

Single Blind Randomized Comparative Clinical Study of Efficacy of *Ashwagandha Taila* (Oil) Ear drop and *Bilva Taila* (Oil) Ear drop in the Management of Presbycusis



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Abstract

With the aim to evaluate the efficacy of *Ashwagandha Taila* (Oil) Ear drop and *Bilva Taila* (Oil) Ear drop in the management of Presbycusis, a Single blind randomized clinical study was done. For the clinical study of Presbycusis, 30 subjects was selected and studied. Subject's fulfilling the criteria of diagnosis was studied irrespective of their religion, caste, sex and socio-economic status from *shalakya-tantra* (ENT) department of the institute after thorough scrutiny and proper consent in his/her language.

The Subject's having age between 55-75 yrs was selected for the clinical Study. Detail history of the patient were elicited, pathological investigation including Hb, TLC, DLC, RBS and required radiological investigation were done in a diagnostic Centre. The examination of the Ear Audiometry, Vestibular examination, Otoscopic examination is also carried out with the help of modern viewing techniques. After observation and analytical study with the help of Wilcoxon sign rank test and Man-whitney test it was concluded that in Presbycusis treatment with *Ashwagandha Taila* (Oil) Ear drop shows more effective Result in relieving sign and symptoms than *Bilva Taila* (Oil) Ear drop.

Keywords: *Bilva Taila* (Oil); *Ashwagandha Taila* (Oil); Ear drop; Presbycusis; Shalakya-tantra; Audiometry; Vertigo; Deafness; Tinnitus; Hearing loss; Ayurvedic Oil

Introduction

Presbycusis is one among the many socio-medical problems, which is considered as a disability in older people [1]. Presbycusis is being described as hearing impairment in elderly people [2]. Hearing impairment among elderly people is a major issue and a person with hearing loss may be unable to hear to respond, this scenario can make them feel frustrated, lonely and depressed [3]. Presbycusis is the third most common chronic condition after arthritis and hypertension among elders. According to WHO nearly 1.2 billion people will be over the age of 60yr consequently the prevalence of age related auditory and vestibular dysfunction will increase by 2025 [4].

Hearing loss can be improved by using the hearing aids, but it may not be a perfect solution for all [5]. In classics of Ayurveda this ailment has been described as *karnabaadhirya* under the heading of ear diseases [5,6]. *Ear dropa* (Instillation of medicated Ayurvedic Oil into the external auditory canal)

is one of the major treatments for ear diseases explained in classics [7]. Clinical observation has shown its effectiveness in the management of presbycusis [8].

Objectives

- To study efficacy of *Bilva Taila* (Oil) Ear drop in Presbycusis.
- To study efficacy of *Ashwagandha Taila* (Oil) Ear drop in Presbycusis.
- Comparing the efficacy of *Bilva Taila* (Oil) Ear drop and *Ashwagandha Taila* (Oil) Ear drop in Presbycusis.

Hypothesis

H_0 -*Bilva Taila* (Oil) Ear drop and *Ashwagandha Taila* (Oil) Ear drop do not have any effect on Presbycusis.

H₁-As ageing and ear audibility are under the influence of Vata (Nervous System), the said *BilvaTaila* (Oil) Ear drop and *Karnabasti* do have effect on Presbycusis.

Simple random sampling technique comparative clinical study [9,10].

Material and Methods

Study design

Patient will be selected from the OPD of department of *Shalaky Tantra* (ENT), after thorough scrutiny and proper consent.

Composition of trial drug₁₀ (Tables 1 & 2)

Table 1: Group A- *Ashwagandha Taila* (Oil).

Sr.No.	Sanskrit Name	Botanical Name	Family	Part Used	Proportion
1	<i>Ashwagandha</i>	<i>Withaniasomniferia</i>	<i>solanaceae</i>	Root	01
2	<i>TilaTaila</i>	<i>Seasamumindicum</i>	<i>Pedaliaceae</i>	seed	04

Table 2: Group B - *Bilva Taila* (Oil).

Sr.No.	Sanskrit Name	Botanical Name	Family	Part Used	Proportion
1	<i>Bilva</i>	<i>Aeglemarmelos</i>	<i>Rutaceae</i>	fruit	01
2	<i>TilaTaila</i>	<i>Seasamumindicum</i>	<i>Pedaliaceae</i>	seed	04

Preposition (Table 3)

Table 3: Preposition.

<i>DRAVYA</i>	<i>BILVA</i>	<i>Ashwagandha</i>	<i>TILA</i>
<i>RASA</i>	<i>Kasaya,Tikta,Madhur</i>	<i>Katu,Tikta,Kashaya</i>	<i>Madhur,Tikta,Kasaya,Katu</i>
<i>GUNA</i>	<i>Tikshna,Ruksha,Laghu</i>	<i>Laghu,Snigdha</i>	<i>Guru,Snigdha,Sushma,Vyavai</i>
<i>VIRYA</i>	<i>Ushna</i>	<i>Ushna</i>	<i>Ushna</i>
<i>VIPAK</i>	<i>Katu</i>	<i>Katu</i>	<i>Madhur</i>
<i>KARMA</i>	<i>Vatahar,kaphahara,Visaghna</i>	<i>Rasayan</i>	<i>Snehan,Balya,Vataghna,Rasayan,Vajikar</i>

Sample size:

Group A= N₁ = 15
 Group B=N₂= 15
 Total=30

Posology

- a) Group A - Ear drop by *Ashwagandha Taila* (Oil) - QS (1-2 ml)
- b) Group B - Ear dropby *BilvaTaila* (Oil) -QS (1-2 ml)

Grouping: 2 groups

- a) Group A: Treatment with *AshwagandhaTaila* (Oil) Ear drop.
- b) Group B: Treatment with *BilvaTaila*(Oil)Ear drop.

Treatment duration

- a) Group A - Ear drop by *Ashwagandha Taila* (Oil) - 14 days
- b) Group B - Ear dropby *Bilva Taila* (Oil) - 14 days

Intervention (Table 4)

Table 4: Intervention.

Grouping	Group A	Group B
Sample size	15	15
Intervention	<i>Ashwagandha Taila</i> (Oil) Ear drop (For 30 minute)	<i>Bilva Taila</i> (Oil)Ear drop (For 30 minute)
Treatment duration	14 days	14 days
Follow up	After 7 days	After 7 days

Criteria for assessment:

- A. Criteria of inclusion:
 - a) Audiometric findings.
 - b) Age group between 55 to 75 years of either gender.
 - c) Hearing loss between 26 - 90db.
- B. Criteria of exclusion:
 - a) Subject suffering from middle ear infectious diseases.
 - b) Patient having profound hearing loss i.e. hearing loss above 90db.
 - c) Patient having perforation to Tympanic Membrane.
- C. Criteria for evaluation:

Assessment will be done on the basis of improvement in Audiological findings of the patient and from Subjective and Objective parameters of data.

- D. Subjective Criteria:
 - 1) Peripheral Vertigo - Alexander's Law (Table 5)

Table 5: Peripheral Vertigo - Alexander's Law.

Grades	Vertigo
1 st Degree	Present only when subject looks in the direction of fast phase
2 nd Degree	Present when subject looks straight ahead
3 rd Degree	Present even when subject looks in the direction of slow phase

- E. Objective criteria:
 - 1) Deafness- Goodman's rule of hearing loss for deafness.
 - I. 0-25 db- Normal hearing
 - II. 26-40db - mild hearing loss
 - III. 41-55db - moderate hearing loss
 - IV. 56-70db - moderate to severe hearing loss
 - V. 71-90db-severe hearing loss
 - VI. > 90 db - profound hearing loss
 - 2) Tinnitus (Ringing in ear) - Obtain by hearing thresholds, loudness, pitch, and masking curves of tinnitus, computer programs enable all of these measures to be obtained in a single session

Investigation

- i. CBC
- ii. ESR
- iii. RBS
- iv. VDRL

- v. Lipid Profile
- vi. Thyroid Profile

Diagnosis

- i. Rinne's test
- ii. Weber's test
- iii. ABC test
- iv. Pure Tone Audiometry
- v. Impedance Audiometry
- vi. BERA

Radiological

- i. X-Ray Mastoid Bone -Schuller's View.
- ii. CT/ MRI Temporal bone.

Results and Discussion

In the Group A the Mean Vertigo was observe to be 1.533 before treatment that reduced to 1.633 after treatment (p value >0.05), the Mean Tinnitus was observe to be 2.5 before treatment that reduced to 0.6667 after treatment (p value <0.05), the Mean Deafness was observe to be 2.325 before treatment that reduced to 0.7000 after treatment (p value <0.05). In the Group B the Mean Vertigo was observe to be 1.500 before treatment that reduced to 1.400 after treatment (p value >0.05), the Mean Tinnitus was observe to be 2.433 before treatment that reduced to 1.234 after treatment (p value <0.05), the Mean Deafness was observe to be 2.400 before treatment that reduced to 1.025 after treatment (p value <0.05).

To examine either the groups differs from each other significantly or not, further data are treated by Mann whitney U score test. For Vertigo the mean difference in value in group A was 0.05647 while that in Group B was 0.1050(p value >0.05). For Tinnitus the mean difference in value in group A was 1.633 while that in Group B was 0.8637(p value <0.05). For Deafness the mean difference in value in group A was 1.667 while that in Group B was 1.133(p value <0.05).

Conclusion

In this series, 30 patients of Presbycusis were studied, no any difference in sex ratio is found i.e. both male to female ratio is equal, 83.33% patients belonging to Hindu religion, maximum number of patient are educated up to mid school and high school i.e. 36.66% each. 70% of patients are from lower socio-economic level, 45% patient were suffering from Presbycusis since more than 5 yrs, 61.66% patient were having *kaphavatajprakriti*, 40.33% patient were having *mandagni*, 67.33% patients were taking sheet *gunatmaka Ahar* while 69.66% patient were taking *rukshagunatmakAhar*, 38.33% patient were taking dominant *katurasatmakaAhar* and 72.33% patients were taking mixed type of diet. In this study 100% patients of both groups were

having *vata dosh dushti* while 75% patient were having *kapha dosh dushti*, 100% patients of both groups were having *Rasa dushyadushti* while *Mansa* and *Majjadushyadushti* were 80% and 71.66% respectively. 25% patients were living in Noisy residential area, 18.33% patients were doing labor work and 30% patients were having history of addictions. After doing inference confidently by Wilcoxon Sign Rank Test, it is found that in group A except for Vertigo difference between before treatment and after treatment are statistically highly significant for Tinnitus & Deafness.

Also in group B treatment with *BilvaTaila* (Oil) Ear drop are effective in relieving symptoms of *Presbycusis* except for symptom Vertigo. After doing Mann-Whitney U Test to examine difference between effect of treatment in both groups it is found that for Tinnitus & Deafness the inference is highly significant. I.e. for above symptoms Group A shows better result than Group B. But for Vertigo the inference is in-significant. The properties of *Ashwagandhataila* (Oil) i.e. Rejuvenating in nature, excess of hydrogen ions are useful for capillary circulation. Increased H⁺ ions concentration dilate the capillary. As *Ashwagandhataila* (Oil) is having excess of H⁺ ions concentration it causes dilatation of capillary. Irritation of the skin produces vasodilatation in the locality. In neurology this reflex is known as Axon reflex. From the above discussion, it is clear that Subjects having clinical features of *Presbycusis* are more significantly reduced

in Group A than Group B which itself prove that treatment with *AshwagandhaTaila* (Oil) Ear drop is better than treatment with *BilvaTaila* (Oil) Ear drop in *presbycusis*.

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