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CHIEF EDITOR – PRAMOD PRAKASHRAO TANDALE

**Clinical Evaluation Of Effect Of Panchakashay Kalpa In Karnasrava
With Special Reference to Granular Myringitis****Vd.Nishad Sathe**
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L.K.R Ayurvedic Mahavidyalaya, Gadhinglaj, Kolhapur.**Abstract**

Ear discharge is a common problem in practice. It is often associated with hearing loss, pain, itching. There are number of causes of Ear discharge, one of them is Myringitis granulosa. Myringitis granulosa is a type of Otitis externa characterized by formation of granulation tissue on lateral aspect of ear drum, sometimes involvement of external auditory canal. Allopathic approaches to treatment have been unsatisfactory and difficult, despite of prompt treatment because there is recurrence of granulation on tympanic membrane. So this disease needs effective and satisfactory treatment. Karnastrava is a disease of ear described in Ayurveda by Acharya Sushruta in Uttartantra. According to modern science ear discharge is a symptom of many diseases of external, middle or inner ear; however Ayurveda considers the ear discharge that is Karnastrava as a individual disease. Panchakashay Kalpa is a unique herbal formulation especially mentioned for Karnasrava with the procedure of karnapurana. To provide clinical evidence and to prove Panchakashay Kalpa as a safe and effective medicine in Granular Myringitis, this study has been carried out. In this study, 23 patients fulfilling the diagnostic and inclusion criteria of granular myringitis were selected and Panchakashay Kalpa was instilled in to 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: Granular Myringitis, Karnasrava, Ear discharge, Panchakashay Kalpa.**Introduction**

Today there is need of Ayurvedic medicines to get popularity and acceptance in the developed countries as the Allopathic system fail and also cause to treat many of the chronic ailments. They the allopathic medicines too cause many adverse reactions. So the Ayurvedic formulations can be accepted in the world but they need scientific data and evidence based clinical data. Karnasrava is one of the diseases of the ear described in many of the classics characterized by ear discharge¹. Ear discharge is a common ENT problem in practice. It is often associated with hearing loss, pain, itching. There are number of causes of Ear discharge, one of them is Granular Myringitis. Granular Myringitis is a type of Otitis externa characterized by formation of granulation tissue on lateral aspect of ear drum, sometimes involvement of external auditory canal. It affects both sexes equally and is still prevalent in world despite of advances in public health and medical care. This disease is common in developing countries especially among the poor because of poor socioeconomic standards, and poor hygienic habits. Allopathic approaches to treatment have been unsatisfactory and difficult, despite of prompt treatment because there is recurrence of granulation on tympanic membrane. So this disease needs effective and satisfactory treatment. As in this disease there is no tympanic perforation, 'Panchakashay Kalpa' trial drug selected in this study doesn't enters the middle ear and thus is safe drug in management of Granular Myringitis. So as to provide

clinical evidence and to prove Panchakashaya Kalpa as a safe and effective medicine in chronic suppurative otitis media, an attempt was made in this study.

Materials And Methods

Source of drug

Panchakashaya Kalpa is a herbal formulation consists Kalka of Tinduk, Lodhra, Manjishtha, Haritaki, Amalaki, Madhu and Kapittha Swarasa. All the raw drugs were collected from L.K.R. Ayurveda pharmacy, Gadhinglaj, India and identified as per classical description in Bhavaprakash, further which were also authenticated by the Department of Dravyaguna, L.K.R Ayurvedic Mahavidyalaya, Gadhinglaj, Kolhapur, India. Panchakashaya Kalpa was prepared strictly as per the reference of Nighantu Ratnakar and guidelines of the classical literature in Rasashastra and Bhaishajya Kalpana practical laboratory of L.K.R Ayurvedic Mahavidyalaya, Gadhinglaj, Kolhapur, India.

Selection of patients

Patients attending *Shalakyatantra* O.P.D. at Late Kedari Redekar Ayurvedic Rugnalaya, P-2, MIDC, Shendri Maal, Gadhinglaj, Dist. Kolhapur and fulfilling the diagnostic and inclusion criteria of Karnasrava (Granular Myringitis) were selected and registered randomly, irrespective of age, sex or religion.

Criteria for Diagnosis

Patients having signs and symptoms of Granular Myringitis 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
- Intrameatal itch.

Signs

Granulation over ear drum.

Inclusion criteria

- Patients willing for trial.
- Patients suffering from Granular Myringitis fulfilling the diagnostic criteria.

Exclusion criteria

- Age below 20 years and above 60 years.
- Granular Myringitis with upper respiratory tract problems like Adenoids, Tonsillitis and Sinusitis.
- Granular Myringitis with systemic disease like Diabetes.
- Granular Myringitis with complications.
- Patients having Tympanic perforation.
- Patients having Polypoidal growth in external auditory canal.

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. Microscopic examination of the ear.

Method of administration of drug

Patient’s attendants are advised to instil 2 drops of lukewarm *Panchakashaya Kalpa* in to the cleaned affected ear three times a day for 10 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 10th day. Follow up was done on 20th day and 30th 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
- Intrameatal itch

Objective parameters

- Granulation over ear drum
- Tuning fork test

Table 1: Scoring table of Objective parameters

Objective Parameter	Finding	Points
Perforation of ear drum	Healed – no Granulation	0
	Inactive – dry Granulation	1
	Active – wet Granulation	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 20 years and maximum was 60 years. Majority of the patients were males (70 %) and females 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 (81 %), followed by 2 patients from Muslim community (19 %). It was observed that Granular Myringitis was more prevalent in lower middle class (56 %), 6 belonged to middle class (26 %), 2 were very poor (8 %) and 2 belonged upper middle class (8 %). The chief occupations of patients noted in the study were housewives (48 %), students (22 %), office workers (17 %) and field workers (13 %). In the present study, it was observed that, 60 % patients belonged to rural area and 40 % patients to the urban area. Maximum patients had ear discharge since 1-2 months (48 %), 17 % patients were belonged to 3-4 months chronicity, 13 % patients had 5-6 months chronicity and 17 % patients were

suffering since 7-8 months. Out of 23 patient 14 were suffering from ear discharge with conductive hearing loss, and 7 had ear discharge with itching.

Effect of therapy on CSOM

Objective parameters

Out of 23 patients, Granulation over the ear drum was found healed in 3 patients (13 %), in 2 patients (9 %) it was remained as wet Granulation and remaining 18 patients (78 %) had dry Granulation 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.

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 %). Out of 14 patients 1 patient had regained normal hearing (7 %) and in remaining patients (93 %) it was still persisted. In 4 patients (29 %) hearing improvement was observed. It was observed that all the patients were free from Intrameatal itch after the treatment.

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.	Granulation over 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

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. Where as Acharya Charaka⁴ and Acharya Vagbhata⁵ mentioned it as one of the symptoms Karnaroga and Karnashula respectively. Karnasrava is a treatable disease as per Ayurveda. 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 period. In this study only 2 drops of lukewarm *Panchakashaya Kalpa* was instilled in to the affected ear. 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 drug should be lukewarm otherwise it may stimulate the labyrinth resulting in giddiness. Tinduk, Lodhra, Manjishtha, Haritaki, Amalaki Kapittha are the ingredients of *Panchakashaya Kalpa* and their properties are almost same i.e. anti-inflammatory and astringent, which are essential for the treatment of chronic suppurative otitis media. Vitiation of kapha and vata dosha is responsible for

the disease Karnasrava and all are Kashaya so they cause Stambhan which helps in reducing ear discharge, also due presence of acetic acid in this Kalpa it acts as cauterization and healing of granulation.

Conclusion

This study was aimed to look for an effective, safe and affordable treatment of Granular Myringitis. This study showed that this herbal formulation better improvement in the sign and symptoms of Granulation. This trail drug was found to be well tolerated by the patients with no side effects. As clinical study was restricted to 10 days of medication, relief was mainly observed in the symptoms like ear discharge and itching.

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