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Research Article

A CRITICAL ANALYSIS STUDY ON OTALGIA MANAGEMENT BY GARLIC DROPS AND BENZOCAINE DROPS- AN ATTEMPT TO COMPARE THE EFFICACY OF MODERN AND AYURVEDA MEDICINE IN A SINGLE AILMENT

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ABSTRACT

Otalgia or ear ache is a symptom which will hamper the daily activities of individual, and a cause of unease or discomfort. There might not be any single individual who has not affected with earache in their lifetime, atleast once in their span of life..Even today there is no specific permanent remedy to this condition in advance modern medical system despite of some Otogesics which will only mask the pain. The common Over the Counter medicines available on medical stores are having side effects on continuous usage. So there is a need for safe Ayurvedic medicine which can acts better like modern analgesics but less side effects. **Methodology:** In this comparative study of *Lasuna putapaka swarasa* (Garlic Drops) and Benzocaine Otogesic drops, 40 patients of Otalgia were randomly selected and divided to two groups of 20 patients each. Group A was treated with the ear drops of *Lasunaputapaka swarasa* (Garlic Drops) and Group B was treated with Benzocaine Otogesic ear drops. **Observations:** It was observed in the present study that Group A showed better results in reducing the symptoms of Otalgia. Re-occurrence of symptoms were merely less in Group A patients compared to Group B patients. **Conclusion:** There is a false assumption that Ayurvedic medicines are slow acting and desperately using for pain management and acute conditions. But this study throwing a light to substantiate that, Ayurvedic medicines are potent enough to manage acute otalgia also, just like Otogesics in Modern Medical Science. The study revealed that the re-occurrence rate of symptoms was very less in patients who used Garlic drops and was safe acting also.

KEYWORDS: *Lasunaputapaka swarasa,* Garlic Drops*, Karnapoorana, Otalgia,* Benzocaine Ear drops*.*

INTRODUCTION

Shalakyatantra, also called *Urdhwanga chikitsa Shastra*, described diseases which are affecting to organs above the clavicle, along with their signs, symptoms and prognosis and also mentioned different methods of management including local therapies and surgical treatments. Otalgia or earache causes the life of common man unease, causing stress and strain which needs immediate medical attention. The specific remedies in modern system of medicine are Otogesics which will just hide the sensation of pain rather than treating the underlying pathology. There are several medicines and regimens regarding *Karnashoola* in *Samhithas* and other literatures. Those Ayurvedic drugs are being proven for safe acting also. It is yet to be prove that these medicines are fast acting in relieving pain as much speedy as a modern medicine can do..Hence should also convince that it cannot be cause any side effects on prolonged use, meanwhile preventing the re-occurance of symptoms. Here the commonest, easiest cost effective and more abundant available drugs are taken for the study. More over these drugs are having antimicrobial, anti-inflammatory and analgesic action.[1]

The present study is instilling drops of *Lasuna putapaka swarasa* (Garlic Drops) and Benzocaine drops, in different patients having symptoms of acute otalgia. *Lasuna Swarasa Karnapoorana* is mentioned in *Sahasrayoga*[2] and praised for its sudden action for reduction of ear ache. A research study on this subject is not yet reported and its efficacy is to be proved statistically, which is being tried here. *Karna poorana*[3] or instilling drops in ear is a simple safe specific therapy mentioned in *Karnashoola*. The drug *Lasuna*[4] is very economical and easily available.

OBJECTIVES

The objectives of present study are

- To evaluate the efficacy of *Lasuna putapaka swarasa karna poorana* in the management of Karnashoola/ Otalgia. (Ayurveda Medicine)
- To evaluate the efficacy of Benzocaine otogesic drops in the management of *Karnashoola*/ Otalgia. (Modern Medicine)
- To compare the effectiveness of *Lasuna putapaka swarasa* (Garlic Drops) and Benzocaine drops in the management of *Karnashoola/* Otalgia.
- Main aim of this study to substantiate the use of Ayurvedic medicine in an acute painful condition, comparing the effect of this Ayurvedic drugs in pain management with allopathy analgesics. Also checking its efficacy in reducing pain in short while duration and expecting its long term potential stability without any reoccurrence of symptoms.

AIM OF THE STUDY

Want to substantiate several facts related to Ayurvedic medicines when comparing to modern system of medicines.

In this present study, trying to disclose certain truth related to Ayurveda medicines to prove its genuinely, as a traditional and evidence based system of medicine by managing *Karnashoola*, a prime disorder in the field of *Shalakya*.

Facts gets proved about Ayurveda medicines in this study

- Fast acting, can beat modern medicine also
- Can use in acute conditions like severe Otalgia
- Never cause Side effects even in long usage also
- Chance of re-occurance of symptoms is very rare
- Proper research work documentation is possible
- Non -Biased, evidence based health system

METHODOLOGY

40 Patients of *Karnashoola*/Otalgia were selected among a large number of patients attending OPD of Shalakyatantra in SJIIM Hospital, Bengaluru (Govt. Ayurveda Medical college Hospital, Bengaluru) and K.C General Hospital, Malleshwaram. The selected patients were randomly divided in to two groups, Group A & Group B consisting of 20 patients.

Group A- Trial group with *Lasuna Putapaka swarasa karnapoorana.*- Garlic Drops.

Group B- Control group with Otogesics Benzocaine drops.

Treatment procedure: Instillation of drops in ears.

Table 1: Showing the treatment plan for Group A and Group B

Group	Treatment procedure	Dose	Duration of treatment	Follow up
Group A	*Lasuna putapaka swarasa* (Garlic Drops)	For *Karna poorana* as much needed. Preferably 6 drops.	5 days	Once in 15 days For one month
Group B	Benzocaine drops	3 drops	5 days	Once in 15days For one month

Inclusion Criteria

- Age group– 18 to 60 years
- Irrespective of caste, religion, sex, economic, social, educational status etc.
- Subjects fulfilling the diagnostic criteria which are based on signs and symptoms of simple otalgia.

Exclusion Criteria

- Referred otalgia
- Subjects suffering from suppurative otitis media.
- *Karnashoola* due to *Abhighata* (injury).
- Perforated ear drum.
- Otalgia associated with other diseases like vascular tumour of middle ear, aneurysms of carotid artery, palatal myoclonus, meningitis etc.
- Other systemic disorders like hypertension etc.
- Pregnant and lactating women
- Patients suffering from any chronic debilitating disease like CA, Koch's, HIV etc

Assessment Criteria

Effect of the *Karnapoorana* assessed by the signs and symptoms before and after the procedure.

It was on the basis of both standard and self formulated scoring scale according to signs and symptoms.

Standard scoring scale

1. Visual analogue scale (VAS)
2. Numeric pain rating scale

Self formulated scoring scale

- Complete Relief: 100% relief in objective and subjective signs and symptoms.
- Marked Relief: 76-99% relief in objective and subjective signs and symptoms.
- Moderate Relief: 51-75% relief in objective and subjective signs and symptoms.
- Mild Relief: 26-50% relief in objective and subjective signs and symptoms.
- No Relief: Upto 25% relief in objective and subjective signs and symptoms.

Parameters

a) Subjective Parameter

Karnashoola– otalgia (As per scale) Visual Analogue scale & Numeric pain scale.
Sense of Fullness of ear– (Mild/ moderate /severe)
Muffled hearing- (Mild/ moderate /severe)
Dizziness- (Mild/ moderate /severe)
Itching in ear- (Mild/ moderate /severe)

b) Objective Parameter

Tenderness:
(mild/moderate/severe/reduced/absent).

Investigations

Blood routine- Hb%, TC, DC, ESR (for necessary patients)

OBSERVATIONS AND RESULT

40 patients were recruited in this clinical trial (20 in each group), all patients received intended treatment for allotted duration and were analyzed for the primary and secondary outcomes. No patient was drop out from the study.

Table 2: Day wise assessment of ear ache of Group A (*Lasuna*/ Garlic drops) by VAS Scale

Day wise analysis	%	SD	SE	t value	p value	Remarks
Day 1	24%	2.36	0.42	4.03	<.001	S
Day 2	31%	3.65	0.53	4.79	<.001	S
Day 3	45%	5.74	0.34	6.49	<.001	S
Day 4	62%	7.45	0.65	9.26	<.0001	HS
Day 5	77%	9.64	0.6	12.53	<.0001	HS

Analysis: Day wise analysis of otalgia in Group A shows in Day 1- 24% improvement in symptoms with t value of 4.03 with p value <.001 considered as significant result. In Day 2, 31% improvement in symptoms with t value of 4.79 with p value <.001 considered as significant result. In Day 3- 45% improvement in symptoms with t value of 6.49 with p value <.001 considered as significant result. In Day 4- 62% improvement in symptoms with t value of 9.26 with p value <.0001 considered as highly significant result. In Day 5-77% improvement in symptoms with t value of 12.53 with p value <.0001 considered as highly significant result.

Table 3: Day wise assessment of ear ache of Group B (Benzocaine drops) by VAS Scale

Day wise analysis	%	SD	SE	t value	p value	Remarks
Day 1	19%	2.43	0.25	2.16	<.01	S
Day 2	27%	3.73	0.46	2.52	<.01	S
Day 3	36%	3.94	0.52	4.54	<.001	H.S
Day 4	44%	5.12	0.64	6.14	<.001	H.S
Day 5	53%	7.45	0.69	7.65	<.001	H.S

Analysis: Day wise analysis of otalgia in Group B shows in Day 1- 19% improvement in symptoms with t value of 2.16 with p value <.01 considered as significant result. In Day 2, 27% improvement in symptoms with t value of 2.52 with p value <.01 considered as significant result. In Day 3- 36% improvement in symptoms with t value of 4.54 with p value <.001 considered as highly significant result. In Day 4- 44% improvement in symptoms with t value of 6.14 with p value <.001 considered as highly significant result. In Day 5- 53% improvement in symptoms with t value of 7.65 with p value <.001 considered as highly significant result.

Table 4: Comparative results of Group A and Group B. Symptoms wise Results

Characteristics	Group A			Group- B		
	Mean score		% of relief	Mean score		% of relief
	BT	AT		BT	AT	
Ear ache	8	1.7	78.75%	8.2	3.8	53.65%
Tenderness in ear	5.3	2.4	54.71%	4.6	2.6	43.47%
Muffled hearing	4.7	2.1	55.31%	4.9	3.4	30.61%
Itching in ear with fullness	5.9	3.1	47.45%	5.4	2	62.96%

Analysis: Comparing the result of Group A and Group B, it is showing that Ear ache: Those patients who were having ear ache, got 78.75% relief with a mean score of 8 before treatment and 1.7 after treatment in Group A, while 53.65% relief from symptoms with a mean score of 8.2 before treatment and 3.8 after treatment in Group B Tenderness in ear: Those patients who were having tenderness in ear got 54.71% relief with a mean score of

5.3 before treatment and 2.4 after treatment in Group A, while 43.47% relief from symptoms with a mean score of 4.6 before treatment and 2.6 after treatment in Group B. Muffled hearing: Those patients who were having muffled hearing, got 55.31% relief with a mean score of 4.7 before treatment and 2.1 after treatment in Group A, while 30.61 % relief from symptoms with a mean score of 4.9 before treatment and 3.4 after treatment in Group B. Itching in the ear with sense of fullness: Those patients who were having itching in the ear with sense of fullness got 47.45 % relief with a mean score of 5.9 before treatment and 3.1 after treatment in Group A, while 62.96 % relief from symptoms with a mean score of 5.4 before treatment and 2 after treatment in Group B.

Table 5: Reoccurrence in Group A and Group B during follow up

Reoccurrence	Group A		Group B		Total	
	No	%	No	%	No	%
	2	10%	7	35%	9	22.5%

Analysis: Among Group A, 2 patients showed reoccurrence of symptoms with in follow up period, 7 patients from Group B and 9 patients out of 40.

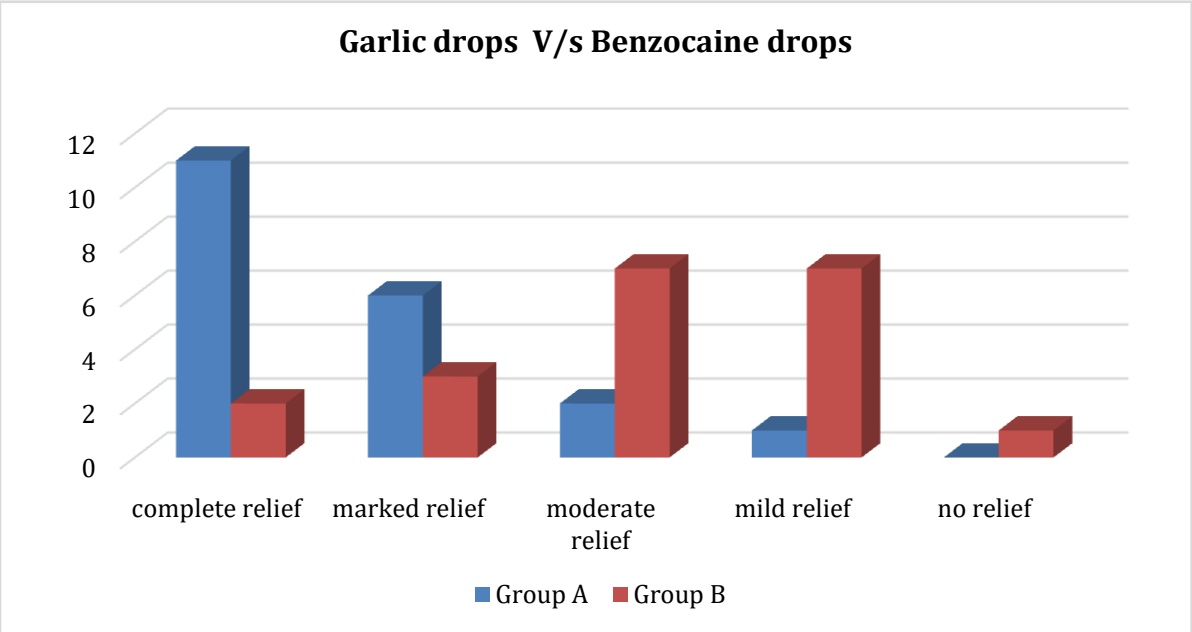
Table 6: Overall effect of Treatment

Overall effect of treatment				
Grading	**Group A**		**Group B**	
	No	**%**	**No**	**Percentage**
No relief (0-25%)	0	0	1	5%
Mild relief (26-50%)	1	5%	7	35%
Moderate relief (51-75%)	2	10%	7	35%
Marked relief (76-99%)	6	30%	3	15%
Complete relief 100%	11	55%	2	10%

Analysis: Group A -11 patients (55%) got complete relief, 6 patients (30%) got marked relief, 10 patients (10%) got moderate relief, 1 patient (5%) got mild relief and no patients (5%) were in no relief category.

Group B -2 patients(10%) got complete relief, 3 patients (15%) got marked relief, 7 patients (35%) got moderate relief, 7 patient (35%) got mild relief and 1 patient(5%) were in no relief category. (FIGURE 1)

Effect of treatment in Group A and Group B



DISCUSSION

Probable mode of action of *Lasuna putapaka* drops (Garlic Drops)

The constituent in this *Lasuna putapaka* drops is *Rasona* –a potent drug which has been explained in Ayurvedic treatises for *Vedhana sthapana krimihara* properties[5]. By checking the phyto constituents lasuna contains diallyl sulphide[6] which is best analgesic and anti-inflammatory. It is having antioxidant activity also, protect the cells from damage caused by free radicals-highly reactive oxygen compounds. It contains vitamin A, C, E, K, carotenoids, terpenoids flavonoids saponins polyphenols and minerals which help in doing analgesic antipyretic and anti-inflammatory actions. The allopropyl disulphide doing inhibition of peripheral prostaglandins which results in reduction of pain.

Also contains thiols, thiosulphinates which is having antimicrobial activity.

Mode of action of Benzocaine drops

This medication is composed of Benzocaine, Chlorbutol, Paradichlorobenzene and Turpentine Oil. The drops work by inhibiting pain signals from the nerves to brain which decreases the sensation of pain. It also exerts antibacterial and antifungal actions. This drug is a local anesthetic that having an anti-inflammatory action also. It binds reversibly to sodium channels and decreases neuron permeability to sodium ions. This inhibits neuronal membrane depolarization, which stops nerve impulse initiation and conduction.

Mode of action of *Karnapurana*

In *Karnapoorana sthanika abhyanga* and *Swedhana* increases the blood supply and helps in absorption of the drug. A group of proteins called the Heat shock proteins in body possess a special property of Chaperon activity. This is something like an anti-oxidant activity. In case of ototoxic drug intake, exposure to loud noise, infections, free radical attack, the Heat shock proteins cover up the outer hair cells i.e. come to lie upon the tip of hair cells and they get destroyed during the defense process, thus protecting the hair cells from getting damaged and there after the effects caused by damage. The Heat shock proteins can be excited and produced with an application of mild heat. This action is brought about by *Karnapoorana*. The fomentation causes local Vasodilatation, thus enhances blood supply in tunica vascularis. The medicines using in the *Karnapoorana* are having properties like antimicrobial anti-inflammatory helps in reducing otalgia associated with infections.

Mode of action of drops instillation in ear

The ear canal is lined by thin keratinized stratified squamous epithelium covering fibrous stroma along entire canal and covering external tympanic membrane. This area is very sensitive and enriched with collagenous villi where there is a maximum chance of absorption taking place. The medicine which are in aqueous and lipid phase will get absorbed easily as depends on the contact time.

The ear canal is of two parts 1. Cartilaginous 2. Osseous parts. The cartilaginous part is pigmented with hairs and glands and Osseous part is non-pigmented without any glands.

The highest rate of absorption is happened in the Osseous part which is rich in columnar epithelium. As the Osseous part is narrow, around 3-4 drops of medicine was sufficient to cover and to facilitate absorption.

CONCLUSION

Karnashoola explained in Ayurveda treatises cannot be merely correlated to the symptom Otalgia of modern science. But the entire terminology of *Karnashoola* engulfs different other symptoms which is always associates with otalgia like muffled hearing tenderness in the ear, sense of fullness, itching and dizziness in the ear. The present study shows that *Karnashoola* need not necessarily be associated with discharge from ear, fever etc. But there is a chance to accompany the symptoms like tenderness in ear, muffled hearing, sense of fullness, dizziness, itching etc without appearing the symptoms of discharge and tympanic membrane perforation. Benzocaine Drops are famous among ENT specialists in treating Otalgia like symptoms. It is one of the best drugs selling "Over The Counter" for curing ear ache. In this study therapeutic procedure *Karnapoorana* with *Lasuna putapaka swarasa* (Garlic Drops) proved effective when compared to Benzocaine drops in reducing otalgia and other symptoms related to *Karnashoola*. Instilling the drops of Benzocaine has shown promising results in reducing the pruritis/itching in the ear canal with associated otalgia. Follow up study showed recurrence of Otalgia is significantly less in patients administered with *Lasuna putapaka swarasa* (Garlic Drops).

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