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# **Research Article**

#### A CLINICO- COMPARATIVE STUDY TO EVALUATE THE EFFECT OF GUGGULUADI DRAVYAS KARNDHOOPAN WITH AND WITHOUT RASNADI GUGGULU IN KARNSRAVA

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#### ABSTRACT

Karnsrava is a type of Karnaroga, explained by Acharya Sushruta in the 20th chapter named as Karnaroga Viavaniva of Uttara tantra. Karnsrava comprises of broad spectrum of diseases under it. And it is hard to find correct correlation of otomycosis with any of the Karnarogas. In the present study otomycosis is one of the reasons of otorrhoea/ Karnsrava which is taken for the study. Otomycosis is a fungal infection of the ear canal that often occurs due to Aspergillus niger, A.fumigatus or Candida albicans. Management of otomycosis can be challenging because of its high recurrence rate and of the limited therapeutic options. Keeping in view all these facts, a randomized clinical trial was done in PG department of Shalakya Tantra, Patanjali Ayurvedic college & hospital, Haridwar. 60 patients were selected and divided into two groups namely group A and group B each consisting of 30 patients. Group A patients were treated with Gugguluadi Dravyas Karndhoopan twice daily for 7 days and Rasnadi guggulu vati twice daily after meal with lukewarm water for 30 days. And Group B patients were treated with Gugguluadi Dravyas Karndhoopan twice daily for 7 days and placebo capsules twice daily after meal with water for 30 days. Dhoopan is most effective therapy for Karnsrava- otomycosis and Karndhoopan is a simple, cost effective procedure which can be done even at the OPD level. Dhoopan dravyas has anti- fungal, anti- microbial, analgesic and anti- inflammatory properties.

It was observed in the present study that group A showed better results than group B. *Gugguluadi dravyas karndhoopan* and *Rasnadi Guggulu vati* are safe, cost effective and free from any side effects in the management of *Karnsrava*.

KEYWORDS: Karnsrava, Otomycosis, Gugguluadi Dravyas, Karndhoopan, Rasnadi guggulu.

#### INTRODUCTION

Avurveda is the historical science of life. It has always focused at the advancement and preservation of desirable fitness in an individual. It is the traditional treatment method of India. Karnsrava is a disease mentioned by Acharva Sushruta in the chapter named Karnaroga Vigyaniya under twenty eight Karnarogas<sup>[1]</sup>. Due to Shiroabhigata, Jala Nimmajjana, Karnapaka, Karna vidradi, vitiated Vata dosha and Karna becomes Avrudha by Vata and results in Karnsrava.<sup>[2]</sup> But Karnsrava comprises of broad - spectrum diseases under it. Thus among of numerous causes, due to immersion of water in ear, fungus may additionally develop within the ear causing the disease otomycosis. In the present study otomycosis is one of the reasons of otorrhoea/ Karnsrava which is taken for the study.

Otomycosis is an inflammatory process of external ear canal due to infection with fungi and is

responsible for>9% of the diagnoses of otitis externa. In 80% of cases, the etiologic agent is aspergillus, whereas Candida is the next most frequently isolated fungus. Other more rare fungal pathogens include phycomycetes, rhizopus, actinomyces and penicillium. Otomycosis is most frequently present with pruritus, aural fullness and otorrhea, and may also complain of otalgia and hearing loss.<sup>[3]</sup>

#### **Prevalence of Otomycosis**

Otomycosis or fungal otitis externa is one of the frequently encountered fungal infections of external auditory canal. Its prevalence has been quoted to range from 9% to 27.2% among patients who show signs and symptoms of otitis externa and up to 30% in the patient with discharging ears. It is worldwide in distribution with a higher prevalence in the hot, humid and dusty areas of tropics and subtropics.<sup>[4]</sup> According to American Academy of Otolaryngology, prevalence of otomycosis is 5.2% all over world and 9.00% in India.  $\ensuremath{^{[5]}}$ 

Predisposing factors for otomycosis include swimming, habitual instrumentation, dermatitis, immune compromised sufferes, unhygienic habits, pre-existing ear disease etc.<sup>[6]</sup> In modern science the treatment of otomycosis includes cleansing and debriding the EAC. Commonly used specific antifungal include clotrimazole. nystatin (otic drops or powder) and ketoconazole.<sup>[3]</sup> Clotrimazole is tolerated by most patients but in some cases local irritation and burning sensation may occur. Oral administration of antifungal drugs such as itraconazole, voriconazole, can be given to resistant cases. But none of them are free from adverse effects like nausea, vomiting, headache, loss of appetite, rashes and hair loss etc.<sup>[7]</sup> Studies concluded that, there has been an increase in the prevalence of otomycosis in recent years that can be linked to the extensive use of antibiotic ear drops, vast use of steroids, broad-spectrum antibiotics etc.<sup>[6]</sup> To prevent the deleterious effect of these treatments, there is need of time to allocate the best, and safe treatment for otomycosis. Besides allopathic treatment natural source compounds may be used to formulate new or more potent and safe anti-fungal agents. According to Acharva Sushruta, Karnsrava is treated bv Shirovirechana (Nasya), Dhoopan, Poorana, Pramarjana, Dhaavana and oral drug therapy etc.<sup>[8]</sup> Considering these points, there is requirement for search of secure, effective, easily available treatment to treat this ear disease.

Here in the present study for the treatment two groups are taken. In Group A *Karndhoopan* was done with *Gugguluadi Dravyas* which is mentioned in *Sushrut Sutrasthana*<sup>[9]</sup> and *Rasnadi guggulu* for oral intake. *Rasnadi guggulu* has been mentioned by *Yogaratnakara* in *Karnaroga Chikitsa Adhyaya*.<sup>[10]</sup> In Group B *Karndhoopan* along with placebo (gelatin) capsules were given.

*Karndhoopan* with *Gugguluadi dravyas* has a property of *Shothaghana, Vednasthapan, Vrana Shodhan, Vrana ropana, Kandughan* and *Jantughan.* Due to these properties fungal growth in otomycosis and inflammation of external auditory canal is prevented by *Dhoopan.* 

The ingredients of *Rasnadi guggulu* are mostly *Ushna virya, katu,* and *Tikta* and *Kashaya rasa*. Due to these properties it alleviates *Vata* and *Kapha dosha*. It is very effective anti- inflammatory and pain relieving formulation. So, this clinical trial has been selected.

#### AIM AND OBJECTIVES OF THE STUDY

- 1. To study *Karnsrava* (otomycosis) in both Ayurveda and its modern aspect to establish the correlation between these diseases.
- 2. To evaluate the combined efficacy of *Gugguluadi Dravyas Karndhoopan* and *Rasnadi guggulu* in the management of *Karnsrava* otomycosis.
- 3. To evaluate the efficacy of only *Gugguluadi Dravyas Karndhoopan* in the management of *Karnsrava.*
- 4. To evaluate the comparative efficacy of both groups in the management of *Karnsrava*.

#### MATERIAL AND METHODS

#### **Selection of Cases**

Patients with classical features of Karnsravaotomycosis were selected randomly from the O.P.D & I.P.D. of Shalakya Tantra Department, Patanjali Bhartiya Ayurvigyan Evam Anusandhan Sansthan, Haridwar.

#### **Inclusion Criteria**

- 1. Patient with the age group of 10-70 years.
- 2. Patient having specific signs & symptoms of *Karnsrava*-otomycosis on Ayurvedic and Modern parameters has been selected.

#### **Exclusion** Criteria

- 1. Age below 10 yrs and above 70 yrs.
- 2. Pregnant women.
- 3. Patients suffering with systemic disease like uncontrolled DM, meningitis, Tuberculosis etc.
- 4. Patients suffering with tympanic membrane perforation and invasive temporal bone infections.

#### **Diagnostic Criteria**

- 1. Patients were thoroughly examined both subjectively and objectively.
- 2. Otoscopic examination.
- 3. KOH Test.
- 4. Routine investigations were done to exclude the other pathologies.
- 5. Haematological: Hb%, TLC, DLC, ESR.
- 6. Routine urine examination.
- 7. Random Blood Sugar.

#### **Collection of Drugs**

The drugs formulations taken for study are-

*Gugguluadi dhoopan dravyas*– The ingredients of *Dhoopan varti dravyas*-

| S.No. | Drug Name        | Latin Name Part Used  |            | Qty (In Part) |
|-------|------------------|-----------------------|------------|---------------|
| 1.    | Guggulu          | Commiphora mukul      | Niryas     | 1             |
| 2.    | Agaru            | Aquilaria agallocha   | Kandsaar   | 1             |
| 3.    | Sarjarasa        | Shorea robusta Gaertn | Niryas     | 1             |
| 4.    | Vacha            | Acorus calamus        | Mula       | 1             |
| 5.    | Gaur sarshapa    | Sinapis alba          | Bijj       | 1             |
| 6.    | Saindhava Lavana | Sodii chloridum       | -          | 1             |
| 7.    | Nimba patra      | Azadirachta indica    | Patra,Twak | 1             |
| 8.    | Ghrita           | -                     | -          | 1             |

#### Table 2: The Ingredients of Rasnadi guggulu vati

|      |            | 0                    | 0 00      |              |
|------|------------|----------------------|-----------|--------------|
| S.No | Hindi Name | Latin Name           | Part Used | Qty(In Part) |
| 1.   | Rasna      | Pluchea lanceolata   | Leaves    | 1 part       |
| 2.   | Amrita     | Tinospora cordifolia | Stem      | 1 part       |
| 3.   | Eranda     | Ricinus communis     | Root      | 1 part       |
| 4.   | Devadaru   | Cedrus deodara       | Resin     | 1 part       |
| 5.   | Shunthi    | Zingiber officinale  | Rhizome   | 1 part       |
| 6.   | Guggulu    | Commiphora mukul     | Resin     | 5 part       |

All the raw material of Gugguluadi dhoopan Proc

*dravyas* were procured from Hans herbals private limited, Haridwar and were identified with the help of Dravyaguna Department of Patanjali, Bhartiya Ayurvigyan Evam Anusandhan Sansthan, Haridwar, Uttarakhand. *Rasnadi gugguluvati* was procured from Baidyanath Pharmacy.

#### Method of Preparation of Karndhoopan Varti

*Dhoopanvarti* was prepared in the Ras-Shastra Department of Patanjali Bhartiya Ayurvigyan Evam Anusandhan Sansthan, Haridwar, Uttarakhand. In *Karnaroga*, particular method of preparation of *Karndhoopan varti* is not mentioned, hence *Karndhoopan varti* was prepared according to classic method which is mentioned in *Charaka Samhita*.<sup>[11]</sup> (ch.su.5/24).

## Material Required For Varti

- Drugs- *Guggulu, Agaru, Sarjras, Vacha, Gaursarshapa, Saindhavalavana, Nimba, Go-Ghrita* (each in equal amount)
- Grinder
- Utensil Stainless steel
- Cotton cloth
- Sieve
- Reed stick/ Sharakhanda (approx 24cm long)

# Procedure

- 1. All the drugs were taken in equal proportion and grinded into fine powder. This powdered drug was then sieved to remove the unwanted size particles and a paste was made of the powdered drug.
- 2. A clean cotton cloth was placed on a flat surface and a thick paste of powdered drug was applied evenly on it which was allowed to dry for 3-4 hrs.
- 3. Reed sticks where placed on the cloth and it was rolled into layers just like the shape of *Yavadhanya*.
- 4. The thickness in middle portion of *Varti* was like the thickness of thumb with tapered ends. Then it was allowed to dry in shade.
- 5. After it was completely dried the reed sticks were removed from the *Varti* and were ready to be used.
- 6. *Vartis* were stored in sterile and moisture free container.

#### **Research Design**

- 1. It is a randomized comparative, open labelled, clinical study. Patients were assigned in two groups consisting of 30 patients each excluding the dropouts.
- 2. Total duration of study- 18 months.
- 3. Randomization was done using software (graph pad).

| Groups | Chikitsa  | Prayoga  | Prayogaavadhi  | Nireekshana |
|--------|---|--|--|-------------|
| A      | <ul> <li>Gugguluadi dravyas<br/>Karndhoopan.</li> <li>Rasnadi Guggulu vati<br/>orally.</li> </ul> | <ul> <li>Twice in a day<br/>about 3-5 min.</li> <li>500mg twice daily<br/>after meal.</li> </ul> | a) For 7 days.<br>b) For 30 days.<br>(after 7 days of <i>Dhoopan</i><br>procedure) | 2months     |
| В      | <ul> <li>Gugguluadi dravyas<br/>Karndhoopan.</li> <li>Placebo capsules orally.</li> </ul>         | <ul> <li>Twice in a day<br/>about 3-5 min</li> <li>Cap.1-1 bd</li> </ul>                         | a) For 7 days.<br>b) For 30 days. (after 7 days<br>of <i>Dhoopan</i> procedure)    | 2 months    |

#### 10% Potasium Hydroxide (KOH) Test

A KOH preparation test is also called potassium hydroxide preparation test or fungal smear is a simple, non- invasive, quick and accurate procedure.

#### **Material Required For 10% KOH Test**

- 10% KOH solution
- Glass slides
- Gauze
- Cover slips
- Ear wax curette
- Alcohol swab
- Sample collected from ear.

## **Preparation of 10% KOH Solution**

- 1. Approximately 10 grams of potassium hydroxide pellets was taken into a screw-cap bottle.
- 2. Then 50ml of distilled water was added to the pellets and mixed till they got completely dissolved in it.
- 3. Later more distilled water was added till 100ml volume was attained and the bottle was labelled as 10% KOH solution.
- 4. Direct microscopy with 10% potassium hydroxide was done on the sample.

#### Procedure

- 1. The material to be examined was placed on a clean glass slide.
- 2. A drop of 10% KOH was added to the material and mixed.
- 3. A cover slip was placed over the preparation without any air bubbles.
- 4. The KOH preparation was kept at room temperature until the material was cleared.
- 5. The slide was examined for fungal elements under the microscope using 10 X and 40 X (high power lens) objectives.
- 6. The presence of fungal elements (hyphae elements, conidiophores, spores) was looked for.

## Karndhoopan Procedure

#### Purvakarma

1. The ear of patient was examined thoroughly and if necessary cleaning and mopping was done.

2. Both eyes were covered with bandages so that they are not harmed with the fumes.

#### Pradhan Karma

- 1. The patient was asked to sit on 1 feet high chair in comfortable position in a place devoid of dust, direct sunlight and cold.
- 2. The patient was asked to concentrate on the treatment without having any other thoughts in mind.
- 3. The patient was asked to avoid talking, laughing, sneezing and movements of head and neck.
- 4. The *Dhooma* varti was ignited with the help of electric heater and allowed to burn till the it produced sufficient *Dhooma*.
- 5. The ignited *Varti* was kept in cone of hard paper so that the *Dhooma* will come out from the aperture made at the tip of cone. The aperture at the proximal part of cone was approximately 0.5cm thus the intensity of *Dhooma* was maintained.
- 6. The patient was asked to tilt his/her head towards affected ear so that *Dhooma* can be properly directed to the EAC of the affected ear.
- 7. The procedure was done for 3-5 minutes.
- 8. The same procedure was done twice daily morning and evening.

## Paschat Karma

- 1. The ear in which *Dhoopan* was given is covered with cotton to prevent its direct exposure to cold.
- 2. The patient was made to sit for 10 minutes wrapping his head and ear in a place which is not direct contact of cold.
- 3. Patient was asked to avoid head bath till the *Karndhoopan* was advised.

#### Follow-Up

 $1^{\mbox{\scriptsize st}}$  followup- 15 days after the completion of treatment.

 $2^{nd}$  followup- 15 days after the  $1^{st}$  visit.

 $3^{rd}$  followup- 1 month after the  $2^{nd}$  visit.

# Criteria for Assessment

The efficacy of the therapy was assessed on the basis of improvement in subjective and objective criteria. Scoring was done as following.

| Subjective parameters        | Grade   |
|------------------------------|---|
| 1. Itching (Karnakandu)      | 0- Nil  |
|                              | 1- Occasional   |
|                              | 2- Often itching throughout the day                                       |
|                              | 3- Itching throughout the day and night and disturb sleep.                |
| 2. Ear Discharge             | 0- Nil  |
| (Karnsrava)                  | 1- Occasional   |
|                              | 2- Continuous discharge in ear with short history or first time history   |
|                              | 3- Continuous discharge in ear with long history or history of recurrence |
| 3. Pain(Karnashula)          | 0- Nil  |
|                              | 1- Mild 1- 4  |
|                              | 2- Moderate 5-7   |
|                              | 3- Severe 8-10  |
| 4. Ear blockage              | 0- No feeling of blockage   |
|                              | 1- Occasionally feeling of the ear blockage.                              |
|                              | 2- Either day or night time feeling of ear blockage                       |
|                              | 3- whole day and night feeling of ear blockage                            |
| <b>Objectives Parameters</b> | Grade   |
| Otoscopic examination –      | 0- Nil  |
| 1. Presence of fungus in     | 1- 50% of acoustic canal is aff <mark>ect</mark> ed                       |
| EAC                          | 2- 75% of a <mark>cou</mark> stic canal affected                          |
|                              | 3- Total length of acoustic canal and tympanic membrane                   |
| 2. KOH/SWAB TEST             | 0-Negative (Fungus hyphae absent)   |
|                              | 1-Positive (fungus hyphae present)  |

## **Ethical Clearance**

This trial has been cleared by Institutional Ethical committee (IEC) of Patanjali Bhartiya Ayurvigyan Evam Anusandhan Sansthan, Haridwar, Uttarakhand. PAC/IEC/2017-2018/16; dated 20/03/ 2018, before starting the clinical trial on patients of *Karnsrava*- otomycosis.

## **Registration in CTRI**

- The present clinical trial has been registered in Clinical Trial Registry- India (CTRI).
- The registration number is CTRI/2019/03/ 018114 [Registered on: 15/03/2019]- Trial registered prospectively.

# **OBSERVATION**

The present study revealed higher incidence of disease maximum numbers of patients i.e., 38.33% were reported to the age group of 21-30 years. 56.67% of the patients were male, 98.33% of patients were from Hindu community, 26.67% were housewives, maximum numbers of patients were from rural habitat i.e., 71.67%, maximum numbers of patients were educated up to higher secondary i.e.

38.33%, maximum i.e. 76.67% patients were doing moderate type of work, 70.00% were married, 48.33% patients were from lower middle class, maximum patients i.e. 75.00% had sound sleep, Majority of patients i.e. 80.00% were purely vegetarian, majority of the patients i.e. 51.67% were having dietary habit of Samashana, maximum numbers of patients i.e. 48.33% were having *Madhvam koshtha.* Maximum numbers of patients i.e. 85.00% were having *Mandagni*, maximum numbers of the patients i.e. 70.00% were having regular bowel habit, maximum numbers of the patients i.e. 56.67% were addicted to tea, majority i.e. 81.67% of the patients had normal built, maximum numbers of the patients i.e. 55.00% were taking *Madhura rasa* dominant diet, maximum numbers of patients i.e., 38.33% were of Vata- Kapha Prakriti, majority of patients 75.00% were having Rajasik Manas Prakriti, majority of patients 65.00% were having Madhyam vikriti, maximum numbers of patients i.e. 76.67% were having Madhvam Sara, maximum numbers of patients i.e. 76.67% had Madhyam samhanana,

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majority of the patients i.e. 68.33% were of Madhyama Pramana, maximum numbers of patients i.e. 85.00% were of Madhyama Satmya, maximum numbers of patients i.e. 75.00% were of Madhvama Satva, majority of the patients i.e. 71.67% were of Madhyama Abhyavaharana Shakti, majority numbers of the patients i.e. 80.00% were of Madhyama Jarana *Shakti*, majority numbers of the patients i.e. 63.33% were of Madhyam Vyayama Shakti, maximum numbers of patients i.e. 78.33% had unilateral otomycosis, maximum numbers of patients i.e. RESULTS

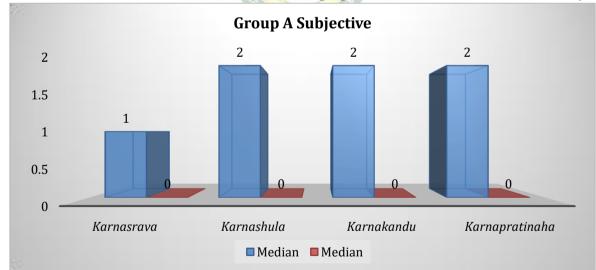
56.67% were having *Nidana* of *Jalanimajjana*/ jalakrida, majority of patients i.e. 41.67% were having Chronicity of <1 week, month wise prevalence of the *Karnsrava* were found in maximum i.e. 25.00% of the patients in September. 100% patients had chief complaints of ear pain and itching were reported, majority of the patients i.e. 41.67% had manifestation of the disease in left ear, whitish types of fungal mass was found in maximum numbers of patients i.e. 51.67%.

| Crown A        | Median Wilcoxon |    | Wilcoxon Signed            | P-Value | % Effect | Docult      |  |
|----------------|-----------------|----|----------------------------|---------|----------|-------------|--|
| Group A        | BT              | AT | Rank W                     | P-value | % Effect | Result      |  |
| Karnsrava      | 1               | 0  | <b>-4.491</b> <sup>a</sup> | 0.000   | 62.34    | Significant |  |
| Karnashula     | 2               | 0  | -4.146ª                    | 0.000   | 63.53    | Significant |  |
| Karnakandu     | 2               | 0  | <b>-4.379</b> ª            | 0.000   | 65.1     | Significant |  |
| Karnapratinaha | 2               | 0  | -4.359ª                    | 0.000   | 63.5     | Significant |  |

#### Table 3: Effect of therapy on subjective criteria in Group A

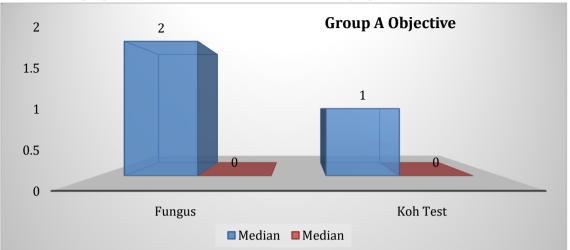
Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that P-Values for all parameters are less than 0.05. Hence we conclude that effect observed in Group A is significant.

Also from above table, it can be observed that, median value for *Karnsrava* was 1 before treatment and it is reduced to 0 after treatment showing significant effect of about 62.34% in the symptoms. Median value for *Karnashula* was 2 before treatment, it is reduced to 0 after treatment showing significant effect of about 63.53% in the symptoms. Median value for *Karnakandu* was 2 before treatment, it is reduced to 0 after treatment showing significant effect of about 65.1% in the symptoms. Median value for *Karnapratinaha* was 2 before treatment, it is reduced to 0 after treatment showing significant effect of about 63.5% in the symptoms.



| Table 4: Effect of therapy on objective criteria in Group A |        |    |                     |         |          |             |  |  |  |
|---|--------|----|---------------------|---------|----------|-------------|--|--|--|
| Crown A   | Median |    | ian Wilcoxon Signed |         | % Effect | Result      |  |  |  |
| Group A   | BT     | AT | Rank W              | P-Value | % Ellect | Result      |  |  |  |
| Fungus  | 2      | 0  | -4.066ª             | 0.000   | 60.12    | Significant |  |  |  |
| KOH Test  | 1      | 0  | -4.413ª             | 0.000   | 62.43    | Significant |  |  |  |

Median value for Fungus was 2 before treatment, it is reduced to 0 after treatment showing significant effect of about 60.12% in the symptom. Median value for KOH's Test was 1 before treatment, it is reduced to 0 after treatment showing significant effect of about 62.43% in the symptom.

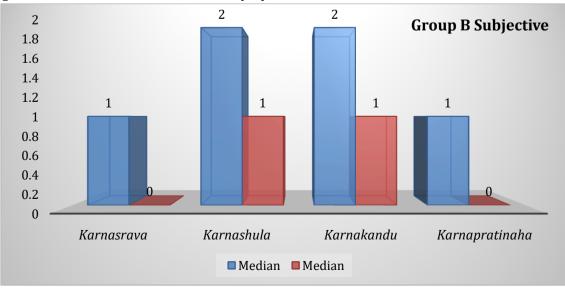


| Crown P        | Median |    | Wilcoxon Signed | P-Value | % Effect | Result      |  |
|----------------|--------|----|-----------------|---------|----------|-------------|--|
| Group B        | BT     | AT | Rank W          | r-value | % Ellect | Result      |  |
| Karnsrava      | 1      | 0  | -4.456ª         | 0.000   | 44.36    | Significant |  |
| Karnashula     | 2      | 1  | -4.234a         | 0.000   | 45.32    | Significant |  |
| Karnakandu     | 2      | 1  | -4.379ª         | 0.000   | 42.4     | Significant |  |
| Karnapratinaha | 1      | 0  | -3.207ª         | 0.000   | 43.5     | Significant |  |

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that P-Values for all parameters are less than 0.05. Hence we conclude that effect observed in Group B is significant.

Also from above table, it can be observed that median value for *Karnsrava* was 1 before treatment, it is reduced to 0 after treatment showing significant effect of about 44.36% in the symptom.

Median value for *Karnashula* was 2 before treatment, it is reduced to 1 after treatment showing significant effect of about 45.32% in the symptom. Median value for *Karnakandu* was 2 before treatment, it is reduced to 1 after treatment showing significant effect of about 42.4% in the symptom. Median value for Fungus was 2 before treatment, it is reduced to 1 after treatment showing significant effect of about 41.5% in the symptom. Median value for *Karnapratinaha* was 1 before treatment, it is reduced to 0 after treatment showing significant effect of about 43.5% in the symptom.

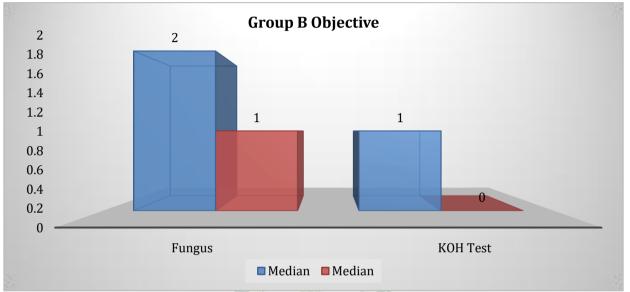


| Table 6: Effect of therapy on objective criteria in Group B |        |    |                        |         |          |             |  |  |  |
|---|--------|----|------------------------|---------|----------|-------------|--|--|--|
| Crown D   | Median |    | Median Wilcoxon Signed |         | 0/ Effe  | Dessilt     |  |  |  |
| Group B   | BT     | AT | Rank W                 | P-Value | % Effect | Result      |  |  |  |
| Fungus  | 2      | 1  | -4.600ª                | 0.000   | 45.13    | Significant |  |  |  |
| KOH Test  | 1      | 0  | -3.606ª                | 0.000   | 42.26    | Significant |  |  |  |

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Median value for Fungus was 2 before treatment, it is reduced to 1 after treatment showing significant effect of about 45.13% in the symptom.

Median value for KOH's Test was 1 before treatment, it is reduced to 0 after treatment showing significant effect of about 42.26% in the symptom.



# Table 7: Comparative effect of therapy between Group A and Group B

|                | Group   | N  | Mean<br>Rank | Sum of<br>Ranks | Mann-<br>Whitney U | P-Value |  |
|----------------|---------|----|--------------|-----------------|--------------------|---------|--|
|                | Group A | 30 | 28.75        | 862.50          |                    |         |  |
| Karnsrava      | Group B | 30 | 23.55        | 706.50          | 139.000            | 0.039   |  |
|                | Total   | 60 |              |                 |                    |         |  |
|                | Group A | 30 | 28.55        | 856.50          |                    |         |  |
| Karnashula     | Group B | 30 | 23.35        | 700.50          | 143.000            | 0.041   |  |
|                | Total   | 60 |              |                 |                    |         |  |
|                | Group A | 30 | 28.20        | 846.00          |                    | 0.046   |  |
| Karnakandu     | Group B | 30 | 23.00        | 690.00          | 150.000            |         |  |
|                | Total   | 60 |              |                 |                    |         |  |
|                | Group A | 30 | 31.85        | 955.50          |                    | 0.000   |  |
| Karnapratinaha | Group B | 30 | 26.65        | 799.50          | 77.000             |         |  |
|                | Total   | 60 |              |                 |                    |         |  |
|                | Group A | 30 | 27.35        | 820.50          |                    |         |  |
| Fungus         | Group B | 30 | 22.15        | 664.50          | 167.000            | 0.043   |  |
|                | Total   | 60 |              |                 |                    |         |  |
|                | Group A | 30 | 28.73        | 861.75          |                    |         |  |
| KOH Test       | Group B | 30 | 23.53        | 705.75          | 139.500            | 0.030   |  |
|                | Total   | 60 |              |                 |                    |         |  |

For comparison between Group A and Group B, we have used Mann Whitney U Test. From above table we can observe that P-Values for all parameters are less than 0.05. Hence we conclude that there is significant difference between Group A and Group B. Further we can observe that mean rank for Group A is greater than Group B. Hence we conclude that effect observed in Group A is more than Group B.

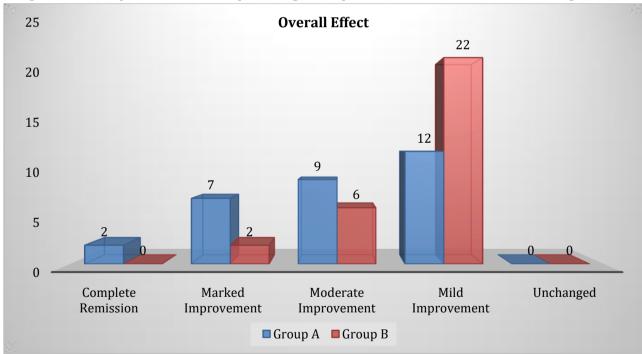
| Overall Effect                |    | Group A |    | Group B |  |
|-------------------------------|----|---------|----|---------|--|
| overall Ellect                | Ν  | %       | Ν  | %       |  |
| Complete Remission (100%)     | 2  | 6.67    | 0  | 0.00    |  |
| Marked Improvement (76-99%)   | 7  | 23.33   | 2  | 6.67    |  |
| Moderate Improvement (51-75%) | 9  | 30.00   | 6  | 20.00   |  |
| Mild Improvement (26-50%)     | 12 | 40.00   | 22 | 73.33   |  |
| Unchanged (< 25%)             | 0  | 0.00    | 0  | 0.00    |  |
| TOTAL                         | 30 | 100.00  | 30 | 100.00  |  |

| Table 8: Assessment of overall effect of therapy on Karnsrava- otomy | vensis |
|--|--------|
| Table 0. Assessment of overall effect of therapy of Narnsrava- otom  | 10313  |

The overall effect of therapy was assessed on the basis of above mentioned assessment criteria.

In group A, 40.00% patients got mild improvement, 30.00% patients got moderate improvement, 23.33% patients got marked improvement and 6.67% patients got complete remission. None of the patients remained unchanged.

In Group B, 73.33% patients got mild improvement, 20.00% patients got moderate improvement and 6.67% patients got marked improvement and no patients got complete remission or remained unchanged.



# DISCUSSION

# Rasnadi Guggulu Vati

According to our classics, Vata dosha is responsible for Karnsrava and Rasna has been referred to as one of the best Vata-hara Agreya Dravya in ch.su.25. (रारना वातहराणाम). The Rasnadi guggulu vati is simple medicine having drugs like Rasna, Amrita, Eranda, Devadaru, Shunthi, Guggulu which are very cheap and easily available in their authentic form. The ingredients of Rasnadi guggulu vati have Shothahara, Kushthaghna, Vedanasthapana, Krimighna, Kaphaghna, Vranaropana, Jantughana, *Vranashodhana, Rasayana, Vatahara* etc., properties. Due to all these properties it can be effective in treating the disease *Karnsrava*- otomycosis. In modern science, some fungus species are resistant to antifungal eardrops and oral antifungal drugs such as itraconazole or voriconazole are not free from side effects like headache, vomiting, nausea etc. Hence, *Rasnadi guggulu vati* has been selected for this study.

## Probable Mode of Action of *Rasnadi Guggulu*

In Ayurveda, the probable mode of action of the drug is based upon the pharmacodynamics of the drug, which includes the *Rasa, Guna, Virya, Vipaka* and *Doshaghnata*.

| Tuble 311 harmaeouyhanne properties of various ingreatents of hashaal gaggata vari |             |                   |                              |       |         |                        |  |  |
|--|-------------|-------------------|------------------------------|-------|---------|------------------------|--|--|
| S. No.   | Ingredients | Rasa              | Guna                         | Virya | Vipaka  | Doshaghnata            |  |  |
| 1.   | Rasna       | Tikta             | Guru                         | Ushna | Katu    | Vata- kapha shamaka    |  |  |
| 2.   | Amrita      | Tikta,<br>Kashaya | Guru, Snigdha                | Ushna | Madhura | Tridosha- shamaka      |  |  |
| 3.   | Eranda      | Madhura           | Snigdha, Sukshma,<br>Tikshna | Ushna | Madhura | Kapha- vata shaman     |  |  |
| 4.   | Devadaru    | Tikta             | Laghu, Snigdha               | Ushna | Katu    | Kapha- vata shamaka    |  |  |
| 5.   | Shunthi     | Katu              | Laghu, Snigdha               | Ushna | Madhura | Vata- kapha<br>Shamaka |  |  |
| 6.   | Guggulu     | Katu-tikta        | Laghu, Ruksha,<br>Tikshna    | Ushna | Katu    | Vata – kapha shamaka   |  |  |

Table 9: Pharmacodynamic properties of various ingredients of Rasnadi guggulu vati

## Action by Doshaghnata

All the drugs of *Rasnadi guggulu vati* are *Vata- kapha shamaka*, whereas *Guggulu* and *Guduchi* (*Amrita*) have *Tridoshahara* property.

#### Action by Rasa

Most of the drugs of *Rasnadi guggulu vati* are dominated by *Tikta, Katu rasa*. So, *Rasnadi vati* has *Kapha shamaka* property by *Katu, tikta rasa* and *Vata* and *Pitta shamaka* property by *Madhura* and *Kashaya rasa*. Acharya Charaka has described *Katu rasa* as *Kandu hara, Krimihara, Agnideepana, Vrana ropana*.<sup>[12]</sup> *Tikta rasa* acts as *Krimihara, Kanduhara* and *Kashaya rasa* acts as *Ropana* and *Sandhanakara*. *Madhura rasa* acts as *Indriyaprasadhana, Ojovardhaka, Dhatu vardhana* and *Daha prashama*. Due to these properties *Rasnadi guggulu vati* helps in alleviating *Karnsrava*- otomycosis.

## Action by Guna

Majority of the ingredients have *Snigdha, Guru guna* which helps in pacifying *Vata dosha* and some others drugs having *Laghu* and *Tikshna guna* which are *Kaphashamaka*.

## Action by Virya

*Virya* is the efficiency of drug via which it really works i.e. quick or slow. *Ushna virya* drugs are those which work fast and efficiently in short period of time in comparison to *sheeta virya*. In *Rasnadi guggulu vati* almost all drugs have *Ushna virya*. So, it breaks the pathology more proficiently.

## Action by Vipaka

Most of the drugs are having *Katu* and *madhura vipaka*. The *Katu vipaka* normalizes the vitiated *Kapha* and the *Madhura vipaka* pacifies the *Vata dosha*.

# Actions of *Rasanadi Guggulu Vati* on *Karnsrava*-Otomycosis

*Rasnadi guggulu* has different ingredients which plays important role in the treatment of *Karnsrava*.

- *Rasnadi guggulu vati* consists of six ingredients. It contains *Rasna, Amrita, Eranda, Devadaru, Shunti* in equal parts and five parts of *Guggulu*.
- *Guggulu* is the chief ingredients in the composition of *Rasnadi guggulu vati*, its *Katu – tikta rasa* and *Ushna virya* reduces *Vata* and *Meda*. It is a demonstrated drug for its anti-inflammatory and anti-septic effect. *Guggulu* is lipid invigorating in action of white bloods cells in the body contributing to the building up of the immune system.
- *Rasayana* drugs are considered as *Samanya Chikitsa* for all *karnarogas* in classics. So, it may be inferred that *Guggulu* has combined effect of anti-inflammatory and immune-modulator thereby bringing relief in *Karnsrava*-otomycosis.
- In *Rasnadi Guggulu vati*, most of the ingredients are having *Tikta*, *Katu*, *Kashaya* and *Madhura rasa*. They are having properties like *Guru*, *Snigdha* and *Laghu guna*, *Ushna virya* along with *Katu* and *Madhura vipaka* which are *Vata- Kapha shamaka* properties. By these properties it reduces *Srava* from the *Karna* leading to dryness of the ear canal.
- The disease *Karnsrava* is mainly due to *Vata dosha* and *Rasnadi guggulu vati* contains drug like *Rasna* (*vata* pacifier), *Eranda* and *Devadaru* which are not only capable of pacifying *Vata* but also very good in promoting the health by normalizing the *doshas*.
- *Rasna* is a known anti-inflammatory drug as well as disease modifying agent. *Amrita, Devadaru,*

*Shunti* have immune modulatory activity which aides in mitigating symptoms of *Karnsrava*-otomycosis.

- As indicated by *Panchmahabhotika* constitution, *Karnsrava* is *Prithvi* and *Jala mahabhuta pradhan*, while *Rasnadi Guggulu* has *Akasha*, *Vayu* and *Teja mahabhoota pradhanata*. The contradictory *Mahabhuta pradhanata* of the *Karnastrava* and *Rasnadi Guggulu* will be supportive to decrease the disease.
- Rasna, Amrita (Guduchi), Guggulu work as a Rasayana because of it possesses the Rasayana property. Hence, Rasnadi guggulu vati helps in alleviating Karnsrava- otomycosis and its symptoms. Because it is said by Acharya Sushruta– सामान्यं कर्णरोगेषु घृतपानं रसायनम्।

अव्यायामोऽशिरः स्नानं ब्रह्मचर्यमकत्थनम्।।<sup>13</sup> (Su.utt.21/3)

#### *Gugguluadi Karndhoopan Dravyas* Selection of Treatment Modality

Karndhoopan is one among natural and traditional procedure which can be beneficial in controlling the infections. Its root lies in Vedas and is broadly used in Ayurveda not only for disinfecting, but additionally as a remedy to prevent the various **Probable Mode of Action of Gugguluadi Dravyas Karndhoopan** 

diseases. In *Atharvaveda*, it is mentioned in description that Yakshma and other diseases won't spread to the areas fumigated by *Guggulu*.<sup>[14]</sup> After going via entire literature of *Guggulu*, it is introduced as a well known Dhoopan dravyas. The Gandha of Guggulu is mentioned as Krimighna and insect repellant. Guggulu is noted as a Devadhoopa in our classics. It tells about importance of *Guggulu* as a Dhoopan dravvas and Guggulu also has an aromatic fragrance. In this present study eight such drugs which are mentioned in Sushruta Samhita for Dhoopan (fumigation) namely Guggulu, Agaru, Sarjras, Vacha, Gaursarshapa, Lavana, Nimba and Ghrita has been selected for Karndhoopan karma. *Karnsrava*- otomycosis is a challenging disease due to its long term treatment and follow-up and Karndhoopan with Gugguluadi dravyas are highly efficient in curing the disease *Karnsrava*- otomycosis. All these *Dhoopan* drugs have qualities of Kushthahara, Krimihara, Kandughna and Vrana ropana. These properties of *Gugguluadi dravya Karndhoopan* not only helps in reducing the *Srava* but also prevent futher progression of the disease Karnsrava- otomycosis.

| S.No | Ingredients          | Rasa               | Guna   | Virya  | Vipaka  | Doshaghnata               |
|------|----------------------|--------------------|--|--------|---------|---------------------------|
| 1.   | Guggulu              | Katu- Tikta        | Lag <mark>hu, T</mark> ikshna,<br>Vishada, <mark>R</mark> uksha. | Ushna  | Katu    | Vata- kapha shamaka       |
| 2.   | Agaru                | Katu- Tikta        | Laghu, Ruksha, Tikshna   | Ushna  | Katu    | Vata- kaphahara           |
| 3.   | Sarjarasa            | Kashaya- Tikta     | Sheeta, Snigdha  | Ushna  | Katu    | Vata- pitta hara          |
| 4.   | Vacha                | Katu- Tikta        | Laghu, Tikshna, Sara   | Ushna  | Katu    | Kapha- vata shamaka       |
| 5.   | Gaur sarshapa        | Katu- Tikta        | Tikshna- Snigdha   | Ushna  | Katu    | Kapha- vata hara          |
| 6.   | Saindhava-<br>Lavana | Lavana-<br>Madhura | Laghu, Snigdha   | Sheeta | Madhura | Tridosha- hara            |
| 7.   | Nimba patra          | Tikta- kashaya     | Laghu  | Sheeta | Katu    | Kapha- pitta shamaka      |
| 8.   | Go-Ghrita            | Madhura            | Guru, Snigdha, Mrdu  | Sheeta | Madhura | Vata- pitta<br>prashamana |

Pharmaco dynamic properties of various ingredients of *Karndhoopan dravyas* are as follows:

# Mode of Action by Doshaghnata

Maximum drugs in *Gugguluadi dravyas dhoopan varti* are *Vata- kapha shamaka*, whereas *Saindhav Lavana* has *Tridoshahara* property and *Nimba* has *Kapha- pitta shamaka* and *Go-Ghrita* has *Vata-Pitta Prashamana* properties.

## Mode of Action as Per Rasa

In *Gugguluadi dravyas dhoopan varti*, most of the drugs have *katu* and *Tikta rasa* followed by *Kashaya* and *Madhura rasa*. *Katu rasa* comprises of *Vayu* & *Agni mahabhuta* which also alleviates *Kapha dosha*. It also has *Deepana*, *Pachana*, *Krimighna*, *Kusthaghna, Kandughan, Vrana ropana* properties.<sup>[12&15]</sup>

*Tikta rasa* is dominated with *Vayu* and *Akasa mahabhuta*. It possesses *Deepana, Pachana, Kandughna* and *Kusthaghna* properties. *Tikta rasa* induces dryness and cleanses with *Krimighna* and *Puyashoshanakara* properties. It will also help to eliminate ear discharge, debris and reduce itching. Due to these properties of *Katu* and *Tikta rasa, Gugguluadi dravyas varti* will encounter *Vata – kapha dosha*.

Kashaya rasa is made up of Prithvi- Vayu Mahabhuta which alleviates Pitta- kapha dosha. It has Ropana and Shoshana properties by which it lysis the fungus and bacteria.

Madhura rasa has dominance of Prithvi and Jala mahabhuta which alleviates Vata and Pitta due to its Snigdha and Guru guna. It is also Saptadhatu Vardhaka, Oja Vardhaka, Indriyaprasadana, Tarpana, Brihmanaya and Sandhanakara. Thus, it is ultimately promoting healing process.

#### Mode of Action as Per Guna

In this drug, majority of the *Gunas* are *Laghu*, *Ruksha*, *Tikshna* and *Vishada* which have *Shoshana* and *Shodhana* property by which they will reduce the discharge in EAC and encounter the *Kapha dosha*. *Laghu guna* has *ropana shakti* which helps in healing wound. Due to *Shighrakari* property of *Tikshna guna* it starts activity very fast and will mitigate both *Vata* and *Kapha dosha*, *Pitta dosha* will be decreased due to its *Sheeta* and *Mridu guna*. *Snigdha* and *Guru guna* will mitigate *Vata dosha*.

#### Mode of Action as Per Virya

*Virya* is the most potent *Guna* present in the drug. Majority of the drugs in *Gugguluadi dravyas dhoopan varti* have *Ushna virya* which has positive effect on vitiated *Vata- kapha dosha. Sheeta virya* will decrease the vitiated *Pitta dosha*.

#### Mode of Action as Per Vipaka

Majority of the ingredients in *Gugguluadi dravyas karndhoopan varti* have *Katu vipaka* which will work on pacifying the *Kapha dosha*. Some drugs have *Madhura vipaka* which will normalize the aggravated *Vata dosha*.

In *Gugguluadi dravyas karndhoopan varti*, all the drugs have *Kushtaghna, Kandughan, Krimighna, Vranaropana, Vrana shodhana* properties which will reduce the symptoms of disease *Karnsrava*otomycosis. Thus, from the above description of *Gugguluadi dravyas karndhoopan varti* drugs, the overall effect appears to be *Tridoshahara*.

#### **Recommendations for Future Research Work**

- *Karndhoopan* with more different drugs can be chosen for the further study.
- The study should be conducted with a longer duration of treatment.
- The impact of Karndhoopan along with Nasya or Nasya alone can be attempted in Karnsravaotomycosis in further research work.
- Advanced investigative procedures can be included for better prognosis and assessment.
- The effectiveness of the therapeutic procedure Karndhoopan can be built up in C.S.O.M & A.S.O.M

and other outer ear infections by further research studies.

#### CONCLUSION

Following conclusions can be drawn from the present study.

- ★ Most common etiology of *Karnsrava* is *Jalakrida /Jalanimajjana*, followed by *Karnakanduyana* in the present study.
- ★ In this study, the prevalence of *Karnsrava*otomycosis is seen additional in 21-30 years age group.
- ★ *Vata- kapha prakriti* persons are seen to be more prone for the disease *Karnsrava-* otomycosis.
- ★ It usually affects unilateral side i.e., 78.33% patients but bilateral side can also be affected.
- ★ In current study, *Varsha Ritu* (Aug-Sep) is favourable season for the diseases *Karnsrava*-otomycosis.
- ★ Incidence of the disease *Karnsrava* was found to be more prevalent in the lower middle class i.e. 48.33%.
- ★ In the disease *Karnsrava* ear discharge, ear pain & itching in EAC were the most significant complaints in almost cases.
- ★ Administration of *Karndhoopan* is safe, painless and harmless procedure which can be done at O.P.D. level without any complications.
- ★ Gugguluadi Dravyas Karndhoopan along with Rasnadi guggulu orally proved more effective when compared to only Karndhoopan with Gugguluadi dravyas.
- ★ All the drugs presents in *Rasnadi Guggulu vati* & *Gugguluadi dravyas karndhoopan* possesses *kaphavata-hara* & *Tridoshahara* properties which play an significant role in pacifying *Doshas*, participating in the pathogensis of the disease *Karnsrava*-otomycosis.
- ★ This clinical study proves that most of the drugs used in this research project possess anti-fungal, anti-bacterial, anti-inflammatory & immunomodulator properties.
- ★ None of the cases aggravated during the study.
- ★ No unfavourable effect of the therapy was observed during the study.

Thus, finally we can conclude that *Gugguluadi dravyas karndhoopan* and *Rasnadi Guggulu vati* is safe, cost effective and free from any side effects in the management of *Karnsrava*.

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