

EFFECT OF AN AYURVEDIC FORMULATION IN THE MANAGEMENT OF POOTIKARANA W.S.R. TO CSOM

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ABSTRACT

Pootikarana (CSOM) is one of the most common complaint encountered in clinical practice of ENT. CSOM involves 65-330 million individuals with draining ears, 50% of whom suffer from significant hearing impairment.^[1] *Pootikarana* is a disease with putrid discharge from the ear.^[2] and occurs mainly due to *Kapha Pitta Dosha*. The severity and chronicity of the disease can lead to many dreadful complications. As the symptoms of *Pootikarana* are same as that of CSOM this disease was selected for the study. The present study was done on 10 patients of *Pootikarana* out of which 2 were drop out and were treated with *Rasnadi Guggulu* as oral drug. The signs and symptoms were studied before and after treatment. Results of study showed marked improvement in 1 patient (12.5%), moderate improvement in 1 patient (12.5%), mild improvement in 5 patients (62.5%) and no improvement in 1 patient (12.5%). The drug show no improvement in hearing loss and in perforation.

KEYWORDS: *Pootikarana*, *Rasnadi Guggulu*, CSOM.

INTRODUCTION

Our *Acharyas* divided *Ayurveda* into eight parts.^[3] which deals with different parts of the body. Among them *Shalaky Tantra*,^[4] deals with the description and treatment of diseases of organs above clavicle. A very common clinical condition, *Pootikarana* (CSOM) is one among them. *Acharya Sushruta* has described 28 *Karan rogas* and *Pootikarna* is described as independent disease under the name of *Pootikarana* in the chapter named *Karanroga vinyaniya*.^[5] *Pootikarana* is explained in *Ayurvedic* system of medicine as condensed and putrid discharge from the ear with or without pain due to liquefaction of the accumulated *Kapha* by the heat of aggravated *Pitta*.^[6] *Pootikarana* can be a source of worry to many patients due to its frequent recurrence. As it is not a self-limiting disease, definite treatment is needed to reduce the complications. The severity and chronicity of the disease can lead to many dreadful complications.

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.^[7] It involves 65-330 million individuals with draining ears, 50% of whom suffer from significant hearing impairment. Although, complications rarely occur in tubotympanic type but persistent infection effects the anatomical structures of the ear besides causing reduced hearing. Therefore it needs an intensive care for its control and cure.

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. In the present study “**Effect of an Ayurvedic formulation in the management of *Pootikarana* w.s.r. to CSOM**” *Rasnadi Guggulu* was used as oral drug.

In this research work 10 patients were taken for study in single trial group out of which 2 patients were drop out. The duration for trial was 2 weeks for *Rasnadi Guggulu*, evaluation based on subjective criteria.

AIMS AND OBJECTIVES

- To study in detail the *Pootikarana* w.s.r. to CSOM.
- To study efficacy of *Rasnadi Guggulu* 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

❖ *Rasnadi Guggulu* as oral drug.

Dose - 500mg tid

Anupana - with Luke warm water

Duration of treatment - 14 days

Follow up - Two follow ups at weekly interval.

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 th 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 Rasnadi Guggulu ¼;ksxjRukdj d.kZjksx fpfdRlk½.^[8]

Sr. No.	Plant name	Botanical name	Doshakarma	Family	Part used	Quantity
1.	Rasna	<i>Pluchea lanceolata</i> C.B. Clarke.	<i>Kaphavatahara</i>	Asteraceae	Patra	1 part
2.	Guduchi	<i>Tinospora cordifolia</i> Willd Miers.	<i>Tridosha</i> <i>Shamaka</i>	Menispermaceae	Stem	1 part
3.	Eranda Moola	<i>Ricinus communis</i> Linn.	<i>Kaphavatahara</i>	Euphorbiaceae	Root	1 part
4.	Devdaru	<i>Cedrus deodara</i> Roxb.	<i>Kaphavatahara</i>	Pinaceae	Stem	1 parts
5.	Shunthi	<i>Zingiber officinale</i> Rose.	<i>Kaphavatahara</i>	Zingiberaceae	Rhizome	1 parts
6.	Shudh Guggulu	<i>Commiphora mukul</i> Hook. Ex Stocks	<i>Tridosha</i> <i>Shamaka</i>	Burseraceae	<i>Niryas</i> (exd.)	5 parts

Rasa Panchaka of Rasnadi Guggulu

Rasnadi Guggulu have Tikta Ras, Snigdha Guna, Ushna Virya, Katu, Madhura Vipaka and Kapha Vata Shamaka properties.

Method of Preparation of Rasnadi Guggulu

The contents Rasna, Guduchi, Eranda moola, Devdaru, Shunthi are powdered in mini pulveriser and dried. Now, Shudh Guggulu is added in it on the fire and stirred thoroughly. After that tablets of 500 mg. are prepared.

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 60% belonged to age 31-40 years, 90% were females, 90% were married, 90% belonged to rural area, 100% patients were Hindus, 70% patients were housewives, 60% were higher secondary educated, 80% were of lower middle class, 80% patients were consuming vegetarian diet, 60% were having no addiction, 70% were of Pittakaphaja Prakriti, 80% were having Madhyama Satva, 70% were have 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 itching, 70% showed pain, 60% showed abnormal condition of middle ear mucosa, 50% showed hearing loss.

Effect Of Therapy

- 1. Discharge:** The initial mean score of discharge before treatment was 1.6 which were reduced to 0.5 after treatment. The percentage relief was 68.75% which is highly significant statistically at level of $p < 0.001$ ($t=7.51$).
- 2. Itching:** The initial score of Itching was 1.3 which was reduced to 0.4 after treatment. The percentage relief was 69.23% which is significant statistically at level of $p < 0.050$ ($t=3.81$).
- 3. Pain:** The initial score of Pain was 1.0 which was reduced to 0.4 after treatment. The percentage relief was 60% which is significant statistically at level of $p < 0.050$ ($t=3.00$).

4. **Perforation:** The initial score of **Perforation** was 1.5 which was 1.5 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 0.5 which was 0.5 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 0.8 which was reduced to 0.5 after treatment. The percentage relief was 37.5% which is insignificant statistically at level of $p > 0.050$ ($t = 1.42$).
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 8 patients, 1 (12.25%) patients was markedly improved, 1 (12.25%) was moderately improved, 5 (62.5%) patients had mild improvement and 1 (12.5%) patient was unimproved. 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*. 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 drug *Rasnadi Guggulu* is having dominance of *Tikta Rasa* (50%), *Snigdha Guna* (25%), *Ushna Virya* (100%), and *Madhura Vipaka* (50%) and *Kaphavata Shamaka* (83.33%) and *Tridosha Shamaka* (11.11%) properties. The dominant *Rasa Tikta* having properties like *Krimighana*, *Kandu Prashmana*, *Lekhana*, *Pitta Shleshma Upshoshano as per Ch. Su. 26/42-5*.^[9] It induces cleanness, dryness and keenness. With these properties it will help to remove ear debris, discharge and reduces itching.

Rasnadi Guggulu, have *Ruksha*, *Laghu*, *Tikshana Guna*. *Ruksha Guna* is having *Shoshana Shakti* which will absorb the discharge in auditory canal and encounter the *Kapha Dosh*. *Laghu Guna* has *Lekhana* and *Ropana* properties which will help in healing of wound. *Tikshana Guna* is *Shighrakaari* which starts its action very quickly by penetrating into minute channels does *Srotoshodhana* and will encounter *Kapha Dosh*. *Ushna Virya* helps in reducing *Kapha* i.e. discharge. *Madhura Vipaka* helps in reducing *Pitta*. Most of ingredients possess anti-inflammatory activities which also prevent inflammatory process.

In this formulation '*Rasna*'^[10] which is main ingredient is having *Vata Kapha Shamaka*, *Shothahara*, *Vednasthapana* properties which helps in the management of *Pootikarana*. '*Guduchi*'^[11] have *Tridosha Shamaka*, *Vednasthapana*, *Krimighana*, *Kaphaghana*, properties. '*Eranda Moola*'^[12] has *Kaphavata Shamaka*, *Shothahara*, *Vednasthapana*, *Krimighana*, *Kaphaghana* properties. '*Devdaru*'^[13] has *Kaphavata Shamaka*, *Shothahara*, *Vednasthapana*, *Kanduhara*, *Krimighana*, *Vranashodhana*, *Vranaropana*, *Kaphanissaraka*, *Shleshmaputihara*, *Lekhana* properties. '*Shunthi*'^[14] has *Kaphavata Shamaka*, *Shothahara*, *Vednasthapana*, *Shoolaprashmana*, and *Shleshmahara* properties. '*Shudh Guggulu*'^[15] has *Vatakapha Shamaka*, *Shothahara*, *Vednasthapana*, *Vranashodhana*, *Vranaropana*, *Pittasaraka*, *Krimighana*, *Kapha durgandhahara* properties and also has *Tridoshahara Prabhava*.

CONCLUSION

The symptomatology of *Pootikarana* and CSOM was found to be same. Hence there is correlation between *Pootikarana* and CSOM.

In the present study the treatment given is proved to be cheap and effective without any complications in the management of this disease.

The drug show no improvement in hearing loss and in perforation.

Overall result of therapy in present study is

Among 8 patients, 1 (12.25%) patients was markedly improved, 1 (12.25%) was moderately improved, 5 (62.5%) patients had mild improvement and 1 (12.5%) patient was unimproved. There was no patient who was cured.

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