



Research Article

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CLINICAL EVALUATION OF EFFECT OF GANDHAKA TAILA IN KARNASRAVA WITH SPECIAL REFERENCE TO CHRONIC SUPPURATIVE OTITIS MEDIA

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Received on: 14/07/13 Revised on: 21/08/13 Accepted on: 07/09/13

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DOI: 10.7897/2277-4343.04517

Published by Moksha Publishing House. Website www.mokshaph.com

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ABSTRACT

Chronic suppurative otitis media (CSOM) is the result of an initial episode of acute otitis media and is characterized by recurrent discharge from the middle ear through a tympanic perforation. It is an important cause of preventable hearing loss, especially in developing countries. Most approaches to treatment have been unsatisfactory or are very expensive and difficult. As per Acharya Sushruta Karnasrava is a disease characterized by ear discharge. Gandhaka taila is a unique oil based herbo-mineral formulation especially mentioned for Karnasrava with the procedure of karnapurana. To provide clinical evidence and to prove Gandhaka taila as a safe and effective medicine in chronic suppurative otitis media, this study has been carried out. In this study, 23 patients fulfilling the diagnostic and inclusion criteria of CSOM were selected and Gandhaka taila was instilled in the affected ear for 7 days. The efficacy of the drug was analyzed in terms of the relief produced in the signs and symptoms before and after treatment. The paired t-test was used to check the significance of subjective and objective criteria. The results of the study were found encouraging and there was also a significant reduction in ear discharge.

Keywords: Chronic suppurative otitis media, Karnasrava, Ear discharge, Gandhaka taila

INTRODUCTION

Ayurvedic medicines are gaining popularity and acceptance in the developed countries due to the failure of the Allopathic system of medicine in various chronic ailments. The adverse effects of chemical drugs are another failure of Allopathic system. Ayurvedic formulations are well accepted in the world but they need scientific data and evidence based clinical data to meet global standards. Karnasrava is one of the diseases of the ear described in many of the classics characterized by ear discharge¹. Amongst the various causes of ear discharge mentioned in contemporary sciences, commonly found ear disease is chronic suppurative otitis media, caused by the invasion of pyogenic organisms, results in the inflammation of middle ear cleft². Chronic suppurative otitis media is still prevalent around the world despite of advances in public health and medical care. It is most common in developing countries, especially among the poor because of poor socio-economic standards, poor nutrition and lack of health education. Since this infection is associated with chronic hearing loss, which may affect certain aspects of child development like speech, language, school performance etc. and the ever present potential damage of life threatening suppurative complications. Effective and preventive treatment is urgently needed. Most approaches to treatment have been unsatisfactory or are very expensive and difficult. Sometimes prolonged use of antibiotic ear drops may give rise to adverse effects like ototoxicity, super infections and these often very difficult to treat. Since this chronic infection is caused by persistent acute otorrhoea, which in turn, is usually secondary to acute otitis media, prevention

should be directed toward prompt and appropriate treatment of the acute middle infection. Repair of chronic perforation should prevent recurrence, but reinjection frequently occurs due to either reflex or insufflations of pathogenic organism from the nasopharynx into the middle ear or water contamination from the external canal. Gandhaka taila is a topical medicine specified by Yogaratnakara in Karnasrava³. Being a formulation of drugs having antimicrobial, anti-inflammatory and astringent properties in combination, found as an effective medicine in chronic suppurative otitis media. So as to provide clinical evidence and to prove Gandhaka taila as a safe and effective medicine in chronic suppurative otitis media, an attempt was made in this study.

MATERIALS AND METHODS

Source of drug

Gandhaka taila is a herbo-mineral formulation consists murchita Katutaila as sneha dravya, Haridra, Shuddha Gandhaka, shuddha Manhashila as kalka dravya, and Dattura patra swarasa as drava dravya. All the raw drugs were collected from S.D.M. Ayurveda pharmacy, Udupi, India and identified as per classical description in Bhavaprakasha and Rasaratnasamuchchaya further which were also authenticated by the Department of Dravyaguna and Rasashastra, S. D. M. College of Ayurveda, Udupi, India. Gandhaka taila was prepared strictly as per the reference of Yogaratnakara³ and guidelines of the classical literature in Rasashastra and Bhaishajya Kalpana practical laboratory of S. D. M. College of Ayurveda, Udupi, India.

Source of data

The ethical clearance No. is SDMCAU/ACAI5/ECO2/09-10 for this study.

Selection of patients

Patients attending O.P.D. and I.P.D. of S. D. M. Ayurveda Hospital, Udupi, India fulfilling the diagnostic and inclusion criteria of Karnasrava (CSOM) were selected and registered randomly, irrespective of age, sex or religion.

Criteria for Diagnosis

Patients having signs and symptoms of benign CSOM were selected for the present study. Detailed history was taken and physical examination was completed on the basis of a special proforma, incorporating the signs and symptoms of the disease.

Symptoms

- Ear discharge
- Deafness
- Earache
- Tinnitus

Signs

Perforation of ear drum

Inclusion criteria

- Patients above the age of 5 years.
- Patients suffering from benign CSOM fulfilling the diagnostic criteria.

Exclusion criteria

- Patients below the age of 5 years
- Benign CSOM with upper respiratory tract problems like Adenoids, Tonsillitis and Sinusitis.
- Benign CSOM with systemic disease like Diabetes.
- Benign CSOM with complications.

Investigations

- Routine hematological, like Hb %, Total count (TC), Differential count (DC), Erythrocyte sedimentation rate (ESR), Random blood sugar (RBS) were carried out in all the patients, to assess the condition of the disease and to exclude any other pathology.
- Before the treatment all patients who entered in the study underwent examination of the ears, nose and throat. Microbiological examination of the ear swab was carried out to determine the type of micro-organism responsible for the disease.

Diet and restriction

Patients were advised to avoid the aggravating factors like exposure to cold wind, intake of cold substances, swimming, head bath with cold water and oil application on head. Advised to clean the ear daily and plug the ear with cotton especially while taking head bath to avoid the entry of water in to the ear.

Method of administration of drug

Patient’s attendants are advised to instill 2 drops of lukewarm Gandhaka taila in to the cleaned affected ear at night time after local snehana with Tila taila and tapasweda, around the affected ear for 7 days.

Criteria for assessment

The efficacy of the trial drug was analyzed in terms of the relief produced in the signs and symptoms before and after treatment i.e. on 7th day. Follow up was done on 14th day and 21st day. To assess the relief in objective parameters, a Proforma was prepared with a grading system ranging from 0 to 2 (Table 1). Patients were evaluated thoroughly to assess the subjective parameters on the basis of Visual Analogue scale.

Subjective parameters

- Ear discharge
- Deafness
- Ear ache
- Tinnitus

Objective parameters

- Perforation of ear drum
- Tuning fork test

Table 1: Scoring table of Objective parameters

Objective Parameter	Finding	Points
Perforation of ear drum	Healed – no perforation	0
	Inactive – dry perforation	1
	Active - wet perforation	2
Tuning fork test-Rinne test	Positive – no conductive deafness	0
	Equivocal – mild conductive deafness	1
	Negative – conductive deafness	2

OBSERVATIONS AND RESULTS

In the present study, 23 patients were registered for the clinical study. The minimum age of the patient registered for the study was 5 years and maximum was 52 years. Majority of the patients were adults (83 %) and 4 patients were children (17 %). Majority of the patients were females (70 %) and males were (30 %). The religion wise distribution of the patients was a projection of geographical predominance of Hindu community in the selected area of the study. Hence, the maximum cases reported belonged to the Hindu community (91 %), followed by 2 patients from Christian community (9 %). It was observed that CSOM was more prevalent in lower middle class (48 %), 6 belonged to middle class (26 %), 4 were very poor (17 %) and 2 belonged upper middle class (9 %). The chief occupations of patients noted in the study were housewives (48 %), students (22 %), office workers (17 %) and field workers (13 %). This data does not have much research significance as majority of them are housewives. This may be due to personally habitual health causes. In the present study, it was observed that, 70 % patients belonged to rural area and 30 % patients to the urban area. Maximum patients had ear discharge since 1-3 months (48 %), 17 % patients were belonged to 4-6 months chronicity, 13 % patients had 10-12 months chronicity and 17 % patients were suffering since 2-5

years range. It was observed that maximum patients were suffered from mucopurulent type of ear discharge (57 %), 6 patients had mucoid discharge (26 %) and 4 had purulent discharge (17 %). Out of 23 patients, 14 patients had deafness along with discharge (61 %) which is of conductive variety, In 12 patients' ear discharge was associated with earache (52 %) and only 8 patients had tinnitus (35 %).

Causative organisms

In bacteriological study, it was found that 22 patients had *Pseudomonas* infection (96 %) and one patient discharge was found as sterile (4 %). This observation supports the textual data of many recent modern books that major bacteria causing CSOM are *Pseudomonas*.

Effect of therapy on CSOM

Objective parameters

Out of 23 patients, perforation of the ear drum was found healed in 3 patients (13 %), in 2 patients (9 %) it was remained as wet perforation and remaining 18 patients (78 %) had dry perforation indicating the relief from ear discharge. In 2 patients (9 %), improvement was observed through tuning fork test as change in mild conductive deafness to normal hearing. In another 2 patients (9 %) hearing was changed from moderate to mild conductive deafness. In one patient (4 %) it was vice versa i.e. mild to moderate conductive deafness. It might be because of

moderate sized central perforation of the ear drum. In remaining patients (78 %) deafness was present as earlier due to persisting ear drum perforation.

Subjective parameters

Complete relief from ear discharge was observed in 21 patients (91 %) and comparative reduction in ear discharge was observed in 2 patients (9 %) and remained as mucoid. Out of 14 patients 1 patient had regained normal hearing (7 %) and in remaining patients (93 %) it was still persisted. It might be because of persisting of dry perforation even after the treatment. In 4 patients (29 %) hearing improvement was observed. It was observed that all the patients were free from earache after the treatment. Out of 8 patients, tinnitus was reduced in 2 patients (25 %), because of formation of thin membrane covering the perforation. In remaining 6 patients (75 %) tinnitus was persisted as it is. But tinnitus was started in 5 patients after treatment, due to conversion of wet perforation in to dry.

The information gathered on the basis of observation with various parameters was subjected to statistical analysis in terms of mean standard deviation (SD) and standard errors (SE). Paired t-test was carried out. A 'P' value < 0.001 was considered to be statistically highly significant. The 'P' value < 0.050 was considered to be non-significant. Results are shown in the Table 2.

Table 2: Showing the effect of the therapy on subjective and objective parameters

S. No	Criterion	Mean difference	SD	SE	Significance level
1.	Perforation of ear drum	0.826	0.388	0.0808	P = < 0.001
2.	Tuning fork test	0.000	0.302	0.0629	P < 0.050
3.	Ear discharge	3.957	1.296	0.270	P = < 0.001
4.	Deafness	0.174	0.650	0.136	P < 0.050
5.	Earache	1.130	1.140	0.238	P = < 0.001
6.	Tinnitus	1.130	1.140	0.238	P = < 0.001

Result expressed from 23 observations (n = 23)

DISCUSSION

Karnasrava is said as an individual disease by Acharya Sushruta¹, which is characterized by ear discharge and pain. Whereas Acharya Charaka⁴ and Acharya Vagbhata⁵ mentioned it as one of the symptoms Karnaroga and Karnashula respectively, were nature of discharge varies according to the involvement of doshas. Chronic suppurative otitis media (CSOM) is a chronic inflammation of the middle ear, which presents with recurrent ear discharge through the tympanic perforation. This disease usually begins in childhood as a spontaneous tympanic perforation due to an acute infection of the middle ear, known as acute otitis media (AOM) or as a sequel of less severe forms of otitis media. The point in time when AOM becomes CSOM is still controversial. Generally patients with tympanic perforations which continue to discharge mucoid material for periods of 6 weeks to 3 months, despite of medical treatment, are recognized as CSOM cases⁶. According to classics, Karnasrava is a treatable disease. Karnapurana is a local procedure done in the ear where ear cavity is filled with lukewarm liquid dosage form of drugs (oil, cow's urine, and juices) for a stipulated period⁷. In the present study only 2 drops of lukewarm Gandhaka taila was instilled in

to the affected ear so as to avoid the complications because of perforation in the eardrum. It was done after proper mopping of the ear; this could facilitate the proper contact of the drug with the affected parts of the ear. Local snehana and swedana around the ear prior to karnapurana is must, this increases the local circulation hence better absorption of the drug. The temperature of the oil should be lukewarm otherwise it may stimulate the labyrinth resulting in giddiness. Shuddha Gandhaka, Shuddha Manhshila, Haridra, Dattura patra swarasa and Katu taila are the ingredients of Gandhaka taila and their properties are almost same i.e. antimicrobial, anti-inflammatory and astringent, which are essential for the treatment of chronic suppurative otitis media. Vitiating of kapha and vata dosha is responsible for the disease Karnasrava. The process of healing is supported by the kapha vata hara properties of ingredients of Gandhaka taila. Tikta, katu, kashaya rasas, ruksha qualities of the ingredients helps to reduce local edema, exudation and inflammation. When applied topically, astringents in low concentrations stimulate the growth of new tissue. Hence the combination of all these drugs might have better therapeutic action due to synergism.

CONCLUSION

The present study aimed to look for an effective, safe and affordable treatment of chronic suppurative otitis media. However the herbo-mineral formulation Gandhaka taila used in the study showed better improvement in the sign and symptoms of chronic suppurative otitis media. This trail drug was found to be well tolerated by the patients with no side effects. As clinical study was restricted to 7 days of medication, relief was mainly observed in the symptoms like ear discharge and earache. By increasing the duration of treatment better results in all the symptoms of chronic suppurative otitis media may be expected.

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Cite this article as:

Sujatha.K, Revanasiddappa S. Sarashetti. Clinical evaluation of effect of Gandhaka taila in karnasrava with special reference to chronic suppurative otitis media. *Int. J. Res. Ayurveda Pharm.* 2013;4(5):708-711 <http://dx.doi.org/10.7897/2277-4343.04517>

Source of support: Nil, Conflict of interest: None Declared