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

Gangaprasad A Waghmare*
K G Mittal Ayurved College, India

Submission: February 07, 2017; Published: February 28, 2017

*Corresponding author: Gangaprasad A Waghmare, K G Mittal Ayurved College, Charni road, Mumbai-02, Tel: +91 9096566633 Email: drgw007@gmail.com

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-whiteny 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 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 karnabadhriya 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

a) To study efficacy of Bilva Taila (Oil) Ear drop in Presbycusis.

b) To study efficacy of Ashwagandha Taila (Oil) Ear drop in Presbycusis.

c) 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.
As ageing and ear audibility are under the influence of Vata (Nervous System), the said Bilva Taila (Oil) Ear drop and Karnabasti do have effect on Presbycusis.

**Material and Methods**

**Study design**

**Composition of trial drug (Tables 1 & 2)**

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Sanskrit Name</th>
<th>Botanical Name</th>
<th>Family</th>
<th>Part Used</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ashwagandha</td>
<td>Withaniasomniferia</td>
<td>solanaceae</td>
<td>Root</td>
<td>01</td>
</tr>
<tr>
<td>2</td>
<td>Tila Taila</td>
<td>Seasamumindicum</td>
<td>Pedaliaceae</td>
<td>seed</td>
<td>04</td>
</tr>
</tbody>
</table>

**Preposition (Table 3)**

<table>
<thead>
<tr>
<th>DRAVYA</th>
<th>BILVA</th>
<th>Ashwagandha</th>
<th>TILA</th>
</tr>
</thead>
<tbody>
<tr>
<td>RASA</td>
<td>Kasaya,Tikta,Madhur</td>
<td>Katu,Tikta,Kashaya</td>
<td>Madhur,Tikta,Kasaya,Katu</td>
</tr>
<tr>
<td>GUNA</td>
<td>Tikshna,Ruksha,Loghu</td>
<td>Laghu,Snigdha</td>
<td>Guru,Snigdha,Sushma,Vyavai</td>
</tr>
<tr>
<td>VIHYA</td>
<td>Ushna</td>
<td>Ushna</td>
<td>Ushna</td>
</tr>
<tr>
<td>VIPAK</td>
<td>Katu</td>
<td>Katu</td>
<td>Madhur</td>
</tr>
<tr>
<td>KARMA</td>
<td>Vatahar,kaphahara,Visaghna</td>
<td>Rasyon</td>
<td>Snehan,Balya,Vataghna,Rasyan,Vajikar</td>
</tr>
</tbody>
</table>

**Sample size:**

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

**Grouping: 2 groups**

- a) Group A: Treatment with Ashwagandha Taila (Oil) Ear drop.
- b) Group B: Treatment with Bilva Taila (Oil) Ear drop.

**Intervention (Table 4)**

<table>
<thead>
<tr>
<th>Grouping</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Intervention</td>
<td>Ashwagandha Taila (Oil) Ear drop (For 30 minute)</td>
<td>Bilva Taila (Oil) Ear drop (For 30 minute)</td>
</tr>
<tr>
<td>Treatment duration</td>
<td>14 days</td>
<td>14 days</td>
</tr>
<tr>
<td>Follow up</td>
<td>After 7 days</td>
<td>After 7 days</td>
</tr>
</tbody>
</table>
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 - 90 db.
B. Criteria of exclusion:
   a) Subjects suffering from middle ear infectious diseases.
   b) Patient having profound hearing loss i.e. hearing loss above 90 db.
   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>
<thead>
<tr>
<th>Grades</th>
<th>Vertigo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Degree</td>
<td>Present only when subject looks in the direction of fast phase</td>
</tr>
<tr>
<td>2nd Degree</td>
<td>Present when subject looks straight ahead</td>
</tr>
<tr>
<td>3rd Degree</td>
<td>Present even when subject looks in the direction of slow phase</td>
</tr>
</tbody>
</table>
E. Objective criteria:
   1) Deafness - Goodman’s rule of hearing loss for deafness.
      I. 0-25 db - Normal hearing
      II. 26-40 db - mild hearing loss
      III. 41-55 db - moderate hearing loss
      IV. 56-70 db - moderate to severe hearing loss
      V. 71-90 db - 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

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 0.6667 while that in Group B was 0.8637 (p value <0.05). For Deafness the mean difference in value in group A was 0.667 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 kaphavatataprakriti, 40.33% patient were having mandagni, 67.33% patients were taking sheet gunatmakAhar while 69.66% patient were taking rukshagunatmakAhar, 38.33% patient were taking dominant katurasatmakAhar 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 *Bilva Taila* (Oil) Ear drop are 
effective in relieving symptoms of *Presbycusis* except for 
symptom Vertigo. After doing Mann-Whiteny 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 
*Bilva Taila* (Oil) Ear drop in *presbycusis*.

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