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A comparative clinical trial to evaluate the efficacy of *Dashamoola Taila Karnapoorana* and *Nasya* and orally *Dashamoola Ghrita* in *Badhirya* (sensory neural hearing loss)

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ABSTRACT

It is estimated that by 2050 over 900 million people will have disabling hearing loss. In Ayurveda hearing loss is described as *Badhirya*, which can be treated with *Nasya, Karna Poorana,* oral administration of *Vatahara Ghrita* and other *Vatashamana* procedures. This is a randomized comparative clinical study of 3 groups with 30 patients in each; namely Group-A of *Dashamoola Taila Karnapoorana,* Group-B of *Dashamoola Taila Nasya* & Group C of *Dashamoola Taila Karnapoorana* and *Dashamoola Taila Nasya. Dashamoola Ghrita* was advised for oral administration to all groups. Total Treatment duration was of 210 days i.e., 7 days (Day 1-7), followed by 48 days administration of *Ghrita* (Day 22-70) and follow up after 140 days. There was mild improvement in hearing in both ears with slight improvement in pure tone audiometric values. There was clinical improvement seen in all three groups, group C has better results compared to other two groups. Statistically there is significant result within the group and no statistical significance between the groups. Since, combined treatment using *Dashamoola Taila Nasya* and *Karnapoorana* and *Dashamoola Ghrita* orally has shown better results, following complete *Chikitsasutra* would be helpful in management of *Badhirya* than treating with single line of treatment.

Key words: *Badhirya, Dashamoola Taila, Dashamoola Ghrita, SNHL, Nasya, Karnapoorana*

INTRODUCTION

The high burden of deafness globally and in India is largely preventable and avoidable. Over 5% of the world's population or 466 million people have disabling hearing loss (432 million adults and 34 million children). It is estimated that by 2050 over 900 million people or one in every ten people will have disabling hearing loss. Disabling hearing loss refers to hearing loss greater than 40 decibels (dB) in the better hearing ear in adults and a hearing loss greater than 30 dB in the better hearing ear in children. The majority of people with disabling hearing loss live in low- and middle-income countries.[1] Nationwide disability surveys have estimated hearing loss to be the second most common cause of disability.[2]

Sensorineural hearing loss (SNHL) is a type of hearing loss or deafness, in which the root cause lies in the inner ear or sensory organ (cochlea and associated structures) or the vestibulocochlear nerve (cranial nerve VIII). SNHL accounts for about 90% of reported hearing loss. SNHL is generally permanent and can be mild, moderate, severe, profound, or total. Treatment modalities fall into three categories: pharmacological, surgical, and management. As SNHL is a physiologic degradation and considered permanent, there are as of this time, no approved or recommended treatments. Pharmacological treatment options are

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very limited and clinically unproven. Surgeries like cochlear implants; because of risk and expense are reserved for cases of severe and disabling hearing impairment. Management of sensorineural hearing loss involves employing strategies to support existing hearing such as lip-reading, enhanced communication etc. and amplification using hearing aids. Hearing aids are specifically tuned to the individual hearing loss to give maximum benefit.[3]

In Ayurveda hearing loss is described as *Badhirya*, which can be treated with *Nasya, Karnapoorana,* oral administration of *Vatahara Ghrita* and other *Vatahara* procedures.[4] Hence this study is emphasised on finding medical management of *Badhirya* (SNHL) through *Karna Poorana* and *Nasya* using *Dashamoola Taila*[5] and *Dashamoola Ghrita Pana.*

Aims and Objectives

1. To evaluate the effect of *Dashamoola Taila Karna poorana* and oral administration of *Dashamoola Ghrita* on *Badhirya*.
2. To evaluate the effect of *Dashamoola Taila Nasya* and oral administration of *Dashamoola Ghrita* on *Badhirya*.
3. To evaluate the combined effect of *Dashamoola Taila Nasya* and *Karnapurana* with oral administration of *Dashamoola Ghrita* on *Badhirya.*

Materials and Methods

Source of Data

- Subject selected incidentally from the OPD of Shree Jagadguru Gavisddheshwara Ayurveda Medical College and Hospital, Gavimath campus, Koppal.
- Specific proforma was prepared for the documentation of the data. Subjects were registered for the study after taking written informed consent.

Inclusion Criteria

1. The cases with features mentioned in *Badhirya* (sensory neural hearing loss only) irrespective of gender, caste, religion, socioeconomic status and chronicity were included.
2. Cases of *Badhirya* (sensory neural hearing loss only) with age > 10 years and < 70 years were selected.

Exclusion Criteria

1. Congenital sensorineural hearing loss.
2. Perforated tympanic membrane.

Diagnostic Criteria

- Clinical features of *Badhirya* (sensory neural hearing loss)
- Reduced hearing with positive Rinne's test.

Investigations

- PTA

Study Design

- It was a randomized comparative clinical study.
- A total 90 cases of *Badhirya* were included for the study and allocated into three groups namely Group-A, Group-B & Group C with 30 patients in each group.

Intervention

Table 1: Showing groups, drugs, dosage, duration and route of administration.

Group	Drug	Route of administration	Dosage	Duration
A	*Dashamoola Taila*	*Karna Poorana*	5ml	7 days (Day 1-7)
	Dashamoola Ghrita	Oral administration	10ml	48 days (Day 22-70)
B	*Dashamoola Taila*	*Nasya Karma*	5ml	7 days (Day 1-7)
	Dashamoola Ghrita	Oral administration	10ml	48 days (Day 22-70)

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C	*Dashamoola Taila*	*Karna Poorana*	5ml	7 days (Day 1-7)
	Dashamoola Taila	*Nasya Karma*	5ml	7 days (Day 1-7)
	Dashamoola Ghrita	Oral administration	10ml	48 days (Day 22-70)

Preparation of trial drugs

- The drugs procured from market were authenticated from *Dravya Guna* department of SJGAMC Koppal.
- The authenticated drugs used and *Dashamoola Taila* and *Ghrita* were prepared using standard preparation method in RSBK pharmacy of SJGAMC Koppal and packaging was done in aseptic measures and labeled.
- The Prepared Drugs were analyzed at Sri Dharmasthala Manjunatheshwara Centre for Research in Ayurveda and Allied Sciences, Udupi.

Criteria for Assessment

Subjective and objective parameter were assessed on day 1 (baseline – before treatment) and day 70 (after treatment) and day 210 (follow-up).

Table 2: Showing World Health Organization Grades of Hearing Impairment (WHO, 2008)[6]

Grade of impairment	Corresponding audiometric ISO value	Performance
0 - No impairment	25 dB (better ear)	No or very slight hearing problems. Able to hear whispers.
1 - Slight impairment	26-40 dB (better ear)	Able to hear and repeat words spoken in normal voice at 1 meter.
2 - Moderate impairment	41-60 dB (better ear)	Able to hear and repeat words spoken in raised voice at 1 meter.
3 - Severe impairment	61-80 dB (better ear)	Able to hear some words when shouted into better ear.
4 - Profound impairment including deafness	81 dB or greater (better ear)	Unable to hear and understand even a shouted voice.

Statistical methods

't' test, Anova test and Tuckey's HSD test were applied using R Programming software.

RESULTS

Table 3: Statistical analysis table between the groups (BT-AT)

Parameter			Mean		SD	f-ratio	p	Remarks
Reduced hearing	RT	A	0.2	A	0.40	2.450	0.0921	N.S
		B	0.33	B	0.47			
		C	0.46	C	0.50			
	LT	A	0.2	A	0.40	1.016	0.366	N.S
		B	0.3	B	0.46			
		C	0.36	C	0.49			
PTA	RT	A	3.70	A	3.35	0.196	0.822	N.S
		B	3.75	B	2.66			
		C	4.18	C	3.62			
	LT	A	2.81	A	3.08	1.16	0.31	N.S
		B	4.01	B	3.11			
		C	3.61	C	3.11			

The mean difference of parameter reduced hearing (RT) for Group A is 0.2, Group B is 0.33 and Group C is 0.46 with SD for Group A is 0.40, Group B is 0.47, and Group C is 0.50. There is no significant difference between the groups in terms of reduced hearing (RT) (f=2.450, p=0.0921).

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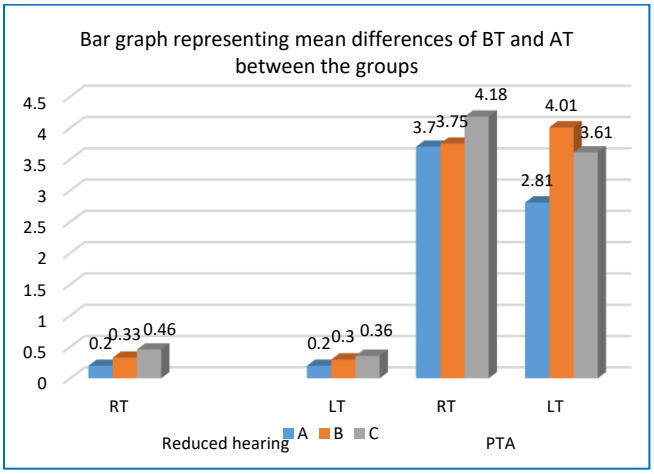
The mean difference of parameter reduced hearing (LT) for Group A is 0.2, Group B is 0.3 and Group C is 0.36 with SD for Group A is 0.40, Group B is 0.46, and Group C is 0.49. There is no significant difference between the groups in terms of reduced hearing (LT) (f=1.016, p=0.366).

The mean difference of parameter PTA (RT) for Group A is 3.70, Group B is 3.75 and Group C is 4.18 with SD for Group A is 3.35, Group B is 2.66, and Group C is 3.62. There is no significant difference between the groups in terms of PTA (RT) (f=0.196, p=0.822).

The mean difference of parameter PTA (LT) for Group A is 2.81, Group B is 4.01 and Group C is 3.61 with SD for Group A is 3.08, Group B is 3.11, and Group C is 3.11. There is no significant difference between the groups in terms of PTA (LT) (f=1.16, p=0.31)



Graph 1: Bar graph representing mean differences of BT and AT between the groups

The simple bar graph is used to represent the difference of means between the groups for BT and AT. The parameter reduced hearing (RT) is having mean differences 0.2 for group A, 0.33 for group B and 0.46 for group C. Similarly reduced hearing (LT) is having the mean differences 0.2 for group A, 0.3 for group B and 0.36 for group C. Group A is having least mean 0.2 for reduced hearing where as group C is having highest mean 0.46 for reduced hearing (RT) and 0.36 for reduced hearing (LT).

The simple bar graph is used to represent the difference of means between the groups for BT and AT. The parameter PTA (RT) is having mean differences 3.7 for group A, 3.75 for group B and 4.18 for group C. Similarly PTA (LT) is having the mean differences 2.81 for group A, 4.01 for group B and 3.61 for group C. Group A is having least mean 3.7 and 2.81 for PTA (RT) and PTA (LT) respectively. Whereas group C is having highest mean 4.18 for PTA (RT) and group B is having highest mean 4.01for PTA (LT).

Table 4: Tuckey's HSD Test (BT & AT)

Parameter	HSD	Q value	P value	Remarks
Reduced hearing (LT)	A:B=0.37	3.97	0.016	S
	A:C=0.27	2.88	0.108	N.S
	B:C=0.10	0.10	0.725	N.S

DISCUSSION

The study was a comparative clinical trial to compare the effect of *Dashamoola Taila Nasya* with *Dashamoola Taila Karnapoorana* in the management of *Badhirya* with special reference to Sensorineural Hearing Loss which presents with mild to severe degree of Hearing impairment based on Audiometric values.

Discussion on results

There is a statistically significant result in treatment of impaired hearing in all 3 groups within the group. The results between the groups were statistically insignificant. Group C showed better improvement in the symptoms Compared to other 2 groups. Among Group A and B, Group B treated with *Nasya* using *Dashamoola Taila* and *Dashmoola Ghrita* orally showed better improvement compared to *Karnapoorana* with same in group A.

Probable mode of action of *Dashamoola Ghrita*

The *Dashamoola Ghrita* was formulated on the basis of *Karna Roga Samanya Chikitsa*[7] (common line of treatment) i.e. ...*Ghritapana Rasayanam*... which means *Karna Rogas* can be treated very well with oral administration of *Vatahara Rasayana Dravya* and *Ghrita Pana*.

The ingredients of *Dashamoola Ghrita* are *Dashamoola* and *Go-Ghrita*. *Dashamoola* has *Madhura*, *Tikta* and

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Kashaya Rasa. It is *Dhatuposhaka* and *Tridoshahara*. It is also a *Rasayana*.[8] It is thus recommended for general weakness, neuropathy, nervine weakness and as well as to boost the immune system.

Ingredients of *Dashamoola* are rich in sitosterols, flavonoids and glycosides that normalize the status of the neuroendocrine system by regulating the function of important hormones. It has a powerful antioxidant effect. It is a rich tonic that stimulates the nervous system.[9] This Ayurvedic medication has following indications including *Balya* (increase strength), *Amanashak* (removes toxins), *Svashahara* (treats asthma), *Deepana* (enhances stomach fire), *Pachana* (helps in digestion), *Rochana* (stimulates appetite), *Kantya* (relieves sore throat), *Kapha-Vatahara* (treats *Kapha* and *Vata* imbalances), *Rasayani* (rejuvenates the whole body), *Shothahara* (treats pain and inflammation).[10]

Go Ghrita has the properties, *Rasa*: *Madhura*. *Guna*: *Snigdha*, *Guru*. *Veerya*: *Sheeta*. *Vipaka*: *Madhura*. *Karma*: *Medhya*, *Agnivardhaka*. It promotes memory, intelligence, *Ojas* and alleviates *Vata* and has special feature "*Samskarasaya anuvartanat*"- carries and enhances the properties of drugs processed with it. Ghee contains 8% lower saturated fatty acids which makes it easily digestible. Due to having 4-5% linoleic acid, an essential fatty acid, it promotes proper growth of human body. Ghee also contains vitamin A, B, E and K. Vitamin A and E are antioxidant in nature and are helpful in preventing oxidative injury to the body. *Ghee* also improves digestibility of other component, mineral absorption from diet. Cow *Ghee* increases the retention of calcium up to 45% and phosphorus up to 57% (kehar 1956, steggarada 1951). As chemically *Ghrita* consists of phospholipids, fatty acids etc., it is helpful in correcting the altered disturbed neurotransmitter. *Ghrita* fortified with *Medhya* drugs releases the *Medhya* effect of the drugs at neurotransmitter working place (synaps etc.). According to Russian Scientist Servos, Cow's ghee has immense power to protect human body from the ill effect of radioactive waves.[11]

Hence, *Dashamoola Ghrita* by virtue of properties of its individual drugs is *Vatashamaka*, *Shotha Hara* and *Rasa*yana in nature. Hence, *Badhirya* being a *Vata* dominant disease with *Shoshana* as type of *Vikriti*, has responded well to *Dashamoola Ghrita* which is best *Vatahara*, *Balya* and *Rasa*yana in nature.

Probable mode of action of *Dashamoola Taila*

Dashamoola Taila was selected for the present study because it has been referred to as "*Parama Aushadha*" for *Badhirya* by *Acharya Chakrapani*.[12]

The ingredients of *Dashamoola Taila* are *Dashamoola* and *Tila Taila*.

Tila Taila has the properties like, *Rasa* - *Madhura*, kashaya, *Tikta*, *Katu*. *Vipak* - *Madhura*, *Virya – Ushna*. *Guna* - Suksma, *Guru*, *Sara*, *Deepana*, *Lekhana*, *Balya* Action on *Dosha* - Alleviates *Tridosha*. It nourishes and strengthens all the *Dhatus*, checks *Dhatukshaya*, and thus alleviates *Vata*. *Snigdha* and *Guru Guna* decreases Rukshata of *Vata*and with the help of *Ushna Guna* and *Veerya* it alleviates *Vata*.[13] The *Vyavayi*, *Vikashi Guna* of *Tila Taila* helps better absorption of the oil prepared with *Tila Taila* as the base. *Tila Taila* is considered as a *Shreshta Vatahara*. It is described as "*Vataghneshu Uttamam*" and *"Na shleshmabhi Vardhana*" by *Charaka*.[14]

Tila Taila is rich in minerals like Calcium and zinc that are good for bones, that act on ossicles and mastoid bone, Magnesium supports respiratory and vascular health that act on middle ear mucosa and improves blood circulation pertaining to ear. Alkaloids are central nervous system stimulants. Flavonoids and phenols give it antioxidant properties also saponins which are antioxidant. It has two components Sesamin and Sesamolin. Sesamin is also known to protect neuronal cells against oxidative stress and it exhibits anti-inflammatory and anti-allergic effects. These components help in scavenging ROS (Reactive Oxygen Species) and thus prevent damage to the neuronal cells during degenerative phase. Thus, these antioxidants have the potential to protect cells from oxidative damage.[15]

Hence, *Badhirya* being a *Vata* dominant disease has responded well to *Dashamoola Taila* treatment which is best *Vatahara* & *Balya* in nature.

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Discussion on Probable mode of action of therapeutic procedure

Mode of action of *Poorva Karma*: *Sthanika Abhyanga* and *Sweda* facilitates drug absorption through nasal mucosa, nasal neuron and para nasal sinuses.[16],[17] Nasal epithelium consists of tightly packed cell line. *Abhyanga* and *Sweda* results in facial efferent stimulation in turn reflecting as 22% dilation in capillaries which is benefitting by 150% increase in blood flow and allowing better passage of drug.[18] Same can be applied to mode of action of *Karnapoorana* also.

Mode of action of *Nasya Karma*: In *Ashtanga Sangraha, Nasa* is described as the gateway of *Shirah*. Hence, the drug is administered through nostrils reaches the *Shringataka* (*Sira Marma*) and spreads in *Murdha* (brain) reaching the *Marmas* of *Netra, Shrotra, Kantha* and *Shiramukha*. It then by virtue of its potency scratches the morbid *Dosha* in supraclavicular region and expels them from *Uttamanga*.[19]

Nasal mucosa is the only location in the body that provides a direct connection between CNS and the atmosphere.[20] Drugs administered to the nasal mucosa rapidly traverse through the cribriform plate into the CNS by three routes: (1) directly via the olfactory neurons, (2) through supporting cells and the surrounding capillary bed, and (3) directly into the cerebrospinal fluid.[21]

Mode of action of *Karnapoorana*: Cells in many tissues are protected from stress-induced apoptosis by the activation of heat shock proteins (HSPs). This protective effect is mediated at least in part by the chaperone activity of HSPs and by direct inhibition of apoptotic signaling pathways. In the inner ear, activation of the heat shock response improves the survival of hair cells exposed to ototoxic drugs.[22] Similar action is brought about by the heat of medicine used in *Karnapoorana*. The heat generated by the warm oil after instillation causes pseudo congestion of vessels of tympanic membrane and thus enhancing drug entry into middle ear. Animal experiments show that the Round Window Membrane behaves like a semipermeable membrane. The permeability of the RWM can be influenced by the factors such as size, configuration, concentration, liposolubility and electrical charge of the substance, and the thickness and the condition of the RWM,[23] thus probably absorbed oil from round window membrane nourishes the nerve terminals and thereby preventing degeneration.

CONCLUSION

Dashamoola Taila, *Dashamoola Ghrita* were administered to the patients in respective groups, according to the protocol approved by Advanced Research wing of Rajiv Gandhi University of Heath Sciences, Bengaluru. Observations were recorded in case proforma specially prepared for the study. Results were drawn statistically by using 't' test, Anova test and Tuckey's HSD test. Combined treatment using *Dashamoola Taila Nasya* and *Karnapoorana* and *Dashamoola Ghrita* orally has shown better results. Hence following complete *Chikitsa Sutra* (complete protocol) would be helpful in management of *Badhirya* than treating with single line of treatment (any one treatment from protocol).

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