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Evaluation of the effect of Lashunadi Taila *Karnpooran* and *Sarivaadi* Vati with and without Ashwagandhadhya Ghrita in *Badhirya*

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Abstract
Background and Objectives: Over 5% of the world's population, or 466 million people – has disabling hearing loss. It is estimated that by 2050 over 900 million people – or one in every ten people will have disabling hearing loss. This statistical data emphasizes the need for strengthening disability statistics in the world. In India itself, out of the 121 cr population, about 2.68 crore persons are disabled which is 2.2% of the total population. In Ayurveda, Hearing loss or impairement can be well correlated with *Badhirya* owing to the marked similarities of the clinical presentations of these two disease entities.
In Modern science, the treatment includes medicinal, surgical & hearing aids. In Ayurveda, along with systemic treatment more emphasis is laid upon local treatment and *Karnpooran* is one of the best local treatment modality mentioned for *Karnarogas*. Ashwagandhadhya Ghrita taken for the study has Rasayan property, whereas *Sarivaadi* Vati is mentioned in all types of *Karna Rogas*. So all these above facts leave a scope to find out the better solution for the disease *Badhirya*.
Materials and Methods: The present study includes a sample size of 60 patients of *Badhirya.* Group A patients received Lashunadi Taila *Karnpooran* 100 Matra, once in a day every evening for 10 days (5-7 pm) and *Sarivaadi* Vati twice a day after food with jal for 2 months and 10 days. Group B patients received Lashunadi Taila *Karnpooran* (10 days) and *Sarivaadi* Vati with Ashwagandhadhya Ghrita 10ml Bhaktoparya at night with Koshna Jal for 2 months and 10 days.
Results: Group A provided moderate improvement in 13.33% of the patient, mild improvement in 50% and unchanged was 36.67% patient after completion of the treatment. Group B provided moderate improvement in 26.67% patients, mild improvement in 50% patients and 23.33% patients were unchanged after completion of the treatment.

Keywords: Ashwagandhadhya ghrita, *badhirya*, lashunadi taila *karnpooran*, *sarivaadi* vati, hearing loss

Introduction
The World Hearing Day, observed on March 3rd every year, is an initiative aimed to raise awareness on how to prevent deafness and hearing care across the world. According to WHO definition, "A person who is not able to hear as well as someone with normal hearing – hearing thresholds of 25 dB or better in both ears – is said to have hearing loss". Hearing loss may be mild, moderate, severe, or profound. It can affect one ear or both ears, and leads to difficulty in hearing conversational speech or loud sounds. The interchangeable term of Hearing loss in Ayurveda is *Badhirya*. As the word *Badhirya* itself has a meaning in it 'Badha' which means obstruction. Any obstruction in the conduction of sound waves from external environment upto hearing centre in brain, leads to *Badhirya* (hearing impairement).

Prevelance Rate [1]
- According to WHO, Over 5% of the world's population, or 466 million people – has 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.
- 1.1 billion young people (aged between 12–35 years) are at risk of hearing loss due to exposure to noise in recreational settings.
- Unaddressed hearing loss poses an annual global cost of 750 billion international dollars.
- As per census 2011, conducted by (MOSPI) Ministry of Statistics and Programme Implementation, Government of India, in India itself, out of the 121 Cr population, about 2.68 Cr persons are 'disabled' which is 2.21% of the total population. 19% of the

total disability rate, hearing loss is the 2nd most highest with the prevelance rate higher in males than in females [2].

The treatment includes medicinal, surgical & hearing aids. Though all these give good results provided a correct diagnosis is made & the respective treatment employed. Unfortunately this is not so and to add to the problem, administration of nasal decongestants and antibiotics for a longer duration can lead to altered manifestations instead curing the causes. The microsurgical procedures too are not without complications. There is a need for the Ayurvedic modalities of treatment to reach the mass for better health care, especially in developing countries where less expensive but effective health care are yet to be developed.

Lashunadi Taila is one of the compound preparations mentioned in context to Karna *Badhirya* [3]. *Sarivaadi* Vati is mentioned in Bhaisajratnavali as Rogadhikaar of all *Karna Rogas* [4]. Acharya Sushruta has mentioned Ghritpaan as basic treatment in all *Karna Rogas* [5]. For Ghrita paan, Ashwagandhadhya Ghrita which has the property of Rasayana also and is useful in all Vatajanya Rogas [6, 7], was planned to give for Ghritpaan.

To serve the purpose, study was planned to evaluate the effects of Lashunadi Taila *Karnpooran* and *Sarivaadi* Vati with and without Ashwagandhadhya Ghrita in *Badhirya* and hence to compare their effect in relieving signs.

Objectives: The objectives of the present study were as follows (Table A) –

1. To evaluate the role of Lashunadi Tail *Karnpooran* in the disease *Badhirya*.
2. To evaluate the role of *Sarivaadi* Vati and Ashwagandhadhya Ghrita in *Badhirya*.
3. A comparison of Lashunadi Taila *Karnpooran* and *Sarivaadi* Vati with and without Ashwagandhadhya Ghrita as a better treatment option for the disease *Badhirya*.
4. To study *Badhirya* and its modern aspect in detail.

Material and Methods

Selection of patients: 60 patients were randomly selected attending the OPD of Shalakyatantra department, (Patanjali Ayurvedic College, Haridwar) on the criteria of diagnosis as per the patient case format.

Collection of drugs: The ingredients of Lashunadi Taila and Ashwagandhadhya Ghrita were procured from the local market of Haridwar city and were identified with the help of Dravyaguna Department and were prepared by the Ras-Shastra Department of Patanjali Bhartiya Ayurvigyan Avum Anusandhan Sansthan, Haridwar, Uttarakhand. Whereas *Sarivaadi* Vati taken for the clinical study was procured by the Divya pharmacy, Haridwar (according to Ayurveda Sarasangraha).

Table A: Inclusion criteria and Exclusion criteria

Inclusion criteria	Exclusion criteria
Patients with hearing loss irrespective of gender, caste, religion and economic status.	Patients with age <16 years and > 65 years.
Patients with the age group of 16-65 years.	Patients with profound degree of hearing impairement i.e. > 91 dB (according to WHO 1980 guidelines).
Patients with mild to severe degree of Hearing impairment i.e. 26 dB to 91 dB (according to WHO 1980 guidelines).	Patients with perforated tympanic membrane.
Patients fit for *Karnpooran* Karma will be taken for the study.	Patients with Otorrhoea.
	Patients with Congenital hearing loss.

Diagnostic criteria: Patients were thoroughly examined both subjectively and objectively. Routine investigations were done to exclude the other pathologies.

- Otoscopic examination.
- Tuning fork tests (Rinne test, Weber test and Absolute bone conduction test).
- Blood and Urine routine examinations.
- PTA (Pure Tone Audiometry).
- Lipid profile in Group B.

Research Design: It was a randomized comparative, open labeled, clinical study. Patients were assigned in two group consisting of 30 patients each excluding dropouts with pre, mid and post-test study design.

Total duration of study – 18 months

Grouping: All the selected patients fulfilling the inclusion and exclusion criteria were randomly divided into two groups. In each group 30 patients will be taken for trial.

Group A: In Group A patients will be given Lashunadi Taila *Karnpooran* and *Sarivaadi* Vati.

Group B: In Group B patients will be given Lashunadi Taila *Karnpooran*, *Sarivaadi* Vati and Ashwagandhadhyam Ghrita internally.

Posology

Lashunadi Taila *Karnpooran*

Amount (Quantity) : 20-24 drops in each ear **(**Karna Purne)

Time (Kala): Once in a day every evening for 10 days.[8]

Duration of *Karnpooran*: 100 Matra (approx. 3 min.)

Karnpooran was carried out as per classical indications. Each patient in the group was subjected to *Karnpooran* followed by Shaman drug.

Procedure: The procedure of *Karnpooran* Karma is divided into three stages such as – Purva Karma, Pradhana Karma and Pashchat Karma.

Purva Karma: The patient was examined with reference to Prakriti, Vikriti etc. ten factors by applying Pratyaksha, Anumana and Aptopadesha which will assess Vyadhibala. Materials required for conduction of *Karnpooran* procedure were collected. They include – medicine, stainless dropper, cotton wick, etc. The procedure was done in between 5 to 7 pm. After entering in to the procedure room, the patient was asked to lie in the left/right lateral position depending on the affected side so as to keep the ear to be treated up. Sthanika Snehana with warm medicated Tila Taila for 5 min. was done and Sthanika Swedana was done for 5-7 minutes around the ear with a clean towel dipped in hot water and squeezed.

Pradhana Karma: After the Purva Karma, depending on the affected side of ear, luke warm Lashunadi Taila was instilled slowly into the ear upto Karna Purne i.e. upto its full capacity and was retained for 100 matra kala (approx. 3 min.)

Paschat karma: After Pradhana Karma, medicated oil was removed from Karna by using clean cotton wick

Following Shaman drugs have been given below in (Table B):

Table B: Shamana drug, *Sarivaadi* Vati and Ashwagandhadhya Ghrita

Shamana drug	*Sarivaadi* Vati	Ashwagandhadhya Ghrita
Amount (Quantity)	2 Vati with Koshana Jal	10 ml with Koshana Jal
Time (Kala)	Twice a day after food	Once only, on Bhaktoparya[9]
Duration	2 months and 10 days (start from 1st day of *Karnpooran*)	2 months and 10 days (start from 1st day of *Karnpooran*)

Criteria for Assessment

- The assessment was made before, during and after the treatment on subjective and objective criteria in affected side.
- Scoring pattern was developed according to severity of symptoms.
- Results were analyzed statistically by using paired 't' test as per the assessment.

1st assessment- Before treatment
2nd assessment- 10 days after treatment
3rd assessment- 2 month and 10 days (70 days) after treatment

Follow up- 2 months with a gap period of 1 month after completion of treatment (100 days & 130 days)

a) Subjective Criteria

Scoring pattern of Tinnitus and Giddiness is mentioned below [10]: (Table C)

Table C: Tinnitus and Giddiness

Tinnitus	Giddiness
▪ Grade 0 – Nil ▪ Grade 1 – Only audible when there is no background noise ▪ Grade 2 – Audible over background noise but does not affect sleep ▪ Grade 3 – Audible over background noise, significant effect on sleep	▪ Grade 0 – Nil ▪ Grade 1 – Mild occasional giddiness, does not affect routine activities ▪ Grade 2 – Can perform routine activities or occupation with difficulty ▪ Grade 3 – Cannot perform routine activities or occupation ▪ Grade 4 – Severely disabled. Lacks confidence in carrying out routine activities

b) Objective Criteria

Hearing loss (Badhirta): Clinical classification of Hearing loss (by WHO)

- Mild - Hearing loss between 26 to 40 dB
- Moderate - Hearing loss between 41 to 55 dB
- Moderately severe - Hearing loss between 56 to 70 dB
- Severe - Hearing loss between 71 to 90 dB
- Profound - Hearing loss 90 dB or greater

Overall Assessment of total effect: The total effect of therapy was assessed as in (Table D);

Table D: Assessment and Score

Assessment	Score
Complete Remission	100% relief in subjective and objective criteria
Marked Improvement	>75% to 99% relief in subjective & objective criteria.
Moderate Improvement	>50% to 75% relief in subjective & objective criteria.
Mild Improvement	>25% to 50% relief in subjective & objective criteria.
Unchanged	< 25% relief in subjective & objective criteria.

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Observations and Result

Table 1: Distribution of Patients by Age

Age Group (In Years)	Number of Patients			Percentage
	Group A	Group B	Total	
16 – 25	6	9	15	25.00%
26 – 35	10	7	17	28.34%
36 – 45	7	7	14	23.33%
46 – 55	2	1	3	5.00%
56 – 65	5	6	11	18.33%
Total	30	30	60	100%

Table 2: Distribution of Patients by Gender

Gender	Number of Patients			Percentage
	Group A	Group B	Total	
Male	15	17	32	53.33%
Female	15	13	28	46.67%

Total	30	30	60	100%

Table 3: Distribution of Patients by Causative/Predisposing/Precipitating factors:

Factors	Number of Patients			Percentage
	Group A	Group B	Total	
No factor	8	9	17	28.33%
Karnakanduyana	4	3	7	11.67%
Marut Sevana	3	4	7	11.67%
Jalkreeda	0	0	0	0%
Ruksha Bhojana Sevana	5	3	8	13.33%
Shabda Atiyoga	4	5	9	15.00%
Avashyaya	5	6	11	18.33%
Shashtra Mithyayoga	1	0	1	1.67%
Total	30	30	60	100%

Table 4: Distribution of Patients by Type of hearing loss:

Type	Number of Patients						Percentage	
	Group A		Group B		Total			
	RE	LE	RE	LE	RE	LE	RE	LE
No	3	4	3	3	6	7	10.00%	11.67%
SNHL	22	22	17	18	39	40	65.00%	66.66%
CHL	4	2	6	4	10	6	16.67%	10.00%
MHL	1	2	4	5	5	7	8.33%	11.67%
Total	30	30	30	30	60	60	100%	100%

Table 5: Presenting Complaints & Test findings in Patients of *Badhirya*

Presenting complaints & findings	Number of Patients			Percentage
	Group A	Group B	Total	
Tinnitus (Right Ear)	27	27	54	90%
Tinnitus (Left Ear)	26	27	53	88.33%
Giddiness	18	19	37	61.67%
Badhirta (Right Ear)	27	27	54	90%
Badhirta (Left Ear)	26	27	53	88.33%

Table 6: Relief Percentage of Individual Symptoms & Test finding

Symptoms &Test findings	Total Symptom Score						Relief Percentage%			
	BT		AT (10 days)		AT (70 days)		10 days		70 days	
GROUP	A	B	A	B	A	B	A	B	A	B
Tinnitus (RE)	71	65	55	47	44	32	22.53	27.69	38.02	50.76
Tinnitus (LE)	68	66	54	45	42	36	20.58	31.81	38.23	45.45
Giddiness	52	51	35	34	30	27	32.69	33.33	42.30	47.05
Badhirta (RE)	1489.57	1477.12	-	-	1391.8	1342.15	-	-	6.56	9.13
Badhirta (LE)	1431.18	1553.64	-	-	1322.05	1402.52	-	-	7.62	9.72

Table 7: Grading of Hearing Impairment Assessment in Patients of *Badhirya*

Grade	Before Treatment								After Treatment							
	Number of patients						%		Number of patients						%	
	RE		LE		Total				RE		LE		Total			
GROUP	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Normal	3	3	4	3	7	6	11.67	10	3	3	4	3	7	6	11.67	10
Mild	8	6	8	6	16	12	26.67	20	10	10	9	8	19	18	31.67	30
Moderate	7	7	6	4	13	11	21.66	18.33	7	7	7	9	14	16	23.33	26.67
Moderately-severe	6	9	5	10	11	19	18.33	31.67	4	5	5	4	9	9	15	15
Severe	6	5	7	7	13	12	21.67	20	6	5	5	6	11	11	18.33	18.33
Profound	0	0	0	0	0	0	-	-	0	0	0	0	0	0	-	-

Statistical Analysis

Table 8: Effects of Therapy on Tinnitus (Right Ear)

Group	Assessment	n	Mean	Mean Diff.	SD	SE	't'	P
A	BT	27	2.63	-	0.97	0.19	-	-
	AT (10 days)	27	2.04	0.59	1.06	0.20	2.15	0.036

	AT (70 days)	27	1.63	1.00	0.97	0.19	3.8	<0.001
B	BT	27	2.41	-	0.93	0.18	-	-
	AT (10 days)	27	1.74	0.67	1.02	0.20	2.51	0.015
	AT (70 days)	27	1.19	1.22	1.00	0.19	4.65	<0.001

Table 9: Effects of Therapy on Tinnitus (Left Ear)

Group	Assessment	n	Mean	Mean Diff.	SD	SE	't'	P
A	BT	26	2.62	-	1.10	0.22	-	-
	AT (10 days)	26	2.08	0.54	1.06	0.21	1.80	0.07
	AT (70 days)	26	1.62	1.00	1.24	0.24	3.08	<0.01
B	BT	27	2.44	-	0.93	0.18	-	-
	AT (10 days)	27	1.67	0.78	0.96	0.18	3.02	0.003
	AT (70 days)	27	1.33	1.11	0.96	0.18	4.31	<0.001

Table 10: Effects of Therapy on Giddiness

Group	Assessment	n	Mean	Mean Diff.	SD	SE	't'	P
A	BT	18	2.89	-	0.76	0.18	-	-
	AT (10 days)	18	1.94	0.94	0.64	0.15	4.04	<0.001
	AT (70 days)	18	1.67	1.22	0.84	0.20	4.58	<0.001
B	BT	19	2.68	-	0.58	0.13	-	-
	AT (10 days)	19	1.79	0.89	0.63	0.14	4.54	<0.001
	AT (70 days)	19	1.42	1.26	0.84	0.19	5.40	<0.001

Table 11: Effects of Therapy on Hearing Loss (Right Ear)

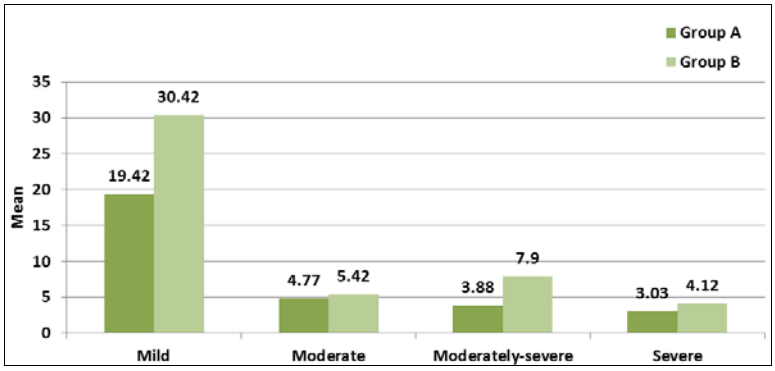
Group	Assessment	Mean		Mean Diff.	Relief %	't'	P	Significance
		BT	AT					
A	Mild	33.41	26.92	6.49	19.42	3.39	<0.01	Yes
	Moderate	45.90	43.71	2.19	4.77	0.79	0.443	No
	Moderately-severe	62.50	60.07	2.43	3.88	0.72	0.488	No
	Severe	87.66	85.00	2.66	3.03	0.59	0.570	No
B	Mild	30.76	21.40	9.36	30.42	4.71	<0.001	Yes
	Moderate	47.37	44.80	2.57	5.42	0.71	0.488	No
	Moderately-severe	62.22	57.30	4.92	7.90	2.08	0.055	No
	Severe	80.20	76.89	3.31	4.12	0.60	0.566	No

Table 12: Effects of Therapy on Hearing Loss (Left Ear)

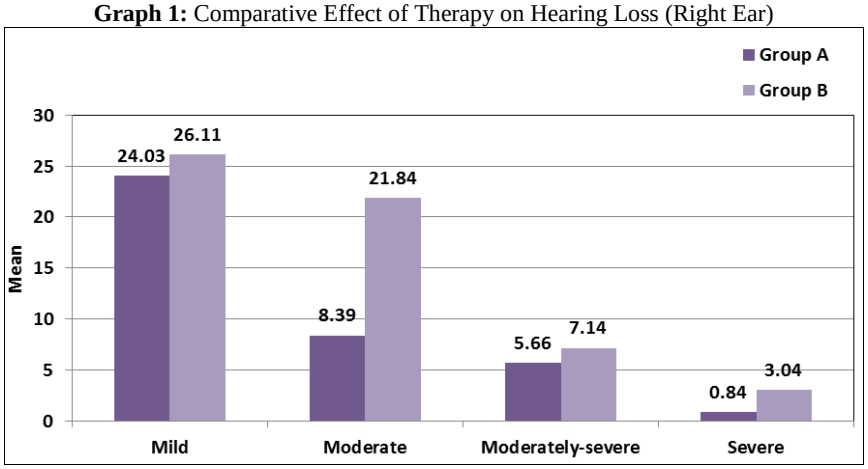
Group	Assessment	Mean		Mean Diff.	Relief %	't'	P	Significance
		BT	AT					
A	Mild	32.78	24.90	7.88	24.03	2.82	<0.01	Yes
	Moderate	47.55	43.56	3.99	8.39	1.81	0.100	No
	Moderately-severe	60.93	57.48	3.45	5.66	1.07	0.316	No
	Severe	82.71	82.01	0.70	0.84	0.17	0.866	No
B	Mild	31.74	23.45	8.29	26.11	2.66	<0.05	Yes
	Moderate	47.66	37.25	10.41	21.84	2.94	<0.05	Yes
	Moderately-severe	58.66	54.47	4.19	7.14	1.87	0.078	No
	Severe	83.71	81.16	2.55	3.04	0.70	0.495	No

Table 13: Assessment of Overall Effects of Therapies on *Badhirya*

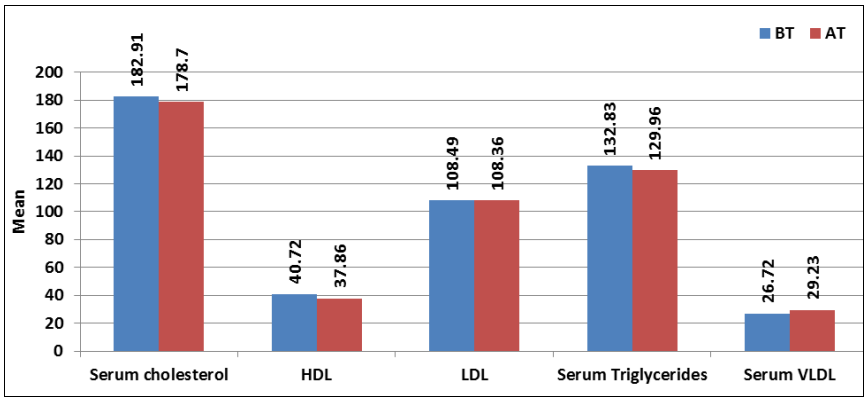
Assessment	Score	Group A		Group B	
		No.of Patients	Percentage	No. of Patients	Percentage
Complete Remission	100%	0	-	0	-
Marked Improvement	>75% to 99%	0	-	0	-
Moderate Improvement	>50% to75%	4	13.33%	8	26.67%
Mild Improvement	>25% to50%	15	50.00%	15	50.00%
Unchanged	< 25%	11	36.67%	7	23.33%



Graph 1: Comparative Effect of Therapy on Hearing Loss (Right Ear)



Graph 2: Comparative Effect of Therapy on Hearing Loss (Left Ear)



Graph 3: Effect of treatment on Lipid Profile

Discussion: Discussion is the vital & mandatory part of every research work. Discussion will be made on the following headings –

(1) Discussion on disease
(2) Discussion on selection of treatment modality
(3) Discussion on Statistical Analysis
(4) Discussion on probable mode of action of trial drugs

1. Discussion on Disease

Badhirya is a disease explained by our Acharyas under major group of diseases called Urdwajatrugata Vikaras in the context of *Karnarogas*. *Badhirya* is one among 28 *Karnarogas* described in Sushruta Samhita [11].

Badhirya is a disease of the ear initiated by Vata and Kapha which when chronic results in complete hearing loss. The pathology reveals Avarana of Vata by Kapha and d Fig. 1 lack of treatment it leads to a total impairment of function of Vata and hence *Badhirya* [12]. These explanations are suggestive of SNHL. *Badhirya* is told as a Nanatmaja Vikara of Vata. But an explanation given by different Acharyas and evaluation of Samprapti of *Badhirya* reveals the role of Kapha in the initial pathogenesis. Here the main symptom is difficulty in hearing even for loud sounds. When this condition is left untreated it leads to complete manifestation of *Badhirya*. Concept of Kaphavrita Vata is the basic principle behind the Samprapti of *Badhirya*.

2. Discussion on selection of Treatment Modality

***Karnpooran*:** In *Karnpooran*, Sthanika Snehana and Swedana increases the blood supply and helps absorption of the drug. The fomentation causes local vasodilatation, thus enhances blood supply in tunica vascularis. The heat generated by the warm oil after instillation causes congestion of vessels of tympanic membrane and enhancing drug entry into middle ear. The epithelium of round window has the capacity to allow drugs into inner ear fluids, thus nourishes the nerve terminals and thereby preventing degeneration.

Snehana is the principle line of treatment for controlling Vata. *Karnpooran* is a type of Bahya snehana. Thus it is a best treatment for vata nigraha. Acharya Charaka has mentioned that Vata Roga doesn't stay in Koshta which is softened by Snehana.

In *Badhirya*, Vata becomes Vimargaga in Shabdavaha Srotas. The Vimarga Gamana could be due to Prakopa of Vata or obstruction by Kapha, and the end result is *Badhirya*. By doing *Karnpooran*, it relieves the obstruction in Shabdavaha Srotas and controls the Vata.

Lashunadi Taila *Karnpooran*

The ingredients in Lashunadi Taila have predominant Snigdha Guna (29%),Ushna Veerya (60%), Katu Vipaka (60%) and Vata (44%) – Kapha (33%) Rogaghnta, as a result of this Kapha and Vata Shamana takes place which will correct the microcirculation in ear and maintains the normal function of hearing and thereby, relieves Badhirta (*Badhirya*). (Fig. 1)

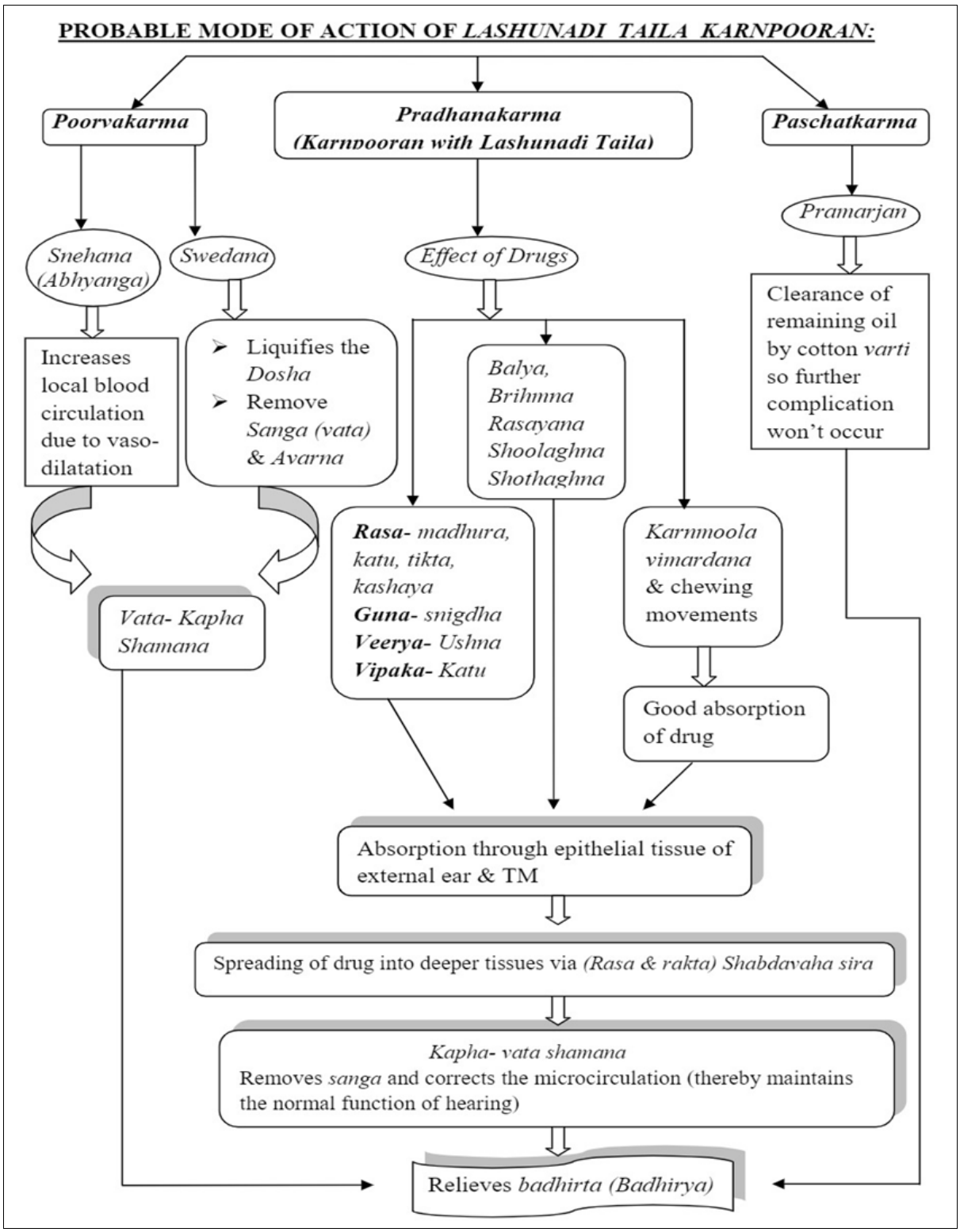


Fig 1: Probable mode of action of Lashunadi Taila Karnpooran

3. Discussion on Statistical Analysis

Effects of Therapy on Tinnitus (Right Ear) of *Badhirya*

The total effect of therapy on Tinnitus (Right ear) of each patient was evaluated before and after completion of the treatment. In group A the initial mean score of 27 patients for Tinnitus was 2.63 which were reduced to 2.04 after 10 days of treatment and 1.63 after completion of treatment (70 days). The total effect of treatment provided statistical significant ($P<0.001$) result with 't' value of 3.8.

In group B, the initial mean score of 27 patients for tinnitus was 2.41 which was reduced to 1.74 after 10 days of treatment and after 70 days of treatment it was reduced to 1.19. The total effect of treatment provided statistical significant ($P<0.001$) result with 't' value of 4.65 after completion of treatment.

Effects of Therapy on Tinnitus (Left Ear) of *Badhirya*

In group A the initial mean score of 26 patients for Tinnitus was 2.62 which were reduced to 2.08 after 10 days of treatment and 1.62 after completion of treatment (70 days). The total effect of treatment provided statistical significant ($P<0.01$) result with 't' value of 3.08.

In group B, the initial mean score of 27 patients for tinnitus was 2.44 which was reduced to 1.67 after 10 days of treatment and after 70 days of treatment it was reduced to 1.33. The total effect of treatment provided statistical significant ($P<0.001$) result with 't' value of 4.31 after completion of treatment.

Giddiness

In group A the initial mean score of 18 patients for Giddiness was 2.89 which were reduced to 1.94 after 10 days of treatment and 1.67 after completion of treatment (70 days). The total effect of treatment provided statistical significant ($P<0.001$) result with 't' value of 4.58.

In group B, the initial mean score of 19 patients for tinnitus was 2.68 which was reduced to 1.79 after 10 days of treatment and after 70 days of treatment it was reduced to 1.42. The total effect of treatment provided statistical significant ($P<0.001$) result with 't' value of 5.40 after completion of treatment.

Effects of Therapy on Hearing Loss (Right Ear)

In group A the initial mean score of mild hearing loss was 33.41 which was reduced to 26.92 after completion of treatment (70 days). The total effect of treatment provided statistical significant ($P<0.01$) result with 't' value of 3.39. In moderate hearing loss the initial mean score was 45.90 which was reduced to 43.71 after completion of treatment provided not significant result with 't' value 0.79. In moderately-severe hearing loss the initial mean score was 62.50 which was reduced to 60.07 after completion of treatment provided not significant result with 't' value 0.72. In severe hearing loss the initial mean score was 87.66 which was reduced to 85 provided not significant result with 't' value 0.59.

In group B the initial mean score of mild hearing loss was 30.76 which was reduced to 21.40 after completion of treatment (70 days). The total effect of treatment provided statistical significant ($P<0.001$) result with 't' value of 4.71. In moderate hearing loss the initial mean score was 47.37 which was reduced to 44.80 after completion of treatment provided not significant result with 't' value 0.71. In moderately-severe hearing loss the initial mean score was 62.22 which was reduced to 57.30 after completion of treatment provided not significant result with 't' value 2.08. In severe hearing loss the initial mean score was 80.20 which was reduced to 76.89 provided not significant result with 't' value 0.60.

Effects of Therapy on Hearing Loss (Left Ear)

In group A the initial mean score of mild hearing loss was 32.78 which was reduced to 24.90 after completion of treatment (70 days). The total effect of treatment provided statistical significant ($P<0.01$) result with 't' value of 2.82. In moderate hearing loss the initial mean score was 47.55 which was reduced to 43.56 after completion of treatment provided not significant result with 't' value 1.81. In moderately-severe hearing loss the initial mean score was 60.93 which was reduced to 57.48 after completion of treatment provided not significant result with 't' value 1.07. In severe hearing loss the initial mean score was 82.71 which was reduced to 82.01 provided not significant result with 't' value 0.17.

In group B the initial mean score of mild hearing loss was 31.74 which was reduced to 23.45 after completion of treatment (70 days). The total effect of treatment provided statistical significant ($P<0.05$) result with 't' value of 2.66. In moderate hearing loss the initial mean score was 47.66 which was reduced to 37.25 after completion of treatment provided statistical significant ($P<0.05$) result with 't' value 2.94. In moderately-severe hearing loss the initial mean score was 58.66 which was reduced to 54.47 after completion of treatment provided not significant result with 't' value 1.87. In severe hearing loss the initial mean score was 83.71 which was reduced to 81.16 provided not significant result with 't' value 0.70.

Effect of Treatment on Lipid Profile (Group B) –

The total effect of treatment on lipid profile of each patients of Group B was evaluated before and after completion of the treatment. The initial mean for serum cholesterol was 182.91 reduced to 178.7 after completion of the treatment. In HDL the mean score before treatment was 40.72 reduced to 37.86 after completion of treatment. LDL was 108.49 reduced to 108.36. Serum triglycerides was reduced from 132.83 to 129.96 and the serum VLDL was increased from 26.72 to 29.23 after completion of 70 days treatment.

Assessment of Overall Effects of Therapies: Group A provided moderate improvement in 13.33% of the patient, mild improvement in 50% and unchanged was 36.67% patient after completion of the treatment.

Group B provided moderate improvement in 26.67% patients, mild improvement in 50% patients and 23.33% patients were unchanged after completion of the treatment. No patient got complete remission in both the groups.

4) Discussion on Probable mode of action of Trial drugs:

- As majority of the ingredients in Lashunadi Taila have Ushna Veerya (60%) and Katu Vipaka (60%) properties, they produce Dravikaran (Vilayana) and Chedana of vitiated Kapha. Madhura rasa and Snigdha guna being predominant, helps in the Anuloman of Vata whereas Katu-Tikta-Kashaya has Kaphanashak property, thus helpful in disintegrating the Kapha Sanga, which clearly acts on the pathogenesis of

Badhirya. Madhura Rasa and Snigdha guna properties are also helpful in the nourishment of Dhatus, in case of any degenerative changes occur in the inner ear. Thus from the above description of various ingredients of Lashunadi Taila, the overall effect seems to be Vata-Kapha Shamaka, Ushna Veerya and Katu Vipaka.

- All ingredients in the Lashunadi Taila has anti-inflammatory and anti-microbial effect, thereby helps in all kind of inflammation and infection related to external, middle or inner ear. They also have antioxidant property which destroy the free radicals which have accumulated in the tissues of body as well in nervous tissues which helps in nourishing the nerve cells, thereby improves the nerve functions of ear. They also contain immunomodulators, which boost up the immunity against all diseases and also help in nourishing the degenerative changes in any part of the ear, thereby helps in rejuvenating the auditory centres in brain and helps in auditory functions of the ear.
- Acharya Sushruta has mentioned the Samanya Chikitsa of *Karna Rogas*[5] as "Samanyam Karnrogeshu Ghritpanam Rasayanam….." which clearly indicates the importance of Ghritpana in *Karna Rogas*. As Ashwagandhadhya Ghrita posses both quality, Ashwagandha has Rasayana effect and Ghrita , being Snehana nourishes the Dhatus and rejuvenate the degenerative changes in the nerves of the ear as well as provide strength to nervous tissue, which helps in maintaining the normal auditory functions of the ear. Thus it is helpful in Vata related degenerative changes in the ear and normalise the vitiated Vata Dosha. It also helps in regulating the normal function of Vata (i.e. conduction of sound signals through sound channels).
- All ingredients in *Sarivaadi* Vati has majority of Vata-Pitta (35% each) and Kaphanashak (30%) property, Laghu (29%) Ruksha (21%) and Snigdha (18%) Guna, where as Sheeta Veerya (63%) and Madhura Vipaka (56%) has predominant percentage. From the above description of ingredients of *Sarivaadi* Vati, the formulation seems to be Tridosha Shamaka, Sheeta Veerya and Madhura in Vipaka
- It is indicated in all types of Karna-Rogas, Prameha, Raktapitta, Kshya, Shwas, Klebya, Jeeran Jwar, Apsmaar, Unmade, Arsha, Hridya Roga, Madatya and Stree Rogas.

On the basis of properties of all three trial drugs, they are antagnoistic to Vata-Kapha, which are the main culprit of the disease. Moreover all the components of trial drugs have Shothaghna, Vranahara, Krimighna, Balya, Brmhana, Vayasthapana, Dhatuposhaka and Rasayana properties. Hence, it disintegrates the pathology of the disease "*Badhirya*"

Conclusion

- *Badhirya* can be correlated to the disease Hearing Loss or Deafness of modern science.
- Treatment with *Karnpooran* using Lashunadi Taila and *Sarivaadi* Vati with and without Ashwagandhadhya Ghrita has shown promising results in subjective & objective criteria.
- In group A the treatment showed significant result in mild degrees of hearing loss whereas, in group B the treatment showed significant result in mild and moderate degree of hearing loss.
- This Treatment modality is also effective in managing tinnitus and giddiness in both Groups.
- Medicines selected for present study are cost effective.
- None of the cases worsened during the study and the effect of treatment is stable.
- No adverse effect of the therapy was observed during the study period.
- Group A provided moderate improvement in 13.33% of the patient, mild improvement in 50% and unchanged was 36.67% patient after completion of the treatment.
- Group B provided moderate improvement in 26.67% patients, mild improvement in 50% patients and 23.33% patients were unchanged after completion of the treatment.

From the observation it can be inferred that if duration of treatment is prolonged better results can be shown. As results of this study are promising further studies can be taken up to fortify the results.

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