

COMPARATIVE STUDY OF EVALUATING EFFICACY OF NISHA TAILA KARNAPICHU AND VACHALASUNADI TAILA KARNAICHU IN THE MANAGEMENT OF KARNASRAVA

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INTRODUCTION

The importance of *Ayurveda* in global scenario is because of its holistic approach towards positive life style. The complete health care system is the outcome of the great power of observation, generalization and analysis of hundreds of investigators spread over thousands of years.

Knowledge is perceived through the five *Gyanendriyas* (sense organs) and these are included among twelve *Prana* by *Acharya Susruta*.

The above description signifies the importance of sense organs. *Sravanendriya* is one among the five *Gyanendriyas*; its *Adhithana* is known as *Srotra* (Ear). *Karna srava* is one among the 28 *Karna rogas* explained by *Acharya Sushruta*.^[1]

Acharya Charaka included *Karnasrava* as a symptom under the four types of *Karnarogas* caused due to vitiation of different *doshas*.^[2] *Acharya Vagbhatta* has not described *Karnasrava* separately but considered it under *Karnashula*.^[3] The term *Karna srava* is self-explanatory which means discharge from ear.

In modern science, any discharge from ear is known as otorrhoea. Otorrhoea can be classified under serous, mucoid or mucopurulent, purulent, sanguineous or water discharge. Chronic suppurative otitis media (CSOM) is the result of an initial episode of acute otitis media and is characterized by a persistent discharge from the middle ear through tympanic membrane perforation. In school children, there will also be hindrance in the learning, because of reduced hearing.^[4] It is important cause of hearing impairment in rural population. It is an important cause of preventable hearing loss, particularly in the developing world.^[5] The principle treatment modalities for CSOM adopted in conventional system of medicine are Aural toilet, systemic antibiotics and surgical management like tympanoplasty, mastoidectomy etc.

Need of the Study

Chronic suppurative otitis media affects about 5% or 31 million of cases with 22.6% of cases occurring annually above the age of five years in 2010-11.^[6] The prevalence rate of CSOM is 46 and 16 persons per thousand in rural and urban population respectively.^[7]

In *Ayurveda* various formulations are described under *Karnaroga Chikitsa Adhyaya*, which signifies the scope of research for better approach to the disease *Karnasrava*.^[8]

In the present study, *Vacha lashunaadi Taila Pichu* and *Nisha Taila Karna Pichu* is taken up for the study. *Vacha Lashunadi Taila* is explained in *Taila Prakarana* of *Sahasrayoga*,^[9] while *Nisha Taila* is explained in *Karnaroga* in *Rasatantra sara*.^[10] As drugs used in these therapies are easily available, easily administered and easily acceptable by the patients, they were selected for the trial.

Along with systemic medication more emphasis is laid upon local treatment by *Acharya Sushruta*. This disease also has chiefly local etiological factors; therefore local drug administration was selected as mentioned by *Acharya Sushruta* in the form of *Karnapichu*.

Hypothesis

Null Hypothesis (H0)

The effect of *Nisha Taila* is not better than *Vacha Lasunadi Taila* in the management of *Karnasrava*.

Alternative Hypothesis (H1)

The effect of *Nisha Taila* is better than *Vacha Lasunadi Taila* in the management of *Karnasrava*.

MATERIALS AND METHOD**Aim**

To evaluate the efficacy of *Nisha Taila Karna Pichu* in the management of *Karna Srava*.

Objective

- To evaluate the efficacy of *Vacha lashunaadi taila Karna Pichu* in the management of *Karna Srava*.
- To compare the efficacies of *Vacha Lashunadi Taila Karna Pichu* and *Nisha Taila Karna Pichu* in the management of *Karnasrava*.

Study Design: Open label randomized Phase-2 clinical study.

Patients were divided into two groups as Group 'A' and Group 'B' with 15 patients each according to their date of admission alternatively.

Subjective Criteria

Assessment of subjective parameter Symptoms	Ear discharge	Impaired hearing	Earache	Headache
Grade 0	No discharge	Absent	No pain	Absent
Grade 1	Mild discharge at TM	Unable to hear whispering	Very mild	Mild
Grade 2	Irrigating the EAC	Unable to hear distant voice	Moderate	Moderate
Grade 3	Discharge coming out the EAC	Unable to hear near voice	Disturbs routine works	Disturbs routine-works
Grade 4	Profuse Discharge	Unable to hear loud voice	severe pain in ear	Severe headache

Objective Criteria**1. Perforation**

Assessment of perforation	Perforation
Grade 0	No perforation
Grade 1	Pin hole perforation
Grade 2	Small perforation
Grade 3	Large perforation
Grade 4	Subtotal perforation

Criteria for Diagnosis

Patients having symptoms of *karna-srava* as per Ayurved and Modern texts, safe or tubo-tympanic chronic suppurative otitis media were included in this study.

F. Study Duration

Total duration of treatment was for 21 days in each group with follow up after 1 month (Post treatment) to check for any recurrence.

Group A (control Group) – in this group patients were treated with *Vacha lashunadi taila^[11] pichu* twice a day for one hour for 7 days followed by rest for 7 days.

Group B (Trial Group) – in this group patients were treated with *Nisha taila pichu^[12]* twice a day for one hour for 7 days followed by rest for 7 days.

Selection Criteria**A. Sample Size: 30****B. Inclusion Criteria**

- Age: above 5 years
- Patient having clinical signs & symptoms of disease CSOM [tubo-tympanic or Safe Type].

C. Exclusion Criteria

1. Attic, marginal and total perforations of tympanic membrane
2. Patient with severe conductive, sensory-neural and mixed deafness.
3. Patients with blood stained ear discharge
4. Ear discharge associated with systemic disorders
5. Advancement of disease with pre-malignant or malignant changes.

G. Assessment of Result: Assessment was done on the basis of clinical observation (subjective and objective parameters) before and after treatment.

Standard Operative Procedure

Route of Administration: *Karna*

Position of patients: right or left lateral position according to affected ear.

Matra: Q. S for *karnapichu* (approximately 3 ml).

Administration time: Morning & Evening.

Purva karma

- Cleaning of ear
- Gentle massage with lukewarm oil around the ear for a short period should be done.

Pradhana Karma

karnapichu for 1 hour.

Paschat karma

- Removal of *Karnapichu* after 1 hour.

Cleaning of ear with dry cotton and ear should be kept open in home, while leaving outside, it should be covered with dry cotton.

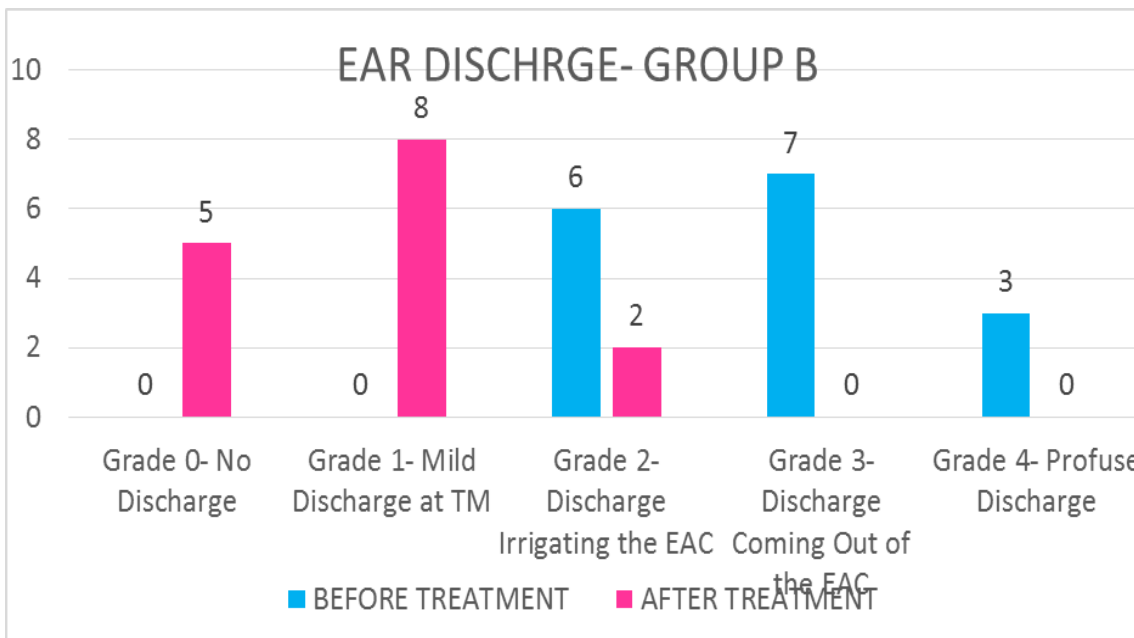
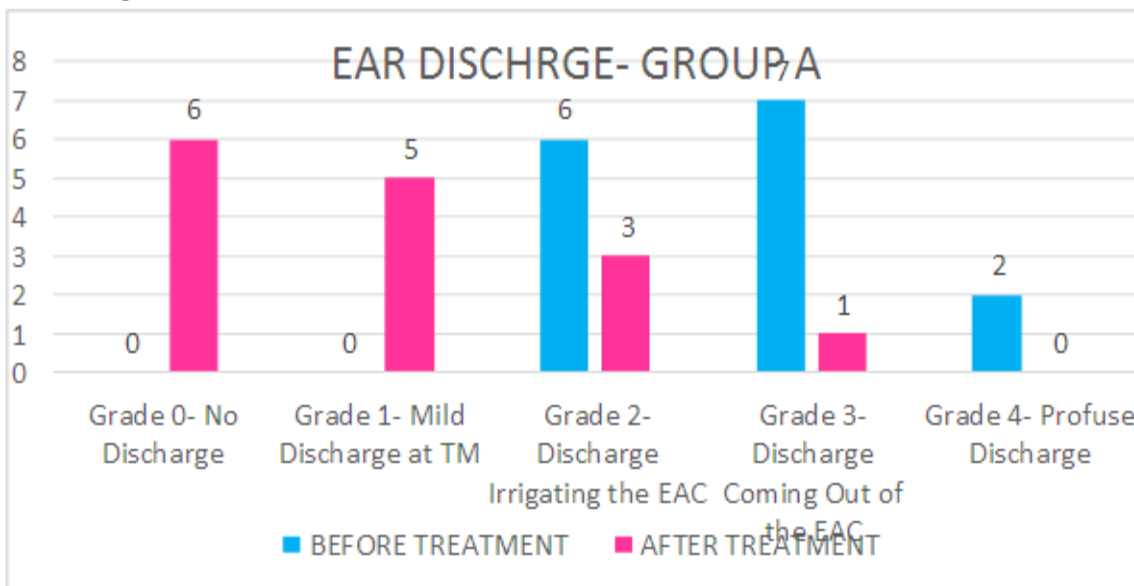
Advice to patients: patients were advised to avoid water entry into ears while bathing, and to avoid exposure to wind, and to keep ear dry.

two groups according to their date of registration alternatively. Out of 48 patients, 18 patients were discontinued from the study. The rest 30 patients completed the clinical trial. Outcomes were measured after the completion of the treatment by both objective and subjective criteria.

OBSERVATION AND DISCUSSION

For the present clinical study 48 patients ranging from age 15-60 years were registered. They were divided into

1) Ear discharge



Out of 15 patients in Group A, before treatment, 6 patients had Grade-2 discharge, 7 patients had grade 3 discharge and 2 patient had grade 4 discharge. After treatment, 6 patient had grade 0 discharge, 5 patient had

grade 1 discharge, 3 patient had grade 2 discharge and 1 patient had grade 1 discharge.

Out of 15 patients in Group B, before treatment, 6 patients had Grade-2 discharge, 6 patients had grade 3 discharge and 3 patient had grade 4 discharge. After treatment, 5 patient had grade 0 discharge, 8 patient had grade 1 discharge, 2 patient had grade 2 discharge.

Comparison between group A and Group B

- Mean B.T in Group A was 2.733 that reduced to 0.933 where as in Group B mean B.T was 2.8 which was reduced to 0.8.
- Group A has shown 65.86 % relief and Group B has shown 71.48 % relief.

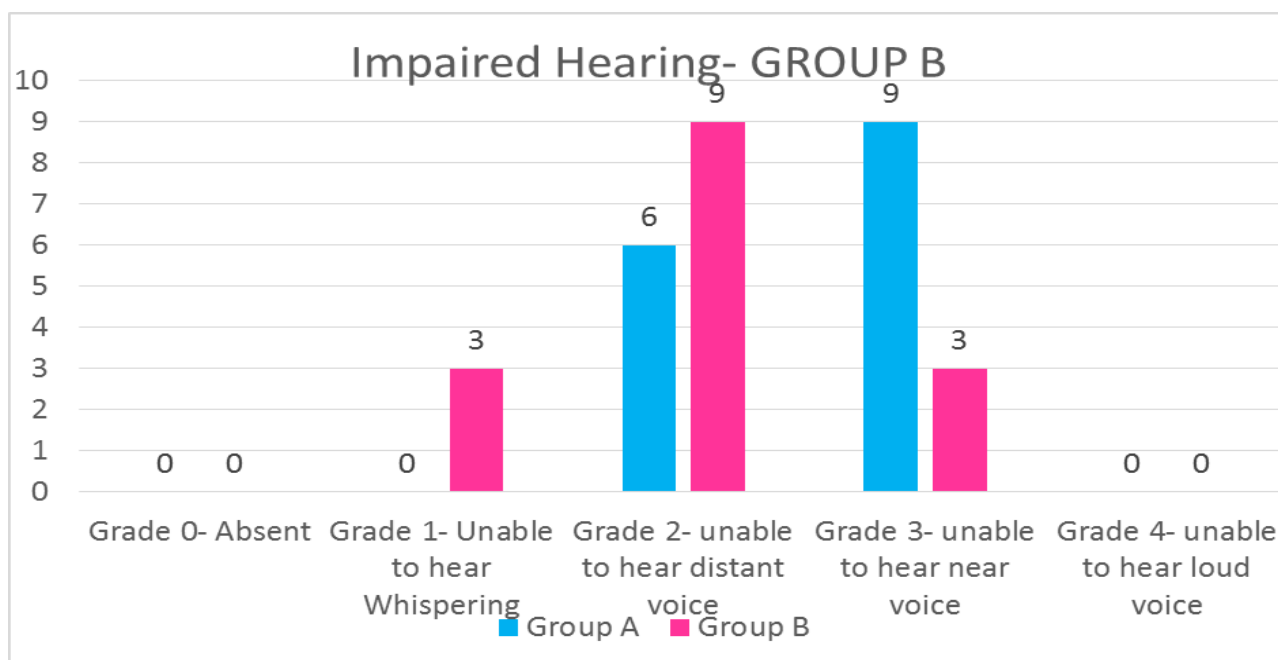
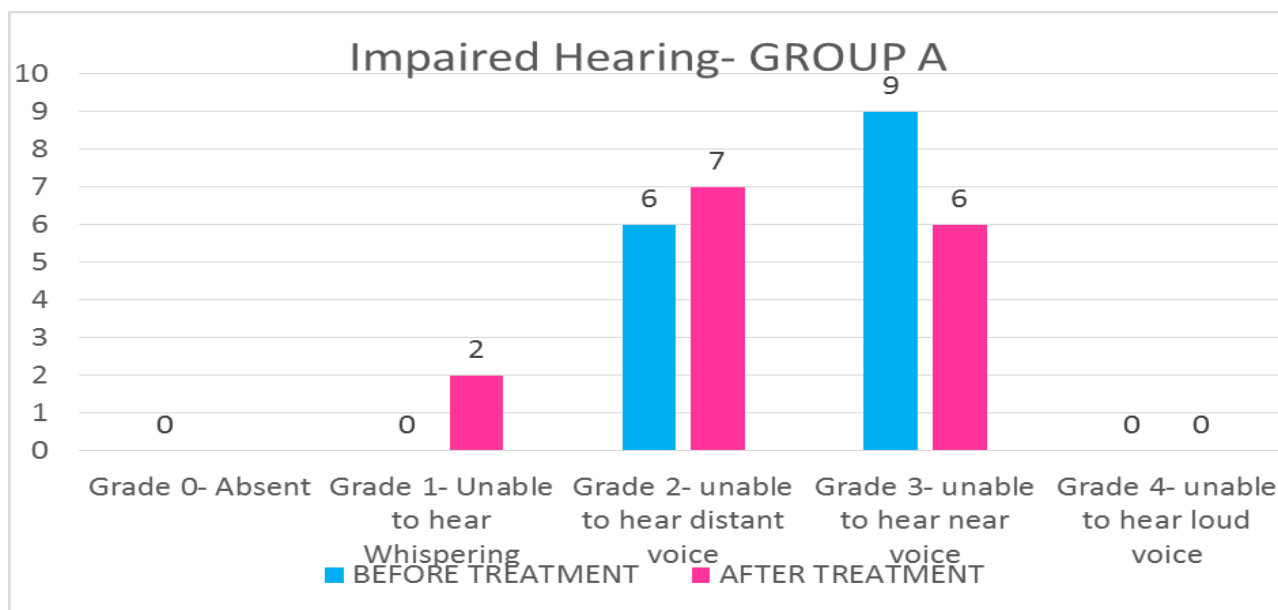
→ Group B is advocated with *Vachalashunadi taila* contains drugs which are having *Katu* and *Tikta Rasa*, *Ruksha*, *Tikshna* and mainly *Kapha Vata hara* properties,

which are antagonistic to *Vata -kapha*, which are the main culprit of the disease.

2) Impaired hearing

Out of 15 patients in Group A, before treatment, 6 patients had grade 2 impaired hearing and 9 patient had impaired hearing of grade 3. After treatment, 2 patients had grade 1 impaired hearing, 7 patients had grade 2 impaired hearing and 6 patients had grade 3 impaired hearing.

Out of 15 patients in Group B, before treatment, 6 patients had grade 2 impaired hearing and 9 patient had impaired hearing of grade 3. After treatment, 3 patients had grade 1 impaired hearing, 9 patients had grade 2 impaired hearing and 3 patients had grade 3 impaired hearing.

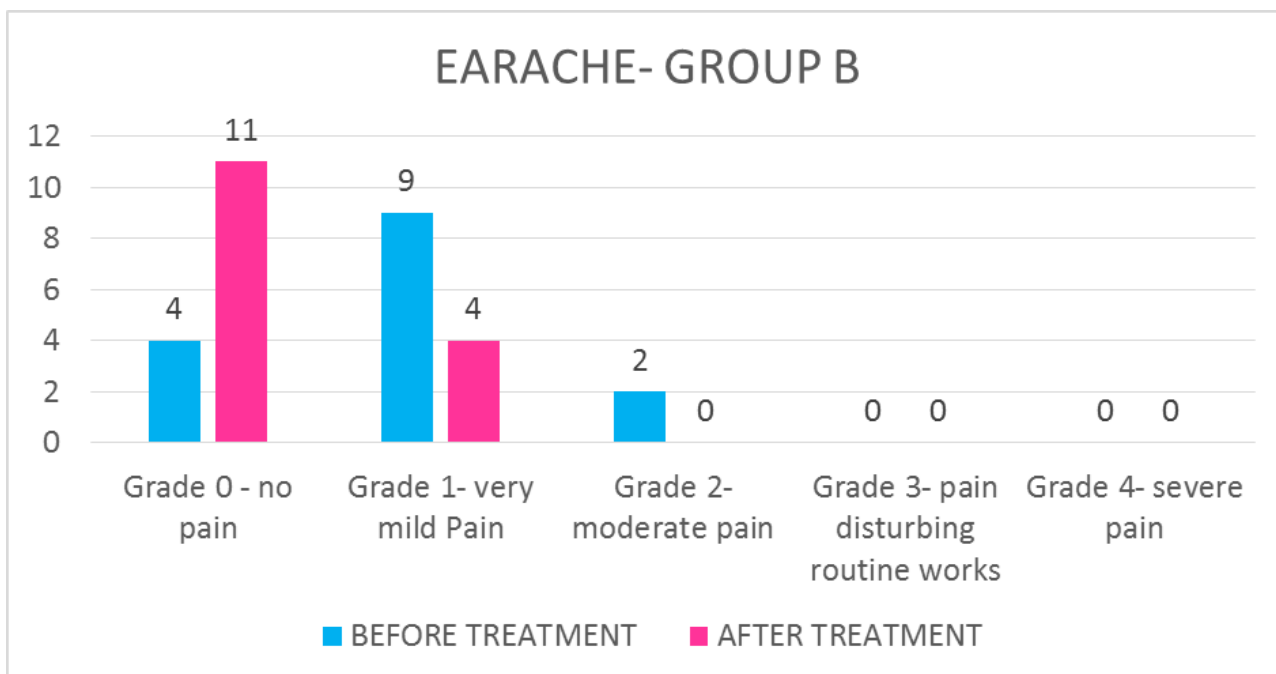
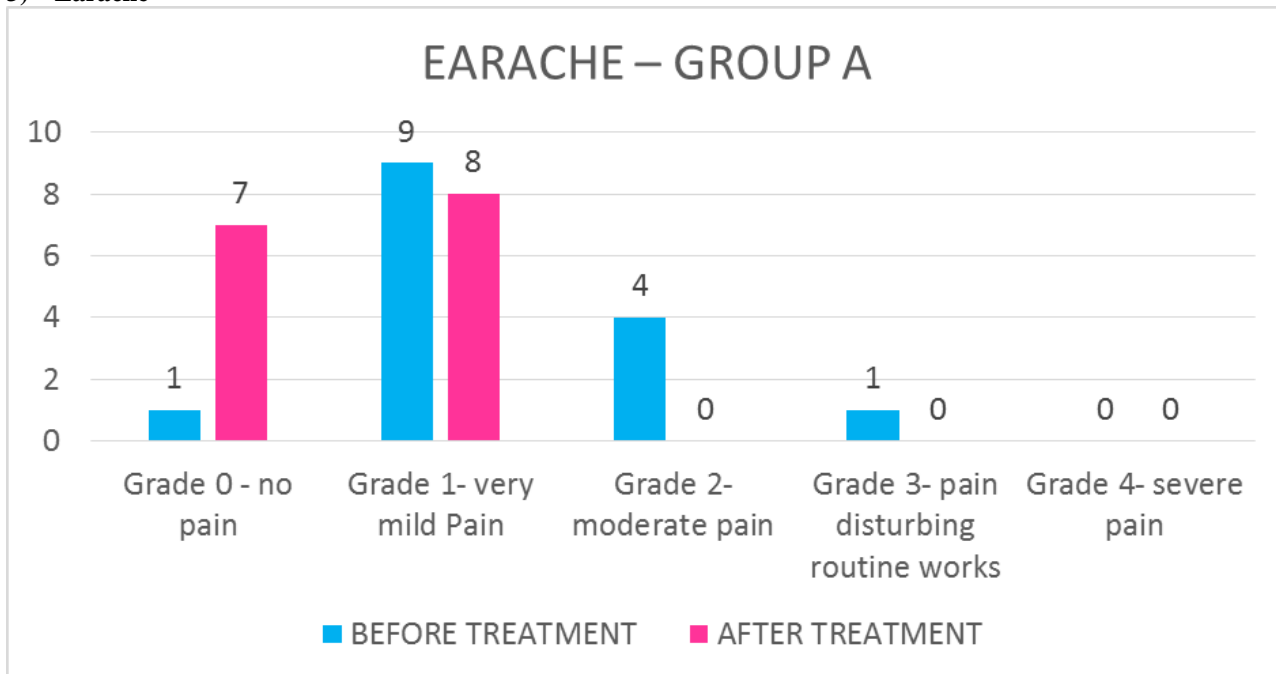


Comparison between group A and Group B

- Mean B.T in Group A was 2.6 that reduced to 2.267 where as in Group B mean B.T was 1.867 which was reduced to 1.533.
- Group A has shown 12.81 % relief and Group B has shown 17.89 % relief.

→ The poor result of the effect on impaired hearing may be due to the shorter period of time of intervention, & also only local application of the drug. Further studies can be done adding oral medications described for treatment of *Badhirya*, adding with local medication to achieve overall result in all the symptoms.

3) Earache



In group A, before treatment, 1 patient had earache absent, 9 patients had grade 1 earache occurring very rarely, 4 patients had grade 2 pain and 1 patient had grade 3 pain. After treatment, 7 patients had grade 0 Pain, and 8 patients had grade 1 pain.

In group B, before treatment, 4 patient had earache absent, 9 patients had grade 1 earache occurring very rarely, 2 patients had grade 2 pain. After treatment, 11 patients had grade 0 Pain, and 4 patients had grade 1 pain.

Comparison between group A and Group B

- Mean B.T in Group A was 1.133 that reduced to 0.533 where as in Group B mean B.T was 0.8667 which was reduced to 0.2667.
- Group A has shown 59.92 % relief and Group B has shown 69.22 % relief.

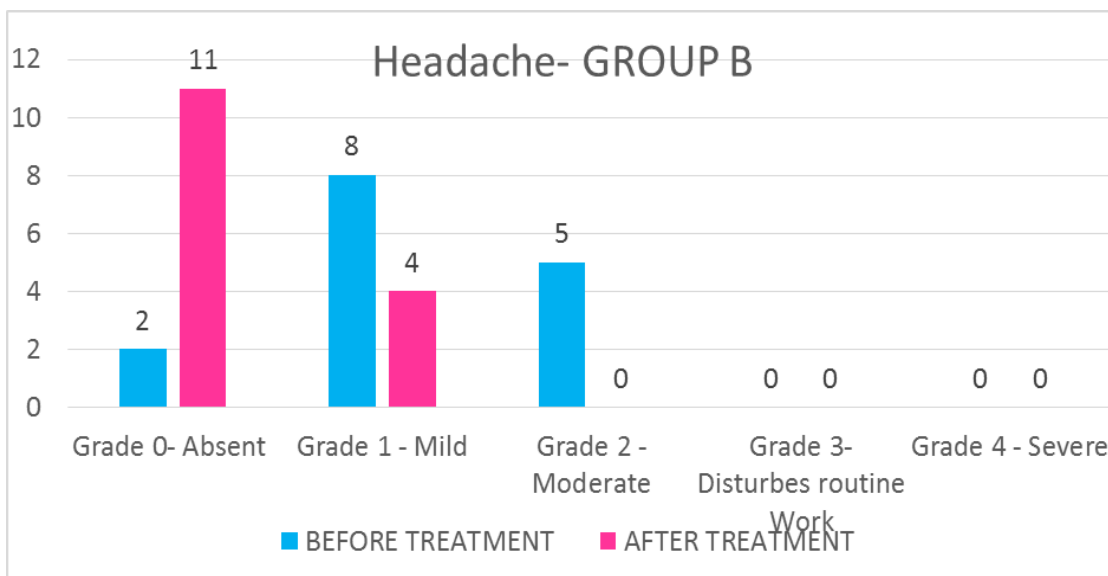
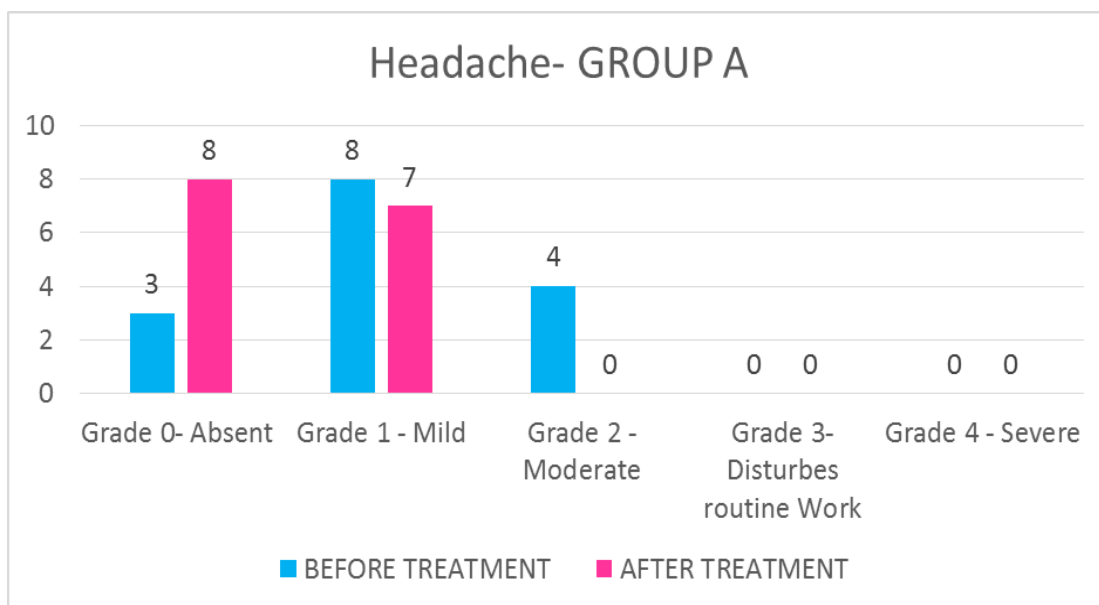
→ CSOM is generally a painless disorder. Out of 30 patients, 5 patients had no pain at all in ear. Out of 25 patients, 17 patient had very mild earache, occurring rarely. Rest 8 patient had moderate pain in ear.

Application of luke warm oil karnapichu for 1 hour gave good symptomatic relief in earache in both the groups.

4) Headache

In group A, before treatment, 3 patients had grade 0 headache, 8 patients had grade 1 headache and 4 patients had grade 2 headache. After treatment, 8 patients had grade 0 headache, 7 patients had grade 1 headache.

In group B, before treatment, 2 patients had grade 0 headache, 8 patients had grade 1 headache and 5 patients had grade 2 headache. After treatment, 11 patients had grade 0 headache, 4 patients had grade 1 headache.



Comparison between group A and Group B

- Mean B.T in Group A was 1.067 that reduced to 0.4667 where as in Group B mean B.T was 1.2 which was reduced to 0.2667.

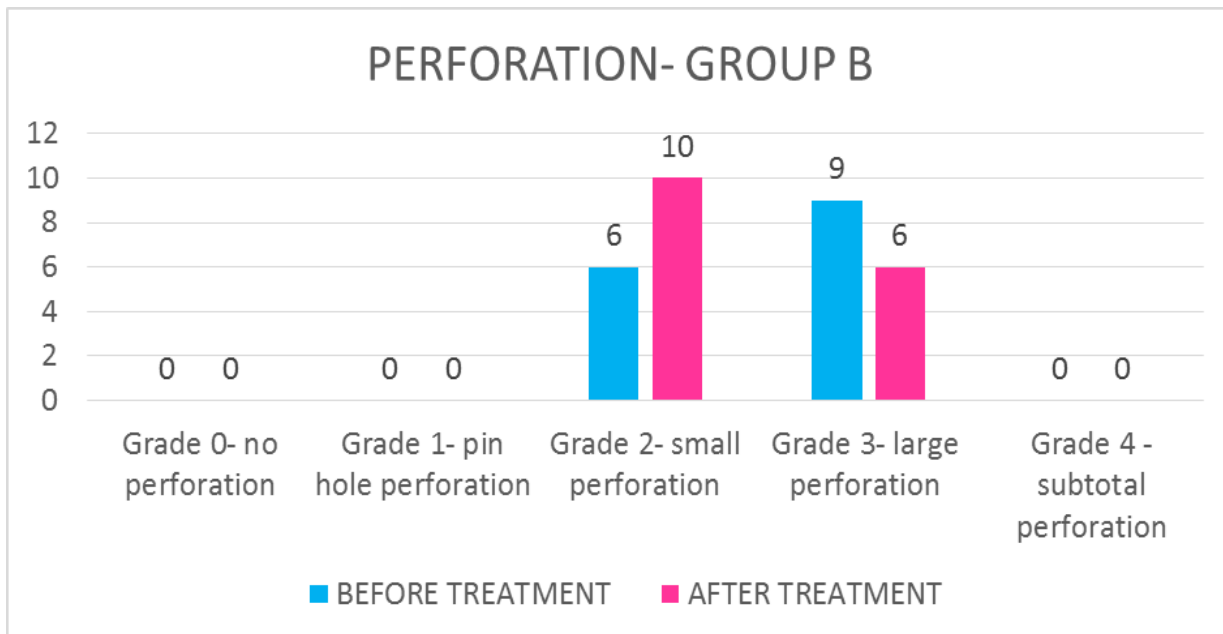
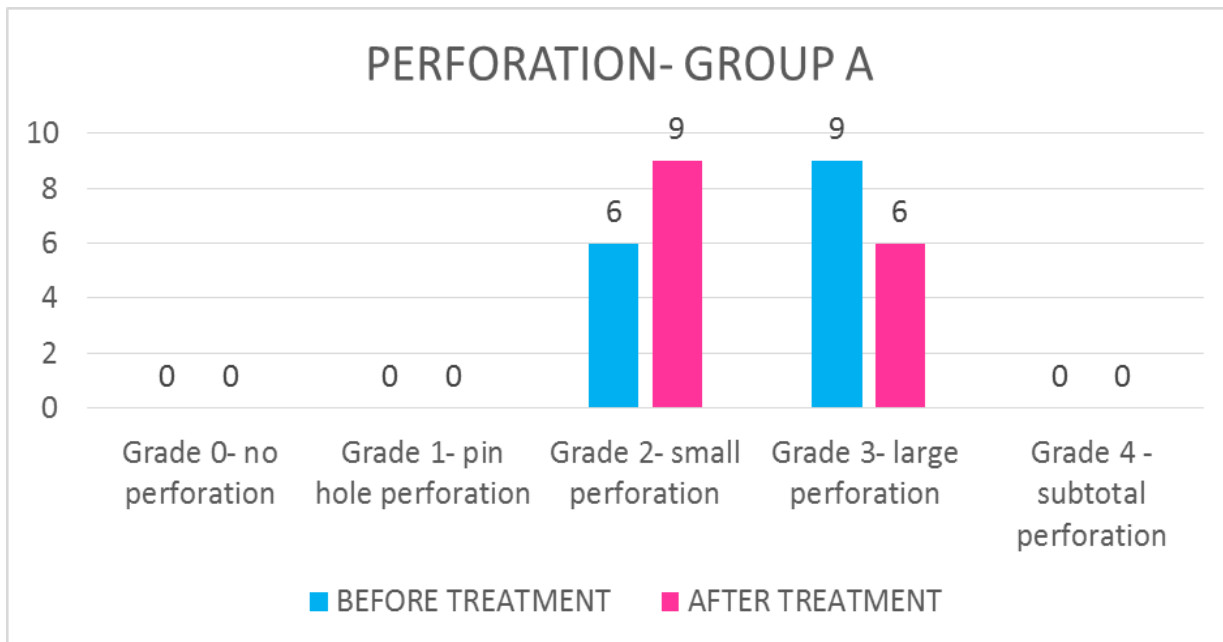
- Group A has shown 56.26 % relief and Group B has shown 66.67 % relief.

→ In most of the cases, headache was referred from other causes. Application of lukewarm oil karnapichu gave symptomatic relief in most of the cases.

5) Tympanic membrane perforation

In group A, before treatment, 6 patients had grade 2 perforation and 9 patient had grade 3 perforation. After treatment, 8 patients had grade 2 perforation and 7 patients had grade 3 perforation.

In group B, before treatment, 6 patients had grade 2 perforation and 9 patient had grade 3 perforation. After treatment, 9 patients had grade 2 perforation and 6 patients had grade 3 perforation.



Comparison between group A and Group B

- Mean B.T in Group A was 2.6 that reduced to 2.467 where as in Group B mean B.T was 2.4 which was reduced to 2.2.
- Group A has shown 5.11 % relief and Group B has shown 8.22 % relief.

→ Not much relief is found in both group in perforation. Further studies can be done adding other medications described for treatment of *karnasrava*,

adding with oral medication to achieve overall result in all the symptoms.

Overall result

80 % cases of Group A have shown moderate response, 13.33 % shown mild response, and 6.67 % shown mild response.

In Group B, 33.33 % have shown good response, 60 % shown moderate response and 6.67 % shown mild response.

CONCLUSION

1. According to statistical study, alternative hypothesis is accepted. With percentage difference of 6.75%, it can be concluded that The effect of *Nisha Taila* is better than *Vacha Lasunadi Taila* in the management of *Karnasrava*.
2. Due to Anti-bacterial & Anti-Fungal Property of *Haridra & Gandhak* (Used in *Nisha taila*) patients treated with *Nisha taila pichu* showed better result than *Vacha Lashunadi taila Pichu*.
3. Both the groups A & B, showed good response for ear discharge, but no result was observed in perforation and impaired hearing in both the groups.
4. Ingredient of both the drug had *Katu- Tikta Pradhan Rasa, Katu Vipak & Ushna Virya*.
5. *Dhatura* is having *Vedanasthapana, Kaphahar & Krimihar* property, *Sarshapa* also possess anti-fungal property by this virtue fungal infection of ear which is seen due to inadequate care by patient after *Karnapurana* or as a complication of CSOM is prevented.
6. During the treatment period *Pathyapathya* should be followed specially head bath should be prohibited.
7. Sufficient amount (approximately 3 ml) of *Taila* should be used to get expected result.

REFERENCES

1. Sushruta Samhita uttatantra 20/3: With commentary by Kaviraj Ambikadutta Shastri; XIth edi, Chaukhambha Sanskrit Sansthan, Varanasi, 1997.
2. Tripathi Brahmanand. Charak Samhita, Chikitsa sthan 26/126. "Charaka Chandrika" hindi commentary. Chaukhamba Surbharati Prakashan, Varanasi, 2008; 891.
3. Tripathi Brahmanand. Astang Hridayam, Uttar sthan 17. "Nirmala" hindi commentary. Chaukhamba Sanskrit Pratishthan, Delhi, 2015.
4. Mackenzie I, Smith A. Deafness – the neglected and hidden disability. Ann Trio Med Parasitol, 2009 Oct; 103(7): 565-571.
5. Tanmoy Deb, Debabrata Ray. A study of the bacteriological Profile of Chronic Supporatiive Otitis Media in Agartala. Indian J Otolaryngol head Neck Surg, Oct- Dec 2012; 64(4): 326-329. DOI 10.1007/s12070-011-0323-6.
6. Monasta, L; Ronfani, I; Marchetti, F; Montico, M; Vrecchi-Brunetti, L; Bavcar, A; Grasso, D; Barbiero, C; Tamburlini, G (April 30). "Burden of disease caused by otitis media: systematic review and global estimates". *PLoS ONE*, 2012 7(4): e36226. doi:10.1371/journal.pone.0036226. PMC 3340347. PMID 22558393.
7. PL dhingra. Disease of ear, nose and throat. 4th edition. Published by Elsevier, a division of Reed Elsevier India Private limited, 68.
8. Kaviraj ambikadatt shashtri, Susrut samhita of maharshi susruta, uttar tantra, chaukhambha Sanskrit samsthan, edition, 2015; 131.
9. Dr. Ramnivas Sharma, Dr. Surendra Sharma. Saharsa Yogam, Chaukhambha Sanskrit Pratisthan, edition: Taila Prakarana, 2012; 98.
10. Krishna Gopal Ayurveda bhavan. Rasatantrasar/ Siddhaprayogasamgrah. Dwitiya Khand. Karnaroga, 503.
11. Dr. Ramnivas Sharma, Dr. Surendra Sharma. Saharsa Yogam, Chaukhambha Sanskrit Pratisthan, edition, Taila Prakarana, 2012; 98.
12. Krishna Gopal Ayurveda bhavan. Rasatantrasar/ Siddhaprayogasamgrah. Dwitiya Khand. Karnaroga, 503.