

An Open Label Double Arm Controlled Clinical Study of Shringaveradi Arka Karna Purana in Badhirya (Sensorineural Hearing Loss)

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ABSTRACT

Background: Badhirya is a common ear disorder described in Ayurveda, mainly caused by vitiation of Vata and Kapha doshas leading to impaired hearing. In modern medicine, it closely resembles Sensorineural Hearing Loss (SNHL), a condition caused by damage to cochlear hair cells or auditory neural pathways. Globally, over 430 million people suffer from disabling hearing loss, and the number is projected to reach 700 million by 2050. Karna Purana, the instillation of medicated liquid into the ear, is an important local therapy described in Ayurveda for ear disorders. Shringaveradi Arka, possessing Vata-Kaphahara properties, is indicated in the management of Badhirya.

Objective: To evaluate the clinical efficacy of Shringaveradi Arka Karna Purana in the management of Badhirya (Sensorineural Hearing Loss).

Methods: This open-label double-arm controlled clinical study included 40 patients diagnosed with Badhirya (SNHL). Participants were randomly divided into two groups: Group A (control group) treated with Vacha Arka Karna Purana and Group B (trial group) treated with Shringaveradi Arka Karna Purana. The treatment was administered for 14 days. Assessment was done before treatment and on the 15th, day using subjective parameters (reduced hearing and tinnitus) and objective parameters such as Pure Tone Audiometry and ERSA questionnaire.

Results: Out of 43 enrolled patients, 40 completed the study (20 in each group). Both groups showed statistically highly significant improvement ($p < 0.01$) in hearing threshold, tinnitus, and ERSA questionnaire scores after treatment. However, intergroup comparison showed no statistically significant difference ($p > 0.05$), indicating comparable efficacy of both interventions.

Conclusion: Karna Purana with Shringaveradi Arka demonstrated significant improvement in symptoms of Badhirya (SNHL). The therapy appears to be a safe and effective Ayurvedic intervention for improving hearing and reducing tinnitus.

Keywords: Badhirya, Sensorineural Hearing Loss, Karna Purana, Shringaveradi Arka.

INTRODUCTION

In Ayurveda, the Karna had been regarded as the seat of Sravanendriya [1], functioning through

Sabdavaha Srotas and Nadis, with hearing linked to Akasha Mahabhoota. Disorders of this system had resulted in Karnagata Rogas, mainly due to Vata Dosha. Acharya Charaka had described four types of Karnagata Roga—Vataja, Pittaja, Kaphaja and Sannipataja [2], while Acharya Sushruta had enumerated twenty-eight Karnaroga, including Badhirya [3]. The Ashtanga Hrudaya and Ashtanga Sangraha had also described twenty-five Karnaroga, including Badhirya [4].

According to Acharya Sushruta, Badhirya occurred due to aggravated Vata or Vata- Kapha obstructing Sabdavaha Srotas, leading to impaired hearing, where early symptoms like Karna Nada could progress if untreated [5]. General causes included Avashyaya, Jalakreeda, Karna Kandu, and improper practices [6], along with trauma of Vidhura Marma [7] and other disease conditions. Acharya Charaka had also described Badhirya as a complication of Dhumapana, Trishna Vega Dharana [8][9], and improper Niruha Basti.

Clinically, Vataja Badhirya correlated with Sensorineural Hearing Loss (SNHL), characterized by impaired hearing and associated symptoms. In modern science, SNHL had been defined as damage to cochlear hair cells or neural pathways, often irreversible. The World Health Organization had reported over 430 million affected individuals, projected to exceed 700 million by 2050 [10], with 63 million affected in India [11].

Ayurvedic management included Nasya, Karna Dhoopana, Karna Pichu, and Karna Purana, the latter being an effective local therapy. Vacha Arka [12] had shown clinical benefits and was used as a control. Arka Prakasha had described Arkas for Karnaroga, and Shringaveradi Arka, indicated for Badhirya, possessed Vatahara properties.

The present study had been undertaken to evaluate the efficacy of Shringaveradi Arka [13] Karna Purana in Badhirya (SNHL), using Vacha Arka as control.

MATERIALS AND METHODS

Study Design

An open-label double-arm controlled clinical study was conducted to evaluate the efficacy of Shringaveradi Arka Karna Purana in Badhirya.

Sample Size

A total of 40 patients diagnosed with Badhirya (SNHL) were selected for the study.

Inclusion Criteria

- Patients aged between 40–70 years
- Mild to moderate SNHL (15–55 dB)
- Presence of clinical features of Badhirya
- Intact tympanic membrane

Exclusion Criteria

- Patients of Sensory Neural Hearing Loss occurred due to infective and Auto immune diseases.
- Patients with Conductive and Mixed deafness.
- Patients with Aural Tumor's, Polyps.
- Hearing loss due to any systemic disorders.
- Tympanic membrane perforation.
- Middle and Inner ear pathology like Acoustic neuroma, Meniere's disease.
- Genetic Sensory Neural Hearing Loss.

INTERVENTION

| Parameter | Group A (Control) – Vacha Arka | Group B (Trial) – Shringaveradi Arka |
|-----------------------|--|--|
| Sample Size | 20 | 20 |
| Drug | Vacha Arka | Shringaveradi Arka |
| Procedure | Karna Purana | Karna Purana |
| Duration of Treatment | 14 days | 14 days |
| Assessment Schedule | Day 0 (Before Treatment), Day 15 (After Treatment) | Day 0 (Before Treatment), Day 15 (After Treatment) |

ASSESSMENT CRITERIA

Subjective Parameters

- Reduced hearing
- Tinnitus

Objective Parameters

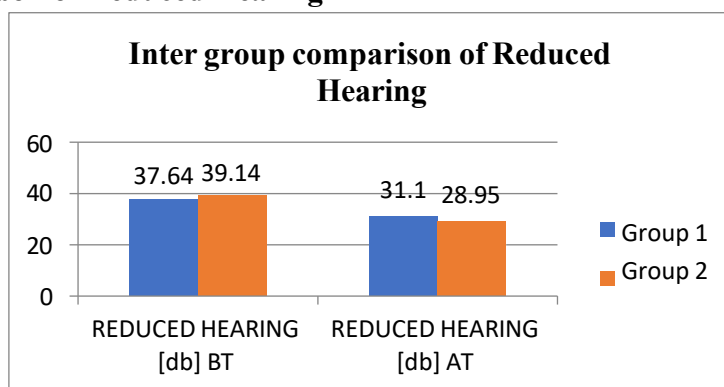
- Pure Tone Audiometry
- ERSA Questionnaire

RESULTS

A total of 43 patients were initially enrolled, out of which 40 completed the study.

Effect on Reduced Hearing

Inter Group Comparison of Reduced Hearing

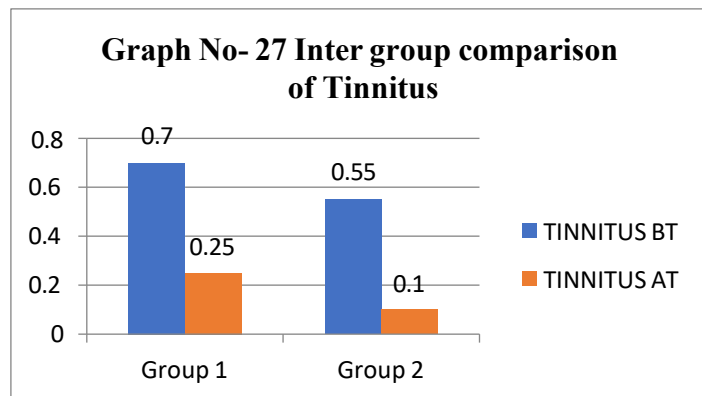


| | Group | N | Mean | Std. Deviation | Mean Rank | Sum of Rank | Median | Mann-Whitney U value | Z value | p value of Mann-Whitney U test |
|----|-------|----|-------|----------------|-----------|-------------|--------|----------------------|---------|--------------------------------|
| BT | A | 20 | 37.64 | 13.2099 | 19.75 | 395 | 38.5 | 185.000 | -0.406 | 0.685# |
| | B | 20 | 39.14 | 15.7220 | 21.25 | 425 | 43.3 | | | |
| AT | A | 20 | 31.10 | 13.196 | 21.35 | 427 | 32.5 | 183.000 | -0.461 | 0.645# |
| | B | 20 | 28.95 | 13.376 | 19.65 | 393 | 29.5 | | | |

Both groups showed statistically highly significant improvement in hearing threshold after treatment ($p < 0.01$). Mean hearing levels improved from 37.64 dB to 31.10 dB in Group A and 39.14 dB to 28.95 dB in Group B.

Effect on Tinnitus

Inter Group Comparison of Tinnitus



| | Group | N | Mean | Std. Deviation | Mean Rank | Sum of Rank | Median | Mann-Whitney U value | Z value | p value of Mann-Whitney U test |
|----|-------|----|------|----------------|-----------|-------------|--------|----------------------|---------|--------------------------------|
| BT | A | 20 | 0.70 | 0.801 | 21.85 | 437 | 0.5 | 173.000 | -0.821 | 0.412# |
| | B | 20 | 0.55 | 0.887 | 19.15 | 383 | 0 | | | |
| AT | A | 20 | 0.25 | 0.444 | 22 | 440 | 0 | 170.000 | -1.233 | 0.218# |
| | B | 20 | 0.10 | 0.308 | 19 | 380 | 0 | | | |

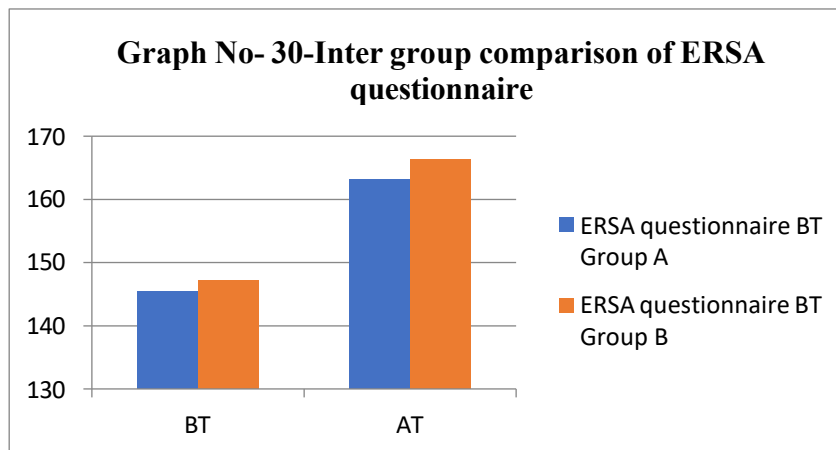
Mann-Whitney U test was applied for between the groups; # indicates statistically non-significant $p > 0.05$. There was a statistically non-significant difference seen ($p > 0.05$) for all values between the groups A and B. Significant reduction in tinnitus scores was observed in both groups. However, the difference between groups was statistically non-significant.

Effect on ERSA Questionnaire

Inter Group Comparison of ERSA Questionnaire

| | Group | N | Mean | Std. Deviation | Std. Error Mean | Mean diff | 95% Confidence Interval of the Difference Lower | 95% Confidence Interval of the Difference Upper | T value | p value of t test |
|----|-------|----|--------|----------------|-----------------|-----------|---|---|---------|-------------------|
| BT | A | 20 | 145.45 | 18.574 | 4.153 | -1.700 | -11.894 | 8.494 | -0.338 | 0.738# |

| | | | | | | | | | | |
|----|---|----|--------|--------|-------|--------|---------|-------|--------|--------|
| | B | 20 | 147.15 | 12.733 | 2.847 | | | | | |
| AT | A | 20 | 163.25 | 16.383 | 3.663 | -3.100 | -12.904 | 6.704 | -0.640 | 0.526# |
| | B | 20 | 166.35 | 14.165 | 3.167 | | | | | |



ERSA scores improved significantly in both groups after treatment. Mean ERSA scores increased from 145.45 to 163.25 in Group A and 147.15 to 166.35 in Group B.

Intergroup comparison showed no statistically significant difference ($p > 0.05$), suggesting comparable therapeutic efficacy.

DISCUSSION

The present study critically evaluates the therapeutic efficacy of Shringaveradi Arka administered through Karna Purana in the management of Badhirya (Sensorineural Hearing Loss). Shringaveradi Arka, described in classical texts, is a distilled formulation indicated in Karnaroga, especially conditions arising from Vata vitiation affecting the Sabdavaha Srotas. The formulation comprises Aardraka, Tila Taila, Saindhava Lavana, and Madhu, processed through Arka preparation, a distillation technique that concentrates volatile bioactive constituents into a light, highly absorbable form. This method enhances bioavailability and makes the formulation particularly suitable for administration in auditory canal. Each component contributes to the overall therapeutic effect: Aardraka, rich in gingerols and shogaols, provides anti-inflammatory, antioxidant, and neuroprotective actions; Tila Taila offers nourishment and structural support to auditory tissues; Saindhava Lavana facilitates drug permeation and maintains ionic balance; and Madhu acts as a Yogavahi, enhancing absorption while imparting antimicrobial and soothing effects. The formulation is also practical in terms of preparation, stability, and shelf life, making it a scientifically and traditionally justified choice for managing Vataja Badhirya.

The analytical ^[14] evaluation of Shringaveradi Arka substantiates its quality, safety, and therapeutic potential. Organoleptic assessment revealed a clear, colorless liquid with a pungent odor and sweet taste, reflecting the intrinsic properties of its constituents and indicating purity. Physicochemical analysis demonstrated favorable characteristics, including low viscosity and appropriate specific gravity, which facilitate easy diffusion and retention within the auditory canal. The acidic pH (4.19) was found to be compatible with the physiological environment of the ear, thereby ensuring safety and minimizing irritation. The presence of both hydrophilic and lipophilic components, as indicated by refractive index values, supports effective drug absorption. Chromatographic profiling showed consistent Rf values and densitometric peaks under different wavelengths, confirming reproducibility and standardization of the

formulation. The identification of lipophilic constituents suggests potential antioxidant, anti-inflammatory, and neuroprotective actions. Furthermore, microbial analysis confirmed sterility, with no bacterial or fungal growth observed, establishing the formulation as safe for ear administration. These analytical findings collectively validate Shringaveradi Arka as a stable, standardized, and biologically active preparation suitable for therapeutic use.

The clinical outcomes of the study further reinforce these findings. Both treatment groups demonstrated statistically highly significant improvement in hearing thresholds ($p < 0.01$), indicating that Karna Purana is an effective modality for managing Badhirya. Although intergroup comparison was not statistically significant, the Shringaveradi Arka group showed comparatively better improvement, suggesting enhanced efficacy due to its multi-ingredient composition. Similarly, tinnitus scores showed significant reduction in both groups, with a greater absolute decrease observed in the Shringaveradi Arka group. These findings indicate that the intervention effectively reduces abnormal auditory sensations and stabilizes neural function.

The observed therapeutic effects can be explained through both pharmacological and Ayurvedic perspectives. Vacha Arka, used in the control group, contains bioactive compounds such as phenylpropanoids and terpenoids that exhibit neuroprotective and anti-inflammatory properties, along with Ushna, Tikshna, and Laghu Gunas that help pacify Vata and improve circulation. In contrast, Shringaveradi Arka, as a multi-ingredient distillate, demonstrates synergistic action due to the combined effects of its constituents. Its favorable physicochemical properties ensure better retention and absorption, while its pharmacological actions contribute to reduced oxidative stress, improved microcirculation, and enhanced neural conduction. From an Ayurvedic standpoint, its combined Ushna, Snigdha, and Tikshna qualities facilitate Vata Shamana, Srotoshodhana, and restoration of auditory function.

Assessment of quality of life using the ERSA questionnaire revealed statistically significant improvement in both groups. The increase in scores reflects better auditory perception, improved communication ability, and enhanced confidence in daily activities. This indicates that the intervention not only improves objective hearing parameters but also alleviates the functional and psychosocial impact of hearing loss.

Overall, the findings suggest that Shringaveradi Arka administered through Karna Purana is a safe, effective, and scientifically validated intervention for Badhirya. Its therapeutic efficacy can be attributed to a combination of favorable analytical properties, targeted drug delivery, and synergistic pharmacological action, resulting in significant improvements in both clinical outcomes and quality of life.

CONCLUSION

Badhirya, predominantly a Vataja disorder involving Sroto-avarodha in Karna Srotas, showed higher prevalence after 40 years, supporting classical Ayurvedic concepts. The study on 40 patients (40–70 years) demonstrated consistent efficacy across age and gender. Analytical and microbial evaluation confirmed that Shringaveradi Arka is safe, stable, and suitable for Karna Purana, with properties facilitating effective absorption and retention.

Its therapeutic effect can be attributed to the synergistic action of Aardraka, Tila Taila, Saindhava Lavana, and Madhu, providing Vata-shamana, Srotoshodhana, and restoration of auditory function. No adverse effects were observed, establishing the therapy as safe and well tolerated. Although intergroup

differences were statistically non-significant, the trial group showed comparatively better improvement, likely due to its multi-ingredient formulation and standardization. Additionally, significant improvement in ERSA scores in both groups indicated enhanced hearing ability and quality of life.

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