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A CLINICAL STUDY ON EFFECT OF *KARANJA TAILA* IN MANAGEMENT OF OTOMYCOSIS

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ABSTRACT

Otomycosis is fungal infection of external ear canal. It is type of otitis externa caused by the fungi. Present study is conducted on 16 patients. In this Group, these16 patients of otomycosis were treated with *Karanj Taila Karnapooran*. Clotrimazole (ear drop) was used as standard drug. Sign and symptoms of otomycosis were studied before and after the treatment. Result showed that *Karanja Taila* application has cured significant no. of patients.

KEYWORDS: *Karnapooran, Otitis externa, Karanja Taila, Otomycosis.*

INTRODUCTION

Otomycosis is the fungal infection of external ear canal. Otomycosis make up to 10% of all outer ear infections. The incidence of otomycosis has increased in temperate region in proportion to the use of topical antibiotic which provide a suitable medium for growth of fungus. The antibiotic remove competition for fungus by killing the bacteria in EAC. The commonest causative organisms are *Aspergillus niger, Candida albicans, Aspergillus flavus and Aspergillus fumigatus*.

Otomycosis is form of otitis externa which is inflammation of skin of external ear canal. The inflammation can be restricted to epithelium or it may involve the deeper tissue like cartilage and bone. Fungal infection of ear canal can be corelated to skin disease (*kushtha roga*) in ayurveda.

In ayurveda *Kushtha* is the umbrella term used for group of skin disease. *Dadru* is a disease which resemble the otomycosis in its signs and symptoms. *Dalhan* commentator of Sushruta Samhita has described two types of *Dadru* which are *Sita* (white) and *Asita* (black*)*. White and creamy appearance of fungi is sign of presence of *Candida albicans* which is common cause of otomycosis. Black spores are present in EAC is due to *Aspergillus niger. Asita* variety is hard to cure similarly *Aspergillus niger* infections are more aggressive than candidal infections.

General line of treatment of *Kushtha* include *Samshaman* and *Sanshodhan chikitsa.* In *Samshaman Chikitsa* of *Kushtha* local application of *Karanja Taila* on lesion is prescribed in *Charak Chikitsa 7*. The aim of research is to know effectiveness of *Karanja Taila* when applied in ear canal. *Karanj* is supposed to exhibit antifungal properties and used to treat many skin diseases included fungal infections.

AIMS AND OBJECTVES

1. To assess the efficacy *Karanja Taila* in the management of Otomycosis.

MATERIAL AND METHODS

Selection of patients

- The patients fulfilling inclusion criteria, attending the O.P.D. of Department of *Shalakya tantra*, Rajiv Gandhi govt postgraduation Ayurvedic college Paprola were selected irrespective of age, sex, religion, race, occupation, etc.
- A detailed proforma was prepared incorporating Ayurvedic and Modern points.

Inclusion criteria

- The selection of patients was done on the basis of signs and symptoms of otomycosis and uncomplicated patients who were willing for enrolment in trial were selected from ENT OPD of R.G.G.P.G.A. Hospital Paprola irrespective of age, gender, religion and occupation.

Exclusion criteria

- Patients with perforated tympanic membrane were excluded from the study.

Sampling method

- Random sampling method

- **PREPARATION OF DRUG**
- Cold compressed *Karanja* oil is used for trial. It contains single drug i.e. *Karanja* (*Pongamia pinnata*).

- **STUDY DESIGN**
- The study was conducted on 16 diagnosed patients of otomycosis separately.

ETHICAL CLREARANCE

- The study was cleared by the institutional ethics committee. Written consent from each patient willing to participate before starting the study was taken. For those patients who were unable to read or write consent of their relative was taken. Patients were free to withdraw their name from the study at any time without giving any reason.

Clinical study was accomplished in three phases:

- Diagnostic Phase
- Interventional Phase
- Assessment Phase

1) Diagnostic phase

Patients were selected for trial based on clinical presentation and finding suggestive of otomycosis. Otoscopic examination of patient's both ears were done to evaluate signs and symptoms suggesting of otomycosis and diagnosis was confirmed on the basis of otoscopic finding.

Then routine blood examination like CBC, ESR and BT, CT, blood sugar were done to rule out any underlying disease.

A special proforma was prepared for the evaluation of the etiopathogenesis and assessment of treatment efficacy. History proforma incorporated all the signs and symptoms of otomycosis. All the points in the perspective of *Dosha, Dushya, Strotas* and *Agni* were also included. A detailed present history of illness was taken and simultaneously general and systematic examinations of the patients were done.

The subjective criteria of diagnosis of otomycosis were based sign and symptoms described in text.

a) Ear discharge
b) Pain in ear
c) Itching in ear
d) Blockage in ear
e) Fungal mass in ear

2) Intervention Phase-

After careful examination,16 patients selected from ENT OPD of *Shalakya Tantra* Deptt. of R.G.G.P.G.A.C. Hospital, Paprola.

- **Group A** - Patients were managed with *Karanj Taila* (*Karnapoorana* -1ml) for 5-7 minutes twice a day for 15 days after ear toileting.
- **Group B** - clotrimazole 1% ear drop (control group)

Follow-up: the patients are asked to come for follow up on day 7 and Day 15 of commencement of trial.

Instruction

- Patients were instructed to avoid entry of water in ear at every cost. Patient is asked to keep cotton wick immersed in petroleum jelly or glycerine while bathing and afterwards.
- Avoid to catch any infection of ear nose throat like rhinitis, pharyngitis etc.

Under all the above circumstances the observations were recorded and result of study was assessed.

3) Assessment phase

Assessment of treatment of the disease was done on the relief in following signs and symptoms. Symptomatic relief obtained by the treatment given was assessed periodically after seven days of initial scoring, till completion of trial.

Symptoms

Itching	**Grade**
Absence of itching	0
Occasional itching	1
Frequent itching but not causing much discomfort	2
Frequent itching and causing discomfort	3

(ii) Pain in Ear	**Grade**
• Absence of pain	0
• Occasional pain with low intensity	1
• Frequent pain with moderate intensity	2
• Continuous pain with severe intensity which hampers hearing	3

(iii) Discharge	**Grade**
• Absence of Discharge	0
• Watery discharge	1
• Thick discharge	2
• Thick, purulent and discharge with smell	3

iv) Blockage in Ear	**Grade**
• No Blockage	0
• Fungal growth is seen only on the walls of external ear canal	1
• Partial blockage external ear canal	2
• Complete blockage of external ear canal	3

(v) Fungal Mass	**Grade**
• No Fungal Mass	0
• Dry white/brownish/yellowish sheet	1
• Wet & darkish white resembling bloating paper	2
• Wet & blackish or brown	3

Overall effect of therapy

- Cured: 100% relief in subjective and objective symptoms.
- Marked improvement: 76-99% relief in signs and symptoms of otomycosis.
- Moderate improvement: 51-75% relief in signs and symptoms of otomycosis.
- Mild improvement: 26-50% relief in signs and symptoms of otomycosis.
- Unchanged: Upto 25% relief in signs and symptoms of otomycosis.

RESULT

The data obtained on the basis of observations was subjected to statistical analysis in terms of mean, standard deviation error by applying the unpaired '*t*' test. The results were interpreted

at the level of $P<0.001$ as highly significant, $P<0.05$ or $P<0.01$ as significant, and $P>0.01$ as insignificant.

Total effect of therapy

The efficacy of *Karanja* oil (*Karnapooran)* was adjudged in 16 patients on various parameters of assessment criteria and result were derived after executing statistical analysis[Table 1].

Table 1

Criteria	Group A	N	Mean		X (d) BT-AT	% of relief.	S.D.	S.E.	t	p	Sig
			BT	AT							
Discharge	Rt	**44**4	0.375	0.00	0.375	100	0.806806	0.202**20**	1.861	0.083	IS
	Lt	4	0.438	0.250	0.188	42.9	0.814	0.203	1.861	0.083	IS
Pain in ear	Rt	7	0.563	0.062	0.501	88.8	0.727	0.182	3.162	0.006	S
	Lt	9	0.875	0.250	0.625	83.3	0.957	0.238	3.478	0.003	S
Itching	Rt	4	0.438	0.125	0.313	75.7	0.727	0.182	1.775	0.096	IS
	Lt	5	0.750	0.250	0.500	66.6	1.125	0.281	2.070	0.003	S
Blockage	Rt	8	0.813	0.250	0.563	69.2	0.981	0.241	3.093	0.007	S
	Lt	11	1.563	0.750	0.813	59.5	1.365	0.341	3.896	0.001	S
Fungal mass	Rt	8	0.688	0.313	0.375	54.5	0.946	0.237	2.423	0.029	IS
	Lt	11	1.188	0.938	0.250	21.04	1.167	0.292	2.236	0.041	S

Overall effect of therapy

Table no.2

	Group A (16)	
	No of patients	**Percentage (%)**
Cured	3	18.75
Markedly Improved	3	18.75
Moderately Improved	5	31.25
Mildly Improved	1	6.25
Unchanged	4	25

In group A, 18.75% patients got completely cured, 31.25% got moderately improved, 18.75% got markedly cure, 6.25% got mild relief in symptoms and 25% patients got no relief in symptoms.

DISCUSION

Otomycosis is a common fungal infection of external ear canal especially occurs in the subtropical countries due to moist and hot climatic condition.

Clinical features of otomycosis are irritation, pain, itching and blockage of ear which is quite troublesome to the patient.

Physical manifestation of otomycosis can be correlated to *Dadru Kushta* explained by *Dalhan* in his Commentary on *Sushruta Samhita.*

Types of *Dadru kushta*

Asita(black)

Sita (white)

'ददुकुष्ठं द्विविधं सितमसितं च ।

असितस्य महोपक्रमसाध्यत्वादनुबन्धित्वप्रकर्षाच्च महकुठेषु ।

सितदद्रुकुष्ठस्य सुखसाध्यत्वादुत्तरोत्तरधात्वानुप्रवेशाभावात्तथाऽत्यर्थपीडारहितत्वाच्च।

Dadru Kushtha is the type of *Kushtha* which we relate with the fungal disorder.
Aacharya Charak has classified it qinto *Kshudrakushtha* and it occurs due to *Pitta Kapha* dosha. *Acharya Sushrut* has put it into *Mahakushtha* and occur due *Kapha dosha*. *Acharya Vagbhat* kept it *Mahakushtha* and it occurs due predominance of *Pitta Kapha Dosha*.

When we emphasize on etiological factor of *Kushtha*, exposure to water is a factor mentioned by *Acharya Sushruta* (*Majjatiapsu*) and *Acharya Bhela. Acharya Sushruta* has said that playing in water (*Jalkrida*), exposure to moisture (*Avshyaya*) are the common etiological factor of all *Karna Rogas*. Similarly in modern science exposure of water in to ear can cause diffuse otitis externa, otomycosis, CSOM recurrence. If we see incidence of otomycosis, no of cases increase during monsoon months of July, August and September due to increased humidity. This humidity and warmth precipitate the growth of fungi in ear canal.

Kandu is also feature of *Dadru Kushtha* which we relate with the fungal disorder. Itching in ear is a common feature found in otomycosis. *Kandu* is a common feature of various *Karna Rogas*. *Kandu* is the feature of *Dadru* mentioned by *Charak*, *Sushruta* and *Vagbhat.*

Acharya Kashyap has mentioned the *Dadru* is *Ruksha (*dry) and *Sraavvanti* (discharging*) mandala*. *Daha* is symptom of *Dadru* given by *Acharya Kashyap*.[1]

Acharya Dalhan has divided *Dadru* into two types *Sita* and *Asita* type. White and creamy appearance of fungi is due to *Candida albicans* which is common cause of otomycosis. Black

spores are present in EAC is due to *Aspergillus niger. Asita* variety is hard to cure similarly *Aspergillus niger* infection are hard to cure than candidal infections.

***Ayurvedic* review**

- *Karanja* is mentioned among the *Kandughna Varga* by *Charaka.*
- *Acharya Sushruta* highlighted the utility of *Karanja Taila in Krimi, Kushta, Prameha* and *Siroroga* and quoted it as *Kapha-Vathara, Shothahara, Kandughna* (anti-itch) and *Bhedana.*
- *Karanja* is *Katu Tikta Rasa Pradhan dravya.* With the properties of *Katu* and *Tikta Rasa*, it will encounter *Vaata* and *Kapha Dosha*. Due to Discharge and fungal mass in ear, healing process is hampered, *Katu* and *Tikta Rasa* contain *Shodhana* property which can help in opening of channels and promotes absorption ultimately promoting healing process.

Karanj taila has *Laghu, Teekshana Guna. Laghu Guna* having *Lekhana* and *Ropana* properties help in healing of wound and encounter *Vaata* and *Kapha Dosha.*

Ushna Veerya is another property of *Karanj Tail.* Due to its *Ushna Veerya* it will encounter *Vaata Dosha* and *Gati* of *Vata* gets normalized (*Anulomana*). This way it will work on functional mechanism.

Kushthgan property is supposed to be due to its *Prabhava*.

Modern review

- There are various phytochemicals isolated from the *Pongamia. pinnata* plant.
- It contains *Karanjin, pongapin, Karanja chromen*. It shows antibacterial, hypoglycaemic activity.
- The essential oil from P. pinnata showed mild antifungal activity.
- However, the antifungal and antibacterial activity of *Karanja* was attributed to Pongarotene, a new rotenoid.
- *Karanjin* is the principal *furanoflavonoid* of the plant. Researcher group established that *karanjin* inhibit oxidative stress via regulating NO, and ATPase. So it acts as anti-inflammatory and antiulcer agent.

CONCLUSION

- Otomycosis can be compared with the *Dadru Kushtha* explained by *Dalhana*.
- Analysis of study reveals that otomycosis was found more commonly in females, housewives, person having *Vatapittaj Prakriti* and literate persons. But no relevant relation of age, gender, diet, bowel habit and urinary habit with occurrence of otomycosis can be concluded. Disease occurs in middle class population but no relevant conclusion can't be drawn from it.
- Unilateral affiliation of ear is maximum but can occur bilaterally.
- Genetic factor didn't play much role.
- *Vattapitttaj Prakriti* are found more prone to this disease.
- Maximum number of patients were registered for trial in the month of July and August.
- Allergic response of pinna was noticed with application of *Karanja Tail* in 18.75 % of patients. aIt causes thickened swelling of pinna with redness and itching which occurs after 10-12 days of regular application of oil. It was treated with use of steroid and antibiotic ointment application.
- Regular cleaning and keeping ear canal dry are necessary for prevention and better efficacy of drugs.

Present study requires to be repeated on large sample and observation of result should be done for longer period to assess duration of the effect and complication.

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