



**“A CLINICAL STUDY TO EVALUATE THE EFFECT OF *GANDHAKADI TAILA* IN THE  
MANAGEMENT OF *POOTIKARANA* W.S.R. TO CSOM”**

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**ABSTRACT**

*Pootikarana* is the condition characterised by thick purulent discharge from the ear having foul smell associated with or without pain. CSOM (safe type-tubotympanic) is a long standing infection of a part or whole of the middle ear cleft characterised by ear discharge, permanent perforation of TM, hearing loss, oedematous middle ear mucosa.<sup>[1]</sup> *Karnapoorana* is the specific treatment modality mentioned for *Pootikarana* along with few other treatment procedures. As it is not a self-limiting disease, definite treatment is needed to reduce the complications. In the present study 10 patients were selected randomly and treated with *Gandhakadi Taila*. The signs and symptoms were studied before and after treatment. Results of study showed marked (10%), moderate (30%), mild (30%) improvement in patients and (30%) patients were unimproved in 2 weeks, except hearing loss and perforation which was found non significant.

**KEYWORDS:** *Pootikarana*, *Gandhakadi Taila*, *Karnapoorana*, CSOM.

**INTRODUCTION**

*Pootikarana* is a disease mentioned by *Acharya Sushruta* in the chapter named *Karnaroga vinyaniya*.<sup>[2]</sup> He has counted *Pootikarana* as a disease entity under 28 *Karnarogas*. *Acharya Charaka* has described 4 *Karnarogas* in which *srava* is a major symptom.<sup>[3]</sup> *Acharya Vagbhatta* has described 25 *Karnarogas* under which *Pootikarana* is described as independent disease.<sup>[4]</sup> It is the condensed and putrid discharge from the ear with or without pain due to liquefaction of the accumulated *Kapha* by the heat of aggravated *Pitta*.<sup>[5]</sup>

Otitis Media in all its form is one of the most common diseases worldwide. It is estimated that 70% of children will have had one or more episodes of otitis by their third birthday.<sup>[6]</sup> CSOM is an important cause of preventable hearing loss, particularly in the developing world.<sup>[7]</sup> The WHO estimated that 65-300 million people worldwide are affected by CSOM, of whom 50% suffers from hearing impairment and approximately 28000 deaths per annum are attributable to the complications of Otitis Media.<sup>[8]</sup> CSOM is characterised by ear discharge, hearing loss, perforation of TM, edematous middle ear mucosa. As it is not a self-limiting disease, definite treatment is needed to reduce the complications.

*Pootikarna* is a *sadhya vyadhi* according to *classics*. The treatment principle explained by our *Acharyas* is common for *Karnasrava*, *Pootikarana* and

*Krimikarna*.<sup>[9]</sup> *Karnapoorana* is the specific treatment modality mentioned for *Pootikarana* along with few other treatment procedures.<sup>[10]</sup> This present study includes detailed study of the disease, its nature and course and to evaluate the effect of *Ayurvedic* drug on chronicity of the disease.

Therefore keeping in view the need of time and gravity of the disease, present study was undertaken with the topic entitled “A Clinical Study to Evaluate the Effect of *Gandhakadi Taila* in the Management of *Pootikarana* w.s.r. to CSOM”.

**AIMS AND OBJECTIVES**

- To study in detail the *Pootikarana* w.s.r. to CSOM.
- To study efficacy of *Gandhakadi taila* and evaluate its role in management of CSOM/*Pootikarana*.
- To study the side effect/toxicity of the drug if any.

**MATERIALS AND METHODS**

**Group, Dose & Duration**

**Single group**

**Study design**

Open uncontrolled study.

Number of patients – 10

**Drug Schedule**

- ❖ *Gandhakadi Taila* as *Karnapoorana*.<sup>[11]</sup>

Dose- Filling the EAC with *Gandhakadi Taila* Upto concha (2ml each ear)  
 Time - Before sunrise and after sunset.  
 Duration - 100 *matra uchharana kaala* (2-3 min approx.)  
**Duration of treatment** - 14 days  
**Follow up** - 7 days

### Selection Criteria

Uncomplicated patients with signs and symptoms of CSOM, attending OPD and IPD of R.G.G.P.G. Ayurvedic Hospital Paprola were selected above 12 years age, after obtaining their consent. Case selection was regardless of sex, occupation, socio-economic consideration & religion etc. All the patients were followed up after 1 week.

### Inclusion Criteria

- Patients presents with sign and symptoms of *Pootikarana*.
- Age above 12 years.

### Exclusion Criteria

- Patients below 12 years of age.
- Congenital deformity
- Malignancy presenting as *Pootikarana*
- Blockage due to stenosis of external auditory canal
- Patient suffering from systemic disease diabetes mellitus, hypertension etc.
- Disease other than ear pathology like :-
  - Cerebrospinal fluid otorrhoea
  - Parotid abscess rupturing in EAC
  - TMJ abscess rupture in EAC
- Pregnant patients.
- Patient not willing to be registered for the trial.

### Plan of work

The study was planned in different steps as mentioned below:

**1. Proforma:** A special proforma will be prepared for the evaluation of the etiopathogenesis and assessment if treatment efficacy. A detailed history will be taken and simultaneously general and systemic examination of the patient was done having signs and symptoms suggesting of CSOM.

### 2. Investigations

Complete haemogram – (Hb%, TLC, DLC, ESR)  
 Biochemistry- FBS.  
 Tuning fork test.  
 Radiology- X ray mastoid schuller's view.  
 Pure tone audiometry.

### Clinical Assessment

Assessment of the effect of treatment has been done on the basis of relief of signs and symptoms of CSOM on the basis of grading and scoring system.

### I) Ear discharge

Not found	0
Serous	1

Mucoid/Mucopurulent	2
Sanguineous	3

### ii. Pain

No ear ache	0
Not continuous	1
Continuous but not incapacitating normal routine activity	2
Continuous throughout and incapacitating normal Routine activity	3

### iii. Itching

No itching	0
Occasional itching	1
Continuous itching	2
Uncontrolled itching	3

### iv. Enlarged pre and post auricular lymph node

Not palpable	0
Palpable on deep palpation	1
Palpable on superficial palpation	2
Visible lymph node	3

### v. Hearing loss

0 – 20 dB	0
20 – 40 dB	1
40 – 60 dB	2
> 60 dB	3

### vi. Perforation (central)

Not present	0
Small (1 quadrant)	1
Moderate (2 quadrant)	2
Large (3/4 <sup>th</sup> of quadrant/subtotal)	3
Total	4

### vii. Abnormal condition of middle ear mucosa

Not visible	0
Pale, Pink, Moist	1
Red	2
Red, Oedematous, Swollen	3

### CRITERIA FOR OVER ALL ASSESSMENT

The total effect of therapy was assessed considering the following criteria-

- Complete remission : 100% relief in the signs & symptoms.
- Markedly Improvement : 75-99% relief in the signs & symptoms.
- Moderately Improvement : 50-74% relief in the signs & symptoms.
- Mild Improvement : 25-49% relief in the signs & symptoms.
- Unchanged : < 25% relief in the signs & symptoms.

## Drug review

Ingredients of *Gandhakadi Taila* ¼<sub>oax</sub> lsu- d.kZ jksx fpfdRlk 94½.<sup>[12]</sup>

Sr. No.	Name of plant	Botanical name	Dosha karma	Family	Part Used	Quantity
1.	<i>Shudh Gandhaka</i>	Sulphur	<i>Kaphavata Shamaka</i>			1 Pal (48 gm)
2.	<i>Shudh Manashila</i>	Realgar (Arsenic disulphide AS <sub>2</sub> S <sub>2</sub> )	<i>Kaphavata Shamaka</i>			1 Pal (48 gm)
3.	<i>Haridra</i>	<i>Curcuma longa</i> Linn.	<i>Tridosha Shamaka</i>	Zingiberaceae	Rhizome	1 Pal (48 gm)
4.	<i>Katu Taila</i>	<i>Brassica campestris</i> Linn.	<i>Kaphavata Shamaka</i>	Cruciferae	Oil	8 Pal (384 ml)
5.	<i>Datura Patra Rasa</i>	<i>Datura metel</i> Linn.	<i>Kaphavata Shamaka</i>	Solanaceae	<i>Patra swaras</i>	8 Pal (384 ml)

**Rasa Panchaka of Gandhakadi Taila**

*Gandhakadi Taila* have *Katu*, *Tikta Ras*, *Ruksha Guna*, *Ushna Virya*, *Katu Vipaka* and *Kapha Vata Shamaka* properties.

**Method Of Preparation Of GANDHAKADI TAILA**

- *Murchna* of *Katu Taila* was done as per *Bhaishjya Ratnawali*.<sup>[13]</sup>
- *Paka* of *Katu Taila* done with *Murchna* drugs.
- Equal part of *Haridra*, *Shudh Gandhaka* and *Shudh Manashila* were coarsely powdered.
- All these were dipped in water whole night and after that *Kalka* form prepared.
- This *Kalka* along with 8 *pal Katu Tail* and 8 *pal Datura Patra Rasa* were added into it and took in a steel vessel and heated over *Madhyama Agni* till complete evaporation of moisture content. Heat was applied with intermediate stirring. Heating duration was adjusted until the appearance or *Lakshana* of *Samyaka Sneha Siddhi*. Its *Khara Paka* was taken. When *Taila Paka* completed with all its examination, allowed to cool and packing done. Then *Gandhakadi Taila* was used as medicine for *Karanpoorana* purpose.

**Statistical Analysis**

The information gathered regarding demographic data is shown in percentage. The scores of criteria of assessment were analysed statistically in form of mean score B.T.(Before treatment), A.T. (After treatment), (B.T.-A.T.) difference of mean, S.D. (Standard deviation), S.E. (Standard error), Student paired 't' test was carried out at p>0.05, p<0.05 and p<0.001.

The results were considered significant or insignificant depending upon value of 'p'.

- Highly significant - p < 0.001
- Significant - 0.05 < p > 0.001
- Insignificant - p > 0.05

**Consent of patient**

All the patients selected for trial were explained the nature of the study and their written consent was

obtained on the proforma before including them in the clinical study.

**OBSERVATIONS**

In the present study of 10 patients 40% belonged to age 41-50 years, 80% were females, 80% were married, 80% belonged to rural area, 100% patients were Hindus, 70% patients were housewives, 40% were higher secondary educated, 50% were of lower middle class, 80% patients were consuming mixed diet, 70% were having no addiction, 60% were of *Pittakaphaja Prakriti*, 90% were having *Madhyama Satva*, *Satmaya* and *Samhanana*, 70% were of *Madhyama Vyayama Shakti*, 80% had unilateral ear discharge, Most of the patients had chronicity >4 years. As incidence of signs and symptoms were concerned almost all patients showed symptoms like Discharge, Perforation, 90% showed abnormal condition of middle ear mucosa, 80% showed hearing loss, 70% showed itching, 3% showed pain.

**Effect Of Therapy**

1. **Discharge:** The initial mean score of **discharge** before treatment was 1.8 which was reduced to 0.5 after treatment. The percentage relief was 72.22% which is highly significant statistically at level of p<0.001 (t=6.09).
2. **Itching:** The initial score of **Itching** was 1.2 which was reduced to 0.3 after treatment. The percentage relief was 75% which is significant statistically at level of p<0.050 (t=3.85).
3. **Pain:** The initial score of **Pain** was 0.6 which was reduced to 0.1 after treatment. The percentage relief was 83.33% which is insignificant statistically at level of p>0.050 (t=1.86).
4. **Perforation:** The initial score of **Perforation** was 2.3 which was 2.3 after treatment. The percentage relief was 0% which is insignificant statistically at level of p>0.050 (t=0.00).
5. **Hearing loss:** The initial score of **Hearing loss** was 1.2 which was 1.2 after treatment. The percentage relief was 0% which is insignificant statistically at level of p>0.050 (t=0.00).
6. **Abnormal condition of middle ear mucosa:** The initial score of **abnormal condition of middle ear**

**mucosa** was 1.7 which was reduced to 1.1 after treatment. The percentage relief was 35.29% which is significant statistically at level of  $p < 0.050$  ( $t=3.00$ ).

7. **Enlarged pre & post auricular lymph nodes:** The initial score of **Enlarged pre & post auricular lymph nodes** was 0. The percentage relief was 0% which is insignificant statistically at level of  $p=1.00$  ( $t=0.00$ ).

Among 10 patients, 1 patient was markedly improved, 3 patients had moderate improvement, 3 had mild improvement and 3 patients had no improvement. There was no patient who was cured.

## DISCUSSION

To treat the disease in a proper way, it is necessary to know the causative factor and the disease process. The study of literature shows that this clinical entity, *Pootikarana* results from the vitiation of *Kapha* and *Pitta*. The aetiopathogenesis also brings out the fact that its causative factors are *Kapha* and *Pitta*. So any drug advocated for this particular disease should have properties to bring the affected *Doshas* to normal level. Hence, the drug selected mainly possesses *Kapha Shamaka* and *Tridosha Shamaka* properties. The trial drug *Gandhakadi Taila* is having dominance of *Katu*, *Tikta Rasa* (83.3%), *Ruksha Guna* (25%), *Ushna Virya* (100%), *Katu Vipaka* (100%) and *Kapha Vata Shamaka* (80%) and *Tridosha Shamaka* (20%) which are countering the *Samprapti* (pathogenesis) of *Pootikarana*. The *Rasa Tikta* & *Katu* having *Shodhana*, *Krimihara*, *Kanduhara*, *Kledahara*, *Vrana Avsaadaka*, *Pitta Shleshma Upshoshano* and *Lekhana* properties as per Ch. Su. 26/42-5<sup>[14]</sup>, which helps to remove ear debris, fungal mass, discharge and reduces itching. Due to *Srava*, healing process is hampered in *Vrana*. *Katu* and *Tikta Rasa* by *Shodhana* property help to open the channels and clean the wound leading to healing process. *Ruksha Guna* is having *Shoshana Shakti* which will absorb the discharge in auditory canal, relieves the oedema of middle ear mucosa and reduce the *Kapha Dosha*. *Ushna Virya* help in reducing *Kapha* i.e. discharge. *Katu Vipaka* have same function as *Katu Rasa*.

In this formulation '*Shudh Gandhak*'<sup>[15]</sup> which is main ingredient is having *Kanduhara*, *Jantughana*, *Shoshak* and *Kaphavata Shamaka* properties which helps in the management of *Pootikarana*. '*Shudh Manashila*'<sup>[16]</sup> have *Srotoshodhana*, *Kanduhara*, *Shoshana* and *Kaphavata Shamaka* properties. '*Haridra*'<sup>[17]</sup> which is *Tridosha Shamaka*, contains *Shothahara*, *Vednasthapana*, *Krimighana*, *Kandughana*, *Vranashodhana*, *Vranaropana* and *Pittarechaka* properties. '*Katu Taila*'<sup>[18]</sup> is *Kaphavata Shamaka* and contains *Jantughana*, *Vednasthapana*, *Krimighana* and *Kaphaghana* properties. '*Datura Patra*'<sup>[19]</sup> it is also *Kaphavata Shamaka*. It shows *Jantughana*, *Vednasthapaka*, *Shoolaprashamana*, *Shothahara* properties.

## CONCLUSION

*Pootikarana* is commonly encountered disease which is caused by the recurrent and prolonged infection of the ear. The people of the lower socio economic group are particularly prone to this disease. The symptomatology of *Pootikarana* and CSOM was found to be same. Hence there is correlation between *Pootikarana* and CSOM. All the *Pootikarana* patients who received proposed formulation tolerated very well and no untoward effect were reported by the patients registered for the current trial. The drug show no improvement in hearing loss and in perforation.

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