it causes vitiation of *vata-kapha* and stops the release of *Ushma*, thus producing *vyadhi* via *dosha* vitiation. *Avashyaya* is generally considered as humidity. High levels of humidity cause the trapping of pollutants within moisture for longer periods worsening air pollution. This *dooshita vata* can produce a variety of disorders, high humidity is thought to trigger chemical and electrical changes in the brain and irritates nerves. In a recent study, high humidity was found to be positively associated with aural fullness, hearing loss, and increased odds of episodes of Meniere's disease (8). *Jalakrida – Shira* is a seat of *Sleshma*, this *Tarpaka kapha* does *Anugraha* on *Indriyas* to perform their natural functions and protect them. *Jaliya Dravya* and *Sleshma* have common *gunas* like *Snigdha, Sheeta*, and *Picchila*, whereas *Jaliya Dravya* and *Vata* have *sheeta guna* in common also *Jaliya Dravya* and *Pitta* have *Drava guna* in common, this *guna samanyatva* results in *Dosha vriddhi* and *Rogotpatti.* Swimming in dirty water may lead to external and middle ear infections. In contrast, barotrauma during diving may perpetuate internal ear injury and this damaged vestibulocochlear system produces vertigo, hearing loss, and tinnitus (8).

Discussion on observation

Age

From 18 to 30 years of age total of 7 patients were enrolled, making 23.33% of the total sample size. The World Health Organization states that in this age group, meningitis, CSOM, smoking, otosclerosis, sudden SNHL, chronic nonsuppurative otitis media, any chronic condition, and meningitis are likely causes of SNHL (9) From 51 to 70 years of age total of 14 patients were enrolled, making 46.66% of the total sample size. This age group will primarily exhibit atrophy of the stria vascularis and degeneration of the cochlear nerve's neurons (9). The cochlear nerve's neurons are primarily degenerating in this age range, and the cochlear stria vascularis is atrophying.[10] Hair cells also deteriorate, but this deterioration does not occur at a constant rate or with age; the date of its commencement varies. However, it can be claimed that the rate of deterioration varies from person to person and rises with age, particularly at high frequencies like 4k, 6k, and 8k. Clinical studies reveal that most onsets occur in middle age, between 40 and 60 years (10).

Aniyamita ahara sevana

About 80% of the subjects were having irregular food intake. Classics say that *Aniyamita ahar sevana kala* will lead to *vata prakopa* and that in *Sarva Shareera, prakupita vata* gets *prasara*. Additionally, the hearing gets affected leading to *Badhirya* by the *Sthana samshraya* of *Vata* in *Shabda vaha Srotas*. An irregular food intake will result in a changed blood glucose level and a changed thermic impact, which will lead to inadequate nourishment (11).

Occupation

The majority of the patients in the study sample were homemakers and had a history of excess use of mobiles, earphones, stress, habitual loud music listening, etc., which could be contributing factors, pathology in this case is identical to noise-induced SNHL (12). On the other hand, aging, family history, persistent stress, and anxiety are also potential causes in businessmen. In situations with Sensory Neural Hearing Loss, factors such as exposure to loud noises, stress, anxiety, trauma, and most crucially, aging and family history, have a greater impact.

Malapravrutti

The majority of patients in the present study were suffering from constipation and irregular bowel habits which may be because of imbalanced *vata* which gets further vitiated (13). This vitiated *vata* circulates all over the body and gets *sthana samshraya* in *Shabdavaha srotas* and affects the hearing leading to *Badhirya*.

Discussion on probable mode of action of drugs

Musalyapamarga Churna

Krishna Musali (*Curculigo orchioides* gaertn) and *Apamarga* (*Achyranthes aspera* Linn) are the two ingredients present in *Musalyapamarga churna*. The medicine's pharmacotherapeutic response to the specific *dosha* leads to the pacification of that specific *dosha*, which explains the mode of action of the trial drug- *"Vishesha Siddhanta"*. The primary cause of the disease manifestation is the vitiation of *vata* or *vata* along with *kapha dosha*, *dravyas* usually recommended in the management of *Badhirya* are *vata shamaka*, *kapha shamaka*, and *shrotoshodaka*. Due *vata shamaka* property of *Musali* and the *kaphavatahara* property of *Apamarga* balance the *vata* and *kapha dosha* which are mostly responsible for the *Badirya*. *Krishna Musali* has *rasayana, balya*, and *brimhana* properties which can prevent aging and degenerative changes in the cochlea and nerves in *Badhirya* (14). *Madhura rasa* which improves the strength of sense organs and helps to pacify *vata dosha* (15). *Tikta rasa* does *vatanulomana* (15). *Krishna Musali* has phytochemicals like flavonoids, tannins, polyphenols, glycoside 5, and curculigoside (16). The pharmacological activities are neuroprotective, antioxidant, anti-inflammatory, and anti-microbial, etc (18) Flavonoids and polyphenols are said to have neuroprotective effects, these phytochemicals might have shown the neuroprotective effect in the current study (17). Glycoside 5 and Curculigoside are said to have neuroprotective properties.

Apamarga which has *kaphavata hara*, and *deepana – pachana* properties helps to balance the vitiated *vata* and *kapha dosha*. *Apamarga moola* contains flavonoids, terpenoids, and alkaloids and has antioxidant, antimicrobial, and anti-inflammatory properties (18). Flavonoids possess various medicinal benefits which include antioxidant, anti-inflammatory, and antiviral properties, and also have a neuroprotective effect (19). Terpenoids have antimicrobial, antiviral, and anti-inflammatory properties and also is useful in the prevention and therapy of several diseases (20). Alkaloids are therapeutically well-known as anti-inflammatory agents (21). *Apamarga moola* contains ecdysterone (22) which has antioxidant and neuroprotective activity (23).

Sarivadi Vati

Various drugs are found in *Sarivadi vati*, such as *Loha bashama*, which is recommended in *Kshaya* and can be used as a *rasayana. Abrakha basama* is a *Pradnya bodhi* that promotes *gyana* perception through *indriyas* and decreases *indriya sosha*, which increases *indriya's* ability to function. As a result, it supports *karnendriya*. It contains medications with a recognized *Shrotho shodana* effect such as *Yashtimadhu* and *Kushta*. For this reason, it is mentioned in *Bhaishjya Ratnavali* in *Karna Roga Adhikara*. Numerous medications, such as *bringaraj*, are used to treat degenerative ear disorders because they have neurotronic properties. Because of *madhura rasa* of *Sariva, yastimadhu*, which is responsible for *indriya tarpana*.

Conclusion

Present study showed that *Msalyapamarga Churna* was effective in the management of *Badhirya. Musalyapamarga Churna* and *Sarivadi Vati* were almost equally effective in the management of *Badhirya.*

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