ROLE OF BALA TAILA NASYA AND RASNADI GUGGULU IN KARNASRAVA (CHRONIC SUPPURATIVE OTITIS MEDIA)

Deepti Negi1*, Radhakrishna Bishwal2, Aditi3
*PG Scholar, 2Professor, 3Assistant Professor, Dept. of Shalakya Tantra, Uttarakhand Ayurveda University, Gurukul Campus, Haridwar, Uttarakhand, India.

ABSTRACT
In Ayurveda, Karnasrava is mentioned as Vata Pradhan Tridoshaja and Sadhya Vyadhi in Shalakya Tantra. The term Karnasrava is self explanatory itself, which means Srava (discharge) from Karna (ear). For this study 30 patients were registered from OPD/IPD of Gurukul Campus, Haridwar; who were clinically diagnosed patients of Karnasrava/CSOM. There was only one group, so combined effect of Bala Taila Nasya and Rasnadi Guggulu was seen in patients. Results of the study indicates that highly significant result was seen in earache, Karnasrava (quantity of discharge), tenderness over mastoid antrum and consistency of discharge. Not significant result was seen in degree of hearing loss while in T.M. perforation size result was only significant.

INTRODUCTION
Karnasrava is a disease mentioned by Acharya Sushruta in the chapter named Karnaroga Vighanyiya under twenty eight Karnaroga[1]. In Ayurveda Karnasrava is described as separate disease as well as symptom of so many Karnaroga like Putikarna and Karnapaka[2], Acharya Charaka mentioned Karnasrava as symptom of four types of Karnarog[3], According to Ashtanga Hridaya and Ashtanga Sangraha Karnasrava is one of the important symptom among all the five Karnashoola Roga[4,5], Karnasrava is the condition described as discharge from Karna and which occurs due to vitiation of all the three Dosha, symptoms of Karnasrava resembles with the Chronic Suppurative Otis Media (CSOM). Chronic Suppurative Otitis Media is a long-standing infection of the middle ear cleft, characterized by a permanent perforation of tympanic membrane and ear discharge. CSOM is of two types: Tubotympanic type (safe or benign) of CSOM and Atticoantral type (dangerous or unsafe) of CSOM[6].

In year 1997, a worldwide survey on prevalence of CSOM was done by WHO. It states that 7.8% of school children of India were affected of CSOM which came under highest (>4%) group who needed urgent attention to deal with a massive public health problem[7].

This disease is commonly observed in developing countries, may be because of low socio-economic standards or lack of health awareness. In modern science main treatment of Chronic Suppurative Otitis Media include topical antibiotics with or without steroids, systemic antibiotics, topical antiseptics and wet or dry aural toileting. According to Acharya Sushruta general treatment of Karnasrava includes Shirovirechana, Dhupana, Karnapurana, Pramarijana, Dhavana, Prakashalana etc[8].

Acharya Sushruta has mentioned Bala Taila in Chikitsa Sthan under Mudhgarbha Chikitsa Adhyaya[9], later on he had mentioned the same Taila in Uttar Tantra under Karnaroga Pratishehda Adhyaya[10], Rasnadi Guggulu is the drug mentioned in Karna Roga Adhikara in Yogratnakara. It is said to be used in Vata Roga, Karna Roga, Shiroroga, Nadivrina and Bhagandar[11].

For this trial 30 patients were registered and treated with Bala Taila Nasya and Rasnadi Guggulu. The duration of treatment was 17 days. Bala Taila Nasya was given in two settings of seven days each with an interval of three days. Madhyama Matra of Shirovirechan Nasya i.e., 6 Bindu (approx 3ml) was indicated for the management of Karnasrava.
Rasnadi Guggulu was given for oral administration for 17 days. Its dose was decided i.e., for patients aged 10-16 yrs - 250mg BD, and for patients aged >16 yrs - 500mg BD.

**MATERIAL AND METHODS**

**AIMS AND OBJECTIVES**

1. Review of conceptual study of Karna Sharira.
2. To study the disease Karnasrava in Ayurvedic and modern classics.
3. To assess the role of Bala Taila Nasya and Rasnadi Guggulu in Karnasrava.

**Criteria for Selection of Patients**

**Inclusion Criteria**

1. Patient between the age group of 10 to 60 years were included for the study.
2. Patient had the symptoms of Vedna (earache), Karnasrava (ear discharge), perforation of TM, hearing impairment and tenderness over mastoid antrum.
3. Clinically confirming the symptoms of Karnasrava (Chronic Suppurative Otitis Media) by Otoscopic examination.
4. Tubotympanic type of Chronic Suppurative Otitis Media.

**Exclusion Criteria**

1. Patient with complications of chronic suppurative otitis media.
2. Patient suffering from Diabetes Mellitus, HTN and Tuberculosis.
3. Pregnant and lactating females.
4. Patient below the age of 10 and above 60 years.
5. Atticoantral type of Chronic Suppurative Otitis Media.
6. Sensorineural hearing loss.

**Nature of Clinical Study**

This clinical study was carried out in three phases:

a) Diagnostic phase
b) Interventional phase
c) Assessment phase

**Criteria for Diagnosis**

Following subjective and objective parameters were considered for diagnosis of Karnasrava (Chronic Suppurative Otitis Media)

**Subjective Parameters**

**Earache**

| Absent | 0 |
|--------|---|
| Mild pain (do not affect sleep and routine work) | 1 |
| Moderate pain (affecting sleep but not routine work) | 2 |
| Severe pain (affecting sleep and routine work) | 3 |

**Karnasrava (Quantity of Discharge)**

| Absent | 0 |
| Secretion near Tympanic membrane | 1 |
| Secretion irrigating in the ear canal | 2 |
| Secretions coming out of ear canal | 3 |

**Degree of Hearing Loss**

| Able to hear whispers | 0 |
| Able to hear and repeat word spoken in normal voice (1m) | 1 |
| Able to hear repeat words spoken in raised voice (1m) | 2 |
| Able to hear words when shouted into better ear | 3 |

**Consistency of Discharge**

| Serous | 0 |
| Mucoid | 1 |
| Mucopurulent | 2 |
| Purulent | 3 |

**Tenderness over Mastoid Antrum**

| Tolerance to pressure | 0 |
| Little response on sudden pressure | 1 |
| Wincing on face on super slight touch | 2 |
| Resists to touch | 3 |

**Objective Parameter**

**T.M. Perforation Size**

| Pin point perforation (<25% and involving one quadrant) | 0 |
| Perforation size (25- 50% and involving two quadrants) | 1 |
| Large perforation (50-75% and involving three quadrants) | 2 |
| Complete or Total perforation (>75% & involving four quadrants) | 3 |

**Functional Examination of Ear**

1. **External examination:** A complete examination of ear was done with the help of torch light to rule out any abnormality.
2. **Palpation:** Tenderness over mastoid antrum was elicited by pressing with tip of forefinger or thumb on area of mastoid.
3. **Otoscopic examination:** This examination was done to rule out T.M. perforation size.
4. **Tunning Fork test:** This examination was done to differentiate between conductive deafness and sensorineural hearing loss. After this examination, patients with sensorineural hearing loss were excluded from this study.
In present study, WHO’s criteria for assessment of hearing loss was taken which was favourable for younger as well as elder patients, where only repetition of words were required.

**Investigations**
- Hb%
- TLC
- DLC
- ESR
- RBS

**Interventional Phase**

**Drugs and Posology**

**Bala Taila Nasya**

Before *Bala Taila Nasya*, regular cleaning of patient’s affected ear was done with sterile cotton tipped jobson horne probe.

**Dose of Nasya-** Madhyama Matra of Shirovirechan Nasya- 6 Bindu (3ml approx)

**Duration-** For seven days in two sittings with an interval of three days (total seventeen days).

**Form - Oil**

Route and form of administration - Nose.

**Rasnadi Guggulu**

**Dose -** 250mg BD for patient less than age of 16yr. 500mg Bd for patients age above 16 years.

**Duration-** For seventeen days.

**Form-** Tablet

Route and form of administration - Oral

**Assessment phase**

**Criteria for the Assessment**

The overall effect of *Rasnadi Guggulu* and *Bala Taila Nasya* was assessed as-

| Category                | Percentage |
|-------------------------|------------|
| Cured                   | 80 - 100%  |
| Marked improvement      | 60 - 79%   |
| Moderate improvement    | 40 - 59%   |
| Mild improvement        | 20 - 39%   |
| No improvement          | less than or equal to 19% |

**Statistical Analysis**

All information on subjective and objective parameters was gathered and statistical study was carried out in terms of Mean, Standard deviation (S.D.), Standard error (S.E.) Wilcoxon’s signed rank- Test and paired t test before and after treatment in all the patients. Results were incorporated in terms of probability (p) as:
- p>0.05 - Insignificant
- p=0.01-0.05 – Significant
- p=0.001-0.01- very significant
- p<0.001- Highly significant

**OBSERVATIONS AND RESULTS**

In this clinical trial of *Karnasrava* (CSOM) total 30 patients were registered and kept in a single group. As per observation out of 30 patients maximum 36.67% patients were from age group 21-30 years. Most of the patients registered in this study who affected more were females (67%). Maximum registered patients were from lower middle class family i.e., 40%, rural patients (87%) were more affected in comparison to urban patients. Majority of patients 43% had chronicity of more than 1 year, 1 patient (3%) had chronicity of 10–12 months, 2 patients (7%) had chronicity of 7-9 months, 5 patients (17%) had chronicity of 4-6 months and 9 patients (30%) had chronicity of 1-3 months. Out of 30 patients 16 patients (60%) had deviated nasal septum. Among 30 patients 6 patients (20%) were of VP Prakriti, 8 patients (27%) were of PK Prakriti and maximum 16 patients (53%) were of VK Prakriti.

Among 30 patients earache, discharge, consistency of discharge and TM perforation were seen in all 30 patients (100%), degree of hearing loss was seen in 24 patients (80%) and Tenderness over mastoid antrum was found in only 13 patients (43.33%).

**RESULTS**

In total registered patients by applying Wilcoxon Signed Rank test on subjective parameters it was found that symptom of earache improved by 90.90% and was statistically highly significant (p value <0.0001). Symptom of discharge improved by 75% which was statistically highly significant (p value <0.0001). Degree of hearing loss improved by only 9.75% which was statistically not significant (p value 0.0625). Symptom of consistency of discharge improved by 85.96% which was statistically highly significant (p value <0.0001). Symptom of tenderness over mastoid antrum improved by 66.66% which was statistically highly significant (p value <0.0002).

By applying Paired t test on objective parameter it was found that sign of TM perforation size improved by only 7.27% which was statistically significant (p value 0.0217).
Result of Effect of Therapy of 30 Patients on Subjective Parameters (Wilcoxon Signed Rank test)

| S.no. | Parameters      | Means | S. D. | S.E. | % Effect | P value     | Result         |
|-------|-----------------|-------|-------|------|----------|-------------|----------------|
|       | N   | BT  | AT  | D   |          |             |                |
| 1     | Earache         | 30    | 2.2  | 0.2 | 2        | 0.6948      | 90.90%         |
|       |                 |       |      |     |          | 0.1269      | < 0.0001       |
|       |                 |       |      |     |          |             | Highly significant |
| 2     | Discharge       | 30    | 2    | 0.5 | 1.5      | 0.5724      | 75%            |
|       |                 |       |      |     |          | 0.1045      | < 0.0001       |
|       |                 |       |      |     |          |             | Highly significant |
| 3     | Degree of Hearing Loss | 24  | 1.70 | 1.54 | 0.16 | 0.3457 | 9.75% | 0.0625 | Not significant |
| 4     | Consistency of Discharge | 30  | 1.90 | 0.27 | 1.63 | 0.4901 | 85.96% | < 0.0001 | Highly significant |
| 5     | Tenderness Over Mastoid Antrum | 13  | 1.84 | 0.61 | 1.23 | 0.7303 | 66.66% | 0.0002 | Highly significant |

% Relief in Patients

In total registered patients symptom of earache improved by 90.90%, symptom of discharge improved by 75%, degree of hearing loss improved by only 9.75%, symptom of consistency of discharge improved by 85.96%, symptom of tenderness over mastoid antrum improved by 66.66% and sign of TM perforation size improved by only 7.27%.

% RELIEF

![Bar chart showing % relief for different parameters]
Overall Assessment of Result

- 04 patients (13.33%) were cured.
- Marked improvement was seen in 14 patients (46.67%)
- Moderate improvement was seen in 10 patients (33.33%)
- Mild improvement was seen in 02 patients (6.67%)
- No improvement was seen in 00 patients (0.00%)

DISCUSSION

Patients belonged to rural area i.e., 26 patients (87%) were more affected. This was due to most area near the hospital came under rural area, and people here were not aware of their health and hygiene, so they neglect early diseased condition of their ear which lead it to chronic condition. Also this area is near to river Ganga and Avashyaya and Jala Nimaajana is said to be key factor in etiology of Karnasrava by our Acharya. This may be because of lack of awareness and hygiene towards health and patients from upper class probably take treatment from private practitioner so there was no one from upper class patient in registered patients.

Patients having Vata-Kapha dominant Prakriti were more affected 53%, followed by 27% Pitta-Kapha Prakriti and 20% Vata-Pitta Prakriti. As the disease mainly is a Vata Pradhan Tridoshaj Vyadi. Observation signifies that Vata-Kapha Prakriti patients are more susceptible for this disease. Majority of patients i.e., 13 patients (43%) had chronicity of more than 1 year, this is because of lack of awareness and negligence towards their health and hygiene, disease reached to chronicity of more than 1 year. In maximum patients i.e., 60% DNS was present. So DNS could be the region of CSOM in patients. As per classics DNS is one of the main cause of Eustachian tube obstruction and prolonged tubal blockage can result into CSOM.[12]

Probable Mode of Action of Bala Taila Nasya

- Bala Taila is mentioned for Nasya which is measure for treating Karnasrava. Before performing Nasya Karma patient's affected ear was mopped with sterile cotton tipped jobson horn probe on regular basis, which was helpful in relieving discharge and maintaining hygiene.
- Drugs of Dashmoola and Kulatha were used for Drava Dravya and Til Taila as base. All drugs are Ushna Veerya thus, eliminate Vata and Kapha dosha.
- Kalka Dravya such as Saindhava, Agaru, Ella, Jatamansi, Vacha acts as Vatanulomaka thus prevented discharge and enhanced clearance of middle ear secretions vis Eustachian tube.
- Balamoola, Yava, Kola and Godugdha used as Drava Dravya are Sheeta Veerya thus, eliminated Pitta Dosha.
- Til Taila, Saindhava, Sarjarasa, Devdaru, Kushtha, Tagara, Madhuka, Guduchi having Vrana Shodhana, Vrana Ropana properties which promoted healing of tympanic membrane perforation.
- Laghu- Ruksha Guna of Bilva, Agnimantha, Patala, Shyonaka, Brihati, Kanthkari, Mudgparni, Kulatha, Vanshlochan, Sarjarasa, Agaru, Manjishtha, Chandana, Kushtha, Shatpushpa and Punarnava vitiates Kapha Dosha was eliminated and Ruksha Guna is helpful in preventing discharge.
- Kalka Dravya which contains Madhur Gana (Kakolayadi Gana) Aushadh Dravya are mainly Balya and Dhatushodhak. So, strengthen the affected Dushya involved in the disease.
- Madhuka, Jeevanti, Ashwagandha, Shatavari, Sariva, Kushtha, Agaru and Godugdha having Rasayana Guna that's how formulation will help in chronic
conditions, and also Rasayana is mentioned in Samanya Chikitsa for Karna Srava.

- Drug administered as Nasya also showed systemic effects and was useful in relieving Karna Srava.

**Probable Mode of Action of Rasnadi Guggulu**

- Some contents of Rasnadi Guggulu such as Rasna, Guduchi, Devdaru, Guggulu, Eranda and Shunthi are Ushna Veerya. Thus, relieving vittiated Vata and Kapha Dosha.

- Eranda and Gaughrita are Madhura in Rasa and Rasna, Devdaru, Guduchi and Guggulu are Tikta in Rasa, which are helpful in relieving Pittashamana Karma.

- Gaughrita have Rasayana Guna, thus, helpful to manage chronic disease.

- Rasnadi Guggulu have anti-inflammatory, analgesic, antipyretic, antiulcer, antisecretory, antibacterial and wound healing properties. Thus, relieve Karnasrava (CSOM).

**CONCLUSION**

- Karnasrava can be correlated with CSOM on the basis of etiology, symptoms, prognosis and treatment modalities.

- In Ayurvedic classics, very detailed and practical description of Srava has been described as in modern classics.

- Vata Kapha Prakrti people were more prone for this disease.

- Study shows that people belonging to unhygienic and poor socio-economic status were more prone for the disease.

- Prevalence of Karnasrava (CSOM) was found to be more in 21-30 years age group.

- Study shows that lower middle class people were mostly affected with this disease.

- It is seen that there was very good result of combined therapy in Karnasrava.

- In present study (13.33%) patients were cured. marked improvement was seen in 46.67% patients, moderate improvement was seen in 33.33% patients, mild improvement was seen in 6.67% patients.

- There were no adverse reactions seen in registered patients during trial.

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