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Research Article

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

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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 Vigyaniya* 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 *Karnaroga*[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 Otitis 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*, *Pramarjana*, *Dhavana*, *Prakshalana* 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 Pratishedha 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, Nadivrana* 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 sittings 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.*

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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-

Cured	80 - 100% relief in symptoms
Marked improvement	60 - 79% relief in symptoms
Moderate improvement	40 - 59% relief in symptoms
Mild improvement	20 - 39% relief in symptoms
No improvement	less than or equal to 19% relief in symptoms

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)

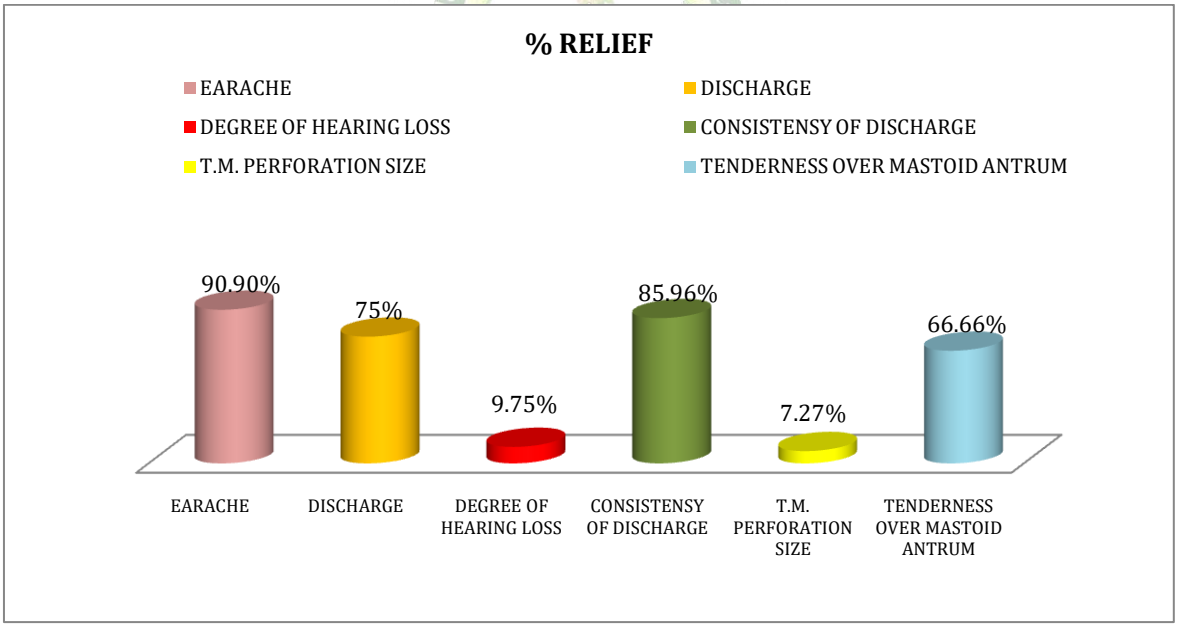
S.no.	Parameters		Means			S. D.	S.E.	% Effect	P value	Result
		N	BT	AT	D					
1	Earache	30	2.2	0.2	2	0.6948	0.1269	90.90%	< 0.0001	Highly significant
2	Discharge	30	2	0.5	1.5	0.5724	0.1045	75%	< 0.0001	Highly significant
3	Degree of Hearing Loss	24	1.70	1.54	0.16	0.3457	0.06312	9.75%	0.0625	Not significant
4	Consistency of Discharge	30	1.90	0.27	1.63	0.4901	0.08949	85.96%	< 0.0001	Highly significant
5	Tenderness Over Mastoid Antrum	13	1.84	0.61	1.23	0.7303	0.1333	66.66%	0.0002	Highly significant

Result of Effect of Therapy of 30 Patients on Objective Parameters (Paired t test)

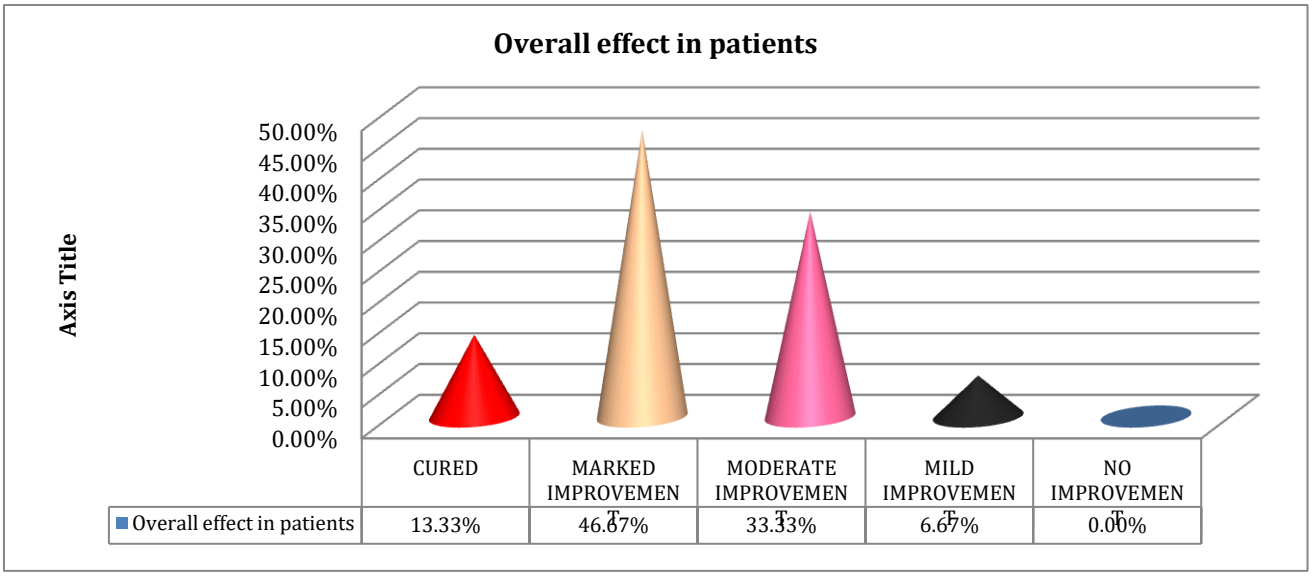
S.no.	Parameters		means			S. D.	S.E.	% Effect	P value	Result
		N	BT	AT	D					
1	**T M Perforation**	**30**	1.83	1.7	0.13	0.3457	0.06312	7.27%	0.0217	Significant

% 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%.



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 00.00% patient.

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 Nimajjana* 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 Vyadhi*. 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 Dravya* 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, Sarjrasa, Agaru, Manjishtha, Chandana, Kushtha, Shatpushpa* and *Punarnava* vitiated *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 *Dhatuvardhak.* 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 vitiated *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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