

Original Research Article

Effect of Arkapatra Swaras in the Management of Karnashool with Special Reference to Diffuse Otitis Externa

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ABSTRACT

Ayurvedic literature regarding otalgia is mentioned in samhitas. Karna is the seat of shraavanendriya, Karnashool is the separate disease entity according to Ayurved, but it is one of the symptoms according to modern otology.

In present study an attempt has been made to work on diffuse otitis externa.

Karnashoolhara yoga which is mentioned in Sharangadhara uttarakhanda 11/32, and Yogratanakar uttarakhanda is made by riped arkapatra extract (Swaras) as the arkapatra is vedansthapan, Shothahara, vrunkhara.

The drug used for control group having contents of ofloxacin3%, beclomethasone0.25%, Clotrimazole1%, lignocaine2%.

In trial group 86.67%, patients got relief in control group 90%, patients got relief in all signs and symptoms.

This analysis shows there was 3.33%, more belief in control group Patients which statistically insignificant. So, no significant difference in treatments of both groups.

Key Words: Arkapatra Swaras, Karnashool, Diffuse Otitis Externa.

INTRODUCTION

Shalakyata tantra one among the 8 branches of Ayurveda deals with precious sense organs, the diseases affecting them and their management. In Ayurvedic literature the karna is the seat of Shraavanendriya, the functional aspect of hearing. Karnashool is the commonest diseases affecting the children to old age people. Karnashool is a separate disease entity mentioned by Acharya Sushruta in the chapter of karnagata vigyaniya. Karnashool especially seen more in children, Hearing impairment may be seen associated with Karnashool. According to Sushruta the pathogenesis of Karnashool explained as in the ear canal the vitiated vata dosha is encircled by pitta kapha Rakta and other

types of vata and causes Vata viloma gati (improper circulation of vata) and produces pain in the ear is known as Karna shool. Pain in the ear may arise from the auricle, the external meatus or the middle ear and mastoid, or it may be referred from other sources. Descriptions of pain vary. Karnashool is one of the symptoms according to modern otology. Karnashool vyadhi can be correlated with diffuse otitis externa. In present study, an attempt has been made to work on diffuse otitis externa. Diffuse otitis externa, defined as generalized inflammation of the external ear canal, with or without involvement of the pinna or tympanic membrane, It is diffuse inflammation of meatal skin which may spread to involve the pinna and epidermal

layer of tympanic membrane. Acharya Sushruta had mentioned about Arkankur to treat the Karnashool. There are several regimens regarding Karnashool in various Samhitas And other literatures; the commonest, easiest and more abundant available plant is Arka. The ghee should be applied on the arka leaves, which are yellow in colour heated on agni and the swarasa should be extracted & pour into the ear, it relieves Karnashoola. Arkapatra swarasa: It may be effective in curing the Karnashool, it is mentioned in Samhitas that it is Vedanasthapana, Shothahara, Vranashodhana, Kushthaghna. Here, an attempt has been made to compile the knowledge of Ancient Ayurvedic Scholars scattered in Ayurvedic texts so as to present it systematically, which is one of the requirements of the Present era.

Need of study:

- Considering the wide popular usage of *ARKA PATRA*, as a medicine taken for Karnashool
- Easily available all over India
- Cost effective
- Home remedy & easily prepared

The prepared Arka patra swarasa is not having any side effects, as compared with modern ear drops, where as the persistent use of modern ear drops may leads to resistance of that medicine. To study the efficacy of topical application of medicine i.e. swarasa in Ayurveda for treating the Karnashool, as compared with modern ear drops. So to expose the Swarasa concept in modern era which were told by our Acharyas, and to highlight the concept, by taking into above consideration it has been decided to work on alternative effective remedy for the patient's compliance. So the Aim of this Study is the Effect of Arka Patra Swarasa in the management of Karnashoola w. s. r to Diffuse Otitis Externa.

Diffuse otitis externa

This condition has received a variety of names in the past, emphasizing its frequent occurrence in hot and humid

climates, for example tropical ear, Singapore ear. However, diffuse otitis externa is widely encountered in all climatic conditions. Although heat, humidity and bathing are aggravating factors in some cases, the most important factor is local trauma. Scratching the ears, vigorous drying of the meatus with dirty towel and unskilled syringing are some of the ways in which minor abrasions of the meatal may be produced. These abrasions provide access for the causative organisms.

The organisms most commonly found in diffuse otitis externa are *Pseudomonas aeruginosa*, *Bacillus proteus* and *staphylococcus aureus*.

Treatment

As in the acute phase, careful cleaning of the meatus with clearance of the deep meatal recess is the essential part of treatment. This is best achieved under the microscope with the use of suction. If there is marked meatal swelling, this can be reduced by packing the meatus daily with 12mm gauze wicks impregnated with an antibiotic such as neomycin or gentamycin or an antiseptic combined with a steroid or as drops applied to a Pope's ear wick. The addition of the steroid helps both to reduce the inflammatory swelling and to control the irritation. When there is no appreciable meatal swelling the antiseptic and hydrocortisone cream may be applied to the meatus. Ear drops of neomycin or gentamycin, and hydrocortisone, are often effective in reaction in some individuals. This may be difficult to recognize as it may be masked by the presence of the hydrocortisone in the preparation clearing up the infection at this stage but may produce a sensitivity Presence of the hydrocortisone in the preparation. In cases which fail to respond to treatment the reasons may be:

- 1) Underlying chronic suppurative otitis media.
- 2) Fungal infection
- 3) Sensitization of the skin to the topical application being used. Diffuse otitis externa.

MATERIALS AND METHODS

ARKA PATRA:

ARKA (Leaf) – The leaves were used in Vedic times in sun worship. The plants were considered sacred.

Arka consists of dried leaves of *Calotropis procera* (Ait.) R.Br. (Fam. Asclepiadaceae) found wild more or less throughout India.

Guna- Laghu, Ushna, ruksha, tikshna

Actions and Uses: The whole dried plant is bitter, thermogenic, laxative, anthelmintic, Anticarcinogenic, expectorant and good tonic

Ayurvedic Properties:

Rasa : Katu, Tikta (Leaves), Tikta, Madhura (Flower).

Guna : Ruksha, Laghu, Tikshna.

Veerya: Ushna.

Vipaka: Katu

Doshagnata: Kaphavatashamaka.

Rogagnata: Sotha - vedanayuktavikara, Shleepada, Amavata, Karnaroga, Vrana, Granthi, Shotha, Khalitya, Charmaroga, Switra, Kusttha, Khalitya, Arsha, Dantashula, Agnimandya, Ajirna, Yakridvikara, Vibandha, Gulma, Udararoga, Krimi, Visuchika, Upadansha, Hriddaurbalya, Raktavikara, Kasa, Shwasa, Kushtha, Jirnajwara, Vishamajwara, Sarpavisha.

Karma: Vedanasthapana, Shothahara, Vranashodhana, Kushthaghna, Jantughna, Vamanopaga, Deepana, Pachana, Pittasaraka, Rechana, Krimighna, Amashayashobhaka, Hridayottejaka, Raktashodhaka. (Flower)

Raktapittaprashamana, Kaphanissaraka, Kushthaghna, Jwaraghna, Vishamajwara - pratibandhaka, Katupaushtika, Balya.

Therapeutic uses

It is used in worms, strangury, and ulcers. The root bark is bitter, Anthelmintic, depurative, laxative and is useful in cutaneous disease, Intestinal worms, cough, and ascitis,

Physical Constants: Root: Foreign matter - Not more than 2%; Total ash - < 4%; Acid soluble ash - Not more than 1%; Alcohol soluble extractive - not less than 2%; water Soluble extractive - Not less than 8%.

Pharmacological Activities: Anticancer, Anti-inflammatory, Antimicrobial, nematocidal, high fibrinolytic, Anticoagulant, Vermicidal, Anthelmintic, Stimulant, Spasmogenic and mild diuretic. Calotropin showed digitalise like action on heart, but its action was not cumulative and less harmful.

GOGHRITA:-

Pharmacodynamics

Rasa : Madhura

Guna : Guru, Snigdha, Mridu

Virya : Sheeta

Vipaka: Madhura

Doshkarma - Tridoshashamaka

Source -Animal fat : Jangama Sneha

Chemical composition:

Triglycerides, Diglycerides, Monoglycerides, Keto acid glyceride, Glycerylesters, free fatty acids, phospholipids sterols, Vit. A, D, E and K. Ghrita contains approximately 8% lower saturated fatty acids Vit. A keeps epithelial tissue of the body intact.

Properties & uses:- Yogavahi, Rasayana, Vajikarana, Rasavardhaka, Svarya, Varnya, Beneficial for Bala.

DETAILS OF MATERIAL (ARKA PATRA) -

★ **1. Collection-** For identifying the varieties and sthana (place) where Arkapatras were available in abundantly for this taken help of from dravyaguna department , *Arka patras* which are ripened were collected freshly from bypass road in Kodoli-kolhapur.

2. Authentication and Standardization - Authentication and standardization tests done in Pharmacy College of our institute.

3. Preparation-

I followed the Sharangdharas concept for preparing the Swarasa, Three-four ripened leaves of arka are taken, the leaves were washed in running water and air-dried, and then applied Goghrita by flat tsp on the leaves (i.e. approximately 3-4 gms) on the leaves, equally spreads all over the leaves then kept these leaves on sieve and steam given for 10-12 minutes, after they become soft taken out and triturated in khalvyantra

and juice extracted by sieving through cloth, then this swarasa was used for karnapuram. After retaining the medicated swarasa for 100 matra (i.e. around 2 min), the ear should be cleaned with dry cotton mopping. This whole procedure was carried out in Rasashastra Department of our college under guidance of H.O.D., Readers and Lecturers of the concerned department

CONTROL DRUG INFORMATION

OFLOXACIN 3%:-

Ofloxacin is a quinolone, a potent antibiotic that inhibits DNA gyrase which is an enzyme necessary for the mitosis and replication of the bacteria.

Spectrum of activity-

- Ofloxacin has a large spectrum of action effective against gram-positive organisms (*Staphylococcus aureus*, *Streptococcus pneumoniae*) and gram-negative organisms (*Haemophilus influenzae*, *Moraxella catarrhalis*, *Pseudomonas aeruginosa*, *Proteus mirabilis*).
- Bacteria already resistant against beta-lactam antibiotics and aminoglycosides are not resistance to ofloxacin.
- Ofloxacin is a fluoroquinolone that has a broad spectrum of activity against otic pathogens but lacks the capacity for ototoxicity. Hence ofloxacin is preferred to aminoglycosides for any application within the middle ear space

Mechanism of action-

- When instilled in the ear, ofloxacin has a good tissue penetration.
- Ofloxacin exerts its antibacterial activity by inhibiting DNA gyrase, a bacterial enzyme that is essential in DNA replication, repair, deactivation and transcription.

Ofloxacin has been shown to be active against the following organisms responsible clinically for otic infections:

- Gram-positive:
 - *Staphylococcus aureus*
 - *Streptococcus pneumoniae*
- Gram-negative:
 - *Escherichia coli*

- *Haemophilus influenzae*
- *Moraxella catarrhalis*
- *Proteus mirabilis*

Indications:

Otitis externa, acute otitis media, purulent otitis media due to several different microorganisms

Dosage and administration:

Instill 2 to 3 drops into the affected ear, 2 to 3 times daily

Contraindication:

Hypersensitivity to ofloxacin or any derivative quinolone children under 1 year old, pregnant women and nursing mothers, Do not instill into the eye.

BECLOMETHASONE 0.25%:-

1. Beclomethasone Dipropionate 0.25 % is a potent steroid as compared with other topical corticosteroids.

2. Beclomethasone Dipropionate is often used in conjunction with acetic acid to reduce inflammation when infection is present

3. It is used topically as an anti-inflammatory agent Beclomethasone is a synthetic steroid of the glucocorticoid family. The naturally-occurring glucocorticoid (cortisol or hydrocortisone) is produced in the adrenal glands.

4. Steroid ear drops may be used in the treatment of otitis externa as steroid use leads to improvement of otological symptoms, particularly erythema, swelling and discharge

5. Beclomethasone like other topical corticosteroids has anti-inflammatory, antipruritic, and vasoconstrictive properties.

6. Corticosteroids like Beclomethasone are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipoproteins.

7. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting their release from the common precursor arachidonic acid.

8. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

CLOTRIMAZOLE 1%:-

Clotrimazole a synthetic imidazole derivative

Spectrum of activity-

1. Clotrimazole is a broad spectrum antifungal agent that has fungicidal activity against fungi responsible for superficial mycotic infections affecting the outer or middle ear including *Candida*, *Microsporum*, and *Trichophyton*.

2. Clotrimazole inhibits fungal cytochrome P-450 synthesis of ergosterol, which decreases fungal cell wall integrity. By inhibiting the biosynthesis of ergosterol for fungal cytoplasmic membrane, clotrimazole inhibits fungal growth.

3. Clotrimazole also has activity against certain gram-positive bacteria such as *Streptococci* and *Staphylococci*. It is the most widely used topical azole. Its antibacterial effect is advantageous in treating mixed bacterial-fungal infections.

Mechanism of action –

It inhibits the fungal cytochrome p 450 enzyme lanosterol 14 demethylase and thus impairs ergosterol synthesis leading to a cascade of membrane abnormalities in the fungus.

Indication

Other indication - Tinea infection, pityriasis versicolor, candidal infections of vulva, penis & oral cavity etc

LIGNOCAINE 2%:-

Lignocaine Hydrochloride is a topical anesthetic with a low index of sensitization and toxicity. It helps reduce pain and stinging in the ear is having anesthetic action.

Dosage - Instill 2-3 drops 2-3 times daily for 2 wks or till all symptoms disappear.

Contraindication: Oral administration of antifungal drugs may be given to resistant cases, but there are having side effects of nausea, vomiting, loss of appetite, headache, paresthesia, rashes and hair loss etc.

METHODOLOGY

The whole study was divided into,

- 1) Conceptual study
- 2) Clinical study

1) CONCEPTUAL STUDY:-

Detailed review of *Ayurvedic* and modern literature was carried out to know about the disease entity and treatment etc. and also information & updates from internet websites related to this subject were taken.

2) CLINICAL STUDY:-

Patients attending the O.P.D., who were having characteristic features of *Karnashool*. 60 patients of *Karnashool* who attended O.P.D. during this period were selected for present study irrespective of sex, caste, creed, race and religion.

Inclusive criteria:

1. Patients of age group 10-60yrs irrespective of sex educational status, socioeconomic status, caste etc.
2. Patient's having complains of *Karnashool*.
3. Patients ready for drug trial, patients will be given ideas of the project, before drug trials.
4. Patients having intact tympanic membrane.

Exclusive criteria:

1. Patients with other systemic disease.
2. Patients aged below 10yrs or above 60yrs.
3. Patients who are having middle ear diseases
4. Patients with perforated tympanic membrane.
5. Patients having malignant otitis externa.

Sampling Technique:

The patients were selected irrespective of caste, creed, religion, income, sex, occupation etc. Random sampling technique was adopted. Patients were divided into two groups i.e. Group A and Group B.

Comparative study will be conducted in two groups [A&B] each group will be consists of 30 patients.

Group A-Trial group [TG]

1. Total 30 patients.
2. These will be treated with Arka patra swarasa.
3. Mode of administration-Karnapurana (Topical application)
Raspuan Kal-morning.
Raspuan matra-100 matra

Duration- 7 days

Group B-Control group

1 Total 30 patients will be advised to take modern medicine i.e. Ear drop of OTRAS OT (ofloxacin 3%, Beclomethasone 0.25% Clotrimazole 1%, Lignocaine 2%, Glycerine q.s.)

Kala- morning & evening

Matra-2 drops twice a day.

Duration- 7 days

Mode of administration- Topical application
Each patient follow up will be taken & clinical findings will be recorded in time period interval in Shalakyia OPD of Yashwant Dharmartha Rugnalaya Kodoli.

METHOD OF STUDY:

Clinically study has accomplished in three phases.

1. Diagnostic Phase.
2. Interventional Phase.
3. Assessment Phase.

1. Diagnostic Phase:

The patients were diagnosed & selected on the basis of signs and symptoms of *Karnashool*. All the patients selected for trial were explained the nature of the study.

Consent- Written and informed consent was obtained from patient or his/ her legal guardian after explaining details about the study.

Criteria adopted for present study as under:

A. Signs:

1. Swelling (shwayathu)
2. Srava (Discharge)
3. Crust formation

B. Symptoms:

1. Pain (Earache)
2. Kandu (itching)

2. Interventional Phase:

The study was intervened by the treatment with *Karnapurana* and ofloxacin, clotrimazole, Beclomethasone, lignocaine solution.

Drug Schedule:

Group A (Trial Group):-Treated with Arkapatra swarasa karnapurana in the diseased ear.

Administration-

- Cleaning of the pinna and surrounding area done, and snehan and swedan to the ear given.
- Arka patra swarasa karnapurana done on the affected ear in the sufficient quantity, i.e. 10-12 drops under all aseptic precaution, For 100 matra then external auditory canal should be cleaned with dry cotton mopping.

Group-B (control group): was treated with *Ear drop OTRAS OT*.

Administration- 4 drops twice a day.

Follow up- Follow up was done on 3rd, 5th and 7th day to see the effect of treatment and on 15th day to see recurrence in both the groups.

Assessment 3Phase:

The effect of the treatment (results) was assessed on 3rd, 5th, 7th and 15th day in regards to the clinical signs and symptoms on the basis of grading and scoring system and overall improvement.

Clinical criteria for assessment:

The signs and symptoms were assessed by adopting suitable scoring method. The details are as follows:

Parameters of Assessment:

Shool (pain)

Subjective phenomenon to be considered as per patient

a) Grade 0: No pain

b) Grade I: Mild pain

c) Grade II: Moderate Pain.

d) Grade III: severe pain

Kandu (itching)

Subjective phenomenon considered as per patient.

a) Grade 0 : No itching

b) Grade I : Mild itching

c) Grade II : Moderate itching .

d) Grade III : severe itching

Shwayathoo (swelling)

Objective Phenomenon to be considered as per patient

a) 0 : No swelling, Lumen of external ear canal remains patent

b) 1+ : Lumen of external ear canal reduced by 10-20%

- c) 2+ : Lumen of external ear canal reduced by 20-40%
- d) 3+ : Lumen of external ear canal reduced by 40-60%
- e) 4+ : Lumen of external ear canal reduced by 60-80%
- Srava (discharge)
Objective Phenomenon to be considered as per patient
- a) 0 : Normal - No discharge
- b) 1+ : Scanty - if cotton bud wets with the discharge
- c) 2+ : Moderate - when discharge can be seen by naked eye at external auditory canal.
- d) 3+ : Profuse - when the discharge flowing out of external auditory canal

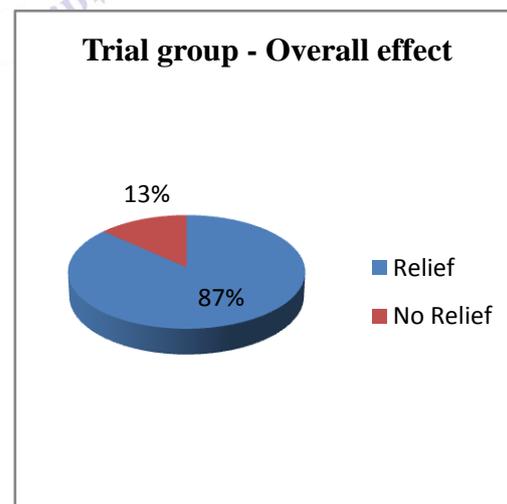
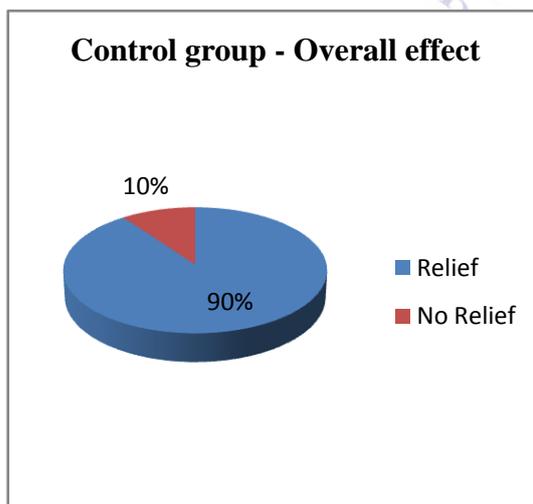
Overall Assessment of Therapy-

It was done on the basis, no. of patients relieved (i.e. score “o” and not relieved (i.e.

Overall effect of treatments in both the groups –

Group	Relief	No Relief	Total	Relief in %	x2	P
Trial	26	4	30.00	86.67	0.0027	> 0.05
Control	27	3	30.00	90.00		

By statistical analysis x2 value is 0.0027 which is lower than p table value (3.84) at 5% level of significance. So, no significant difference in both the treatment.



Overall effect of treatment of both groups-

This observation is based on table and graph. These graphs shows, out of 30 patients of *Karnashool* 26 (i.e. 86.67%) patients got relief in all signs and symptoms

score not “o”) in all signs and symptoms on the 15th day of treatment in both the groups. Then statistical analysis done and significance of difference between both groups was assessed by applying Chi-square test.

OBSERVATIONS AND RESULTS

The present study is based on 60 cases divided in two groups as Trial Group and Control Group. 30 cases were registered in each group. They were registered in college O.P.D. and completed the study. For this more than 60 patients were registered. The present study is based on the patients who came for regular follow-up and completed study satisfactorily. So the demographic and clinical data is based on 60 patients.

in Trial group and out of 30 of patients of Control group 27 (i.e. 90.00%) patients got relief in all signs and symptoms of *Karnashool*. By statistical analysis value is 0.0027 which is lower than p table value

(3.84) at 5% level of significance. So no significant difference in both the treatment.

Discussion on effect of therapy:

Effect of therapy was assessed on the basis of changes observed in cardinal signs & symptoms and statistical analysis.

The present study has involved 60 patients of *Karnashool*, who have completed treatment satisfactorily. The diagnosis was made on the basis of signs and symptoms described in *Ayurvedic* and Modern texts.

The selected patients were randomly categorized into two groups:-

Group A- TRIAL GROUP:

30 patients were included in this group. They were treated with *Arka patra Swarasa Karnapurana* daily for 7 days.

Group B- CONTROL GROUP:

30 patients were included in this group. They were treated with OTRAS ot Ear drops four drops twice in a day for 7 days.

Statistical Assessment:-

For the assessment of results *Ayurvedic* and Modern parameters were followed. The results obtained were statistically analyzed and significance of difference between both groups was assessed by applying Chi-square test.

Overall effect of treatment -

In Trial group 86.67% patients got relief and in Control 90% patients got relief in all signs and symptoms.

This analysis shows there was 3.33% more relief in Control group patients which statistically insignificant. So no significant difference in treatments of both groups

So the Effect of *Arka patra Swarasa Karnapurana* is nearly same as that of Control group drug on *Karnashool*.

There was no side effect of *Arka patra Swarasa Karnapura*.

DISCUSSION

As the Arkapatra and Goghrita both are having vranahara properties so it repairs the discontinuation of the epithelium in the external auditory canal.

Also Arka patra is having ushna Veerya, it helps to subsiding the Sheeta guna of vata dosha and due to madhur rasa,

snigdha guna and madhur vipak of ghrita vatashman takes place and pain gets subsided. Also laghu guna of arka patra is lekhan and vrunaropan, and ghrita is having snigdha guna which is mardavkar, balakara, and vranahara.

Arka patra is mainly having property of vatakaphahara so it easily break the etiopathogenesis of this present clinical study karnashula, (Diffuse otitis externa), in which more involvement of vata and kapha dosha is there. The property of katu Tikta rasa of arka patra and katu vipak & usna Veerya all the properties of the trial drug are antagonistic to vata kapha, which are the main culprit of the disease.

In leaves mudarine is isolated as principal active constituent. Besides a yellow bitter acid, resin and 3 toxic glycosides calotropin, uscharin and calotoxin. In latex a powerful bacteriolytic enzyme is present.

Ghrita is Yogavahi thus it potentiates the penetrating properties of the above drugs resulting into delivery of the above drug to sukshmasrotasas. It pacifies Rukshata of vata by snigdha guna, and Shaitya and kapha by processing with kaphahara drugs.

More ever all the components of the trial drug have shothaghna, Vedanasthapana, Vranashodhana, Krimighna & vishaghna properties. due to these trial drug cures the disease diffuse otitis externa successfully.

The efficacy of Arka patra swarasa Karnapurana in Karnashul was found to be nearly same as instillation of ofloxacin (3%), Beclomethasone (0.25%), Clotrimazole (1%) Lignocaine 2% Ear drops. There was slightly less relief % with Arka patra swarasa Karnapurana than control group remedy; which was statistically insignificant.

It has been observed that the relief rate in a properly mooped ear canal is more quick than unmooped ear canal which signifies frequent mooping of external auditory canal is essential.

CONCLUSION

The diagnosis was made on the basis of signs and symptoms described in *Ayurvedic* and Modern texts, the symptoms present in diffuse otitis externa it can be correlate with Karnashool, more ever vataj karnashool and also Kaphaja karnashool. Male patients are more prone for karnashool (diffuse otitis externa) it may be due to more exposure to polluted air and strain. It is seen that diffuse otitis externa has no religion wise distribution. In Trial group 86.67% patients got relief and in Control 90% patients got relief in all signs and symptoms. This analysis shows there was 3.33% more relief in Control group patients which statistically insignificant. Arka patra Swarasa was proven to effective drug of choice for the management of Karnashool.

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