

**CLINICAL STUDY OF EFFICACY OF YASHTIMADHU GHRITA
KARNAPOORAN IN THE MANAGEMENT OF PITTAJA KARNASHOOLA
W.S.R.TO OTITIS EXTERNA**

Dr.Manisha Shailesh Irali ¹,

¹ PG student, Department of Shalyakya Tantra, ADAMC, ASHTA

Dr.Jayawant Kharat ²

² Assistant Professor, Department of Shalkyatantra,
Hon. Shri. Annasaheb Dange Ayurved Medical College, Ashta, Tal. Walwa, Dist. Sangli,

ABSTRACT:

Karnashoola is the common problem noticed in majority of patients in our Clinical practice. In modern medical science, quite effective and wide range of antibiotics and analgesics are available. The modern treatment modalities for Earache are expensive and not free from side effects. Prevalence of this disease is 10-29% in India. Recurrence is also observed in 15% subjects (American academy of Otolaryngology (Head & neck Surgery foundation – 2006). Considering all these points, there is need for search out of a safe drug. *Pittaja Karnashool vyadhi* can be correlated with otitis externa. A lot of Treatment modalities are explained by *Acharyas* for this disease according to the Condition of patient and progression of disease. No work has been done on *pittajakarnashoola* as per my knowledge. Here very simple, easily available and economically less expensive *Yashtimadhu Ghrita* is used in *pittaja Karnashoola*, described by *Sushruta*

KEYWORDS: *Jayapala Beeja* , *Shodhana* , Physico-chemical analysis

INTRODUCTION

Ayurveda is the one and only medical system which gives the way of perfect living with nature. It is science which developed as a result of various discussions and researches. It gives equal importance to preventive and curative aspect of diseases. *Ayurveda* has its strong root in its own basic principles. It made the science to live so long starting from the basic *panchabhautic* elements. *Shalakya tantra* one among the 8 branches of *Ayurveda* deals with precious sense organs, the diseases affecting them and their management. The history of *Ayurveda* reveals that this branch has witnessed phenomenal growth in the ancient era since *Vedas* to *Samhita* period. *Karnashoola* is a disease mentioned by *Acharya Sushrut* in the chapter of *karnarog vignaniy in uttarsthan*. *Sushruta* explained various types of *karna roga*.

Acharya Sushruta counted *karnashoola* as disease. *Sushrutacharya* has mentioned the pathogenesis of *Karnashool* and elaborate the treatment of the diseases as per *doshajbheda*. Exposure to cold, polluted water, pricking or probing of ear canal, infection, fungus, use of improper instruments are some causes of *karnarogas*. Due to above causes *vatadidoshas* vitiate *shabdavahastrotas* and causes ear disease. The symptoms mentioned in *Karnashool* are mild, moderate to severe pain, restlessness, discomfort and disturbance to the patient in the routine work. *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 *vatadosha* is encircled by *pittakaphaRakta* and other types of *vata* and causes *Vatavilomagati* (improper circulation of *vata*) and produces pain in the ear is known as *Karnashool*. According to *Sushrutacharya*, only *vatadosha* causes pain. *Acharya Sushrut* counted earache as disease itself but sign and symptoms as per *doshajbheda* of is not elaborated. In *uttartantrakarnarogpratishehadhyaya* *Sushruta* described treatment of *karnashoola* as per *doshajbheda*. *Acharya vagbhata* explained *Karnashool* according to *dosha* predominance.

SIGN AND SYMPTOMS OF PITTAJA KARNASHOOLA:

zÉÔsÉÇ ÌmÉ"ÉÉiÉÇ xÉsÉwÜÉâwÉÉzÉliÉâcNÜÉµÉrÉjÉÑeuÉUqÉÇ |

AÉzÉÑmÉÉMÇü mÉëmÉYuÉÇ cÉ xÉMÉliÉsÉÍxÉMüÉxŞÉÑliÉ ||

xÉÉ sÉÍxÉMüÉ xmÉ×vÉâ±±"É"ÉimÉÉMüqÉÑmÉæliÉ cÉ|

(A.™.E.A.17/4-5)

1. Earache
2. Burning sensation in ear - local warmth
3. Swelling
4. Blister formation and its spread through the discharge coming out.
5. Ripens quickly, and after ripening exudates yellowish watery discharge through ear and all places this fluid comes in contact there will be ripening.
6. Affinity for cold thing
7. Fever

According to modern Sciences 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 in intensity, frequency etc. *Karnashool* is one of the symptoms according to modern otology. *Karnashool* vyadhi can be correlated with otitis externa. In present study, an attempt has been made to work on otitis externa. Otitis externa, defined as generalized inflammation of the external ear canal. Aetiology of earache as per modern science is by scratching the ear canal with hair pins or match sticks, unskilled instrumentation to remove foreign bodies and vigorous cleaning of air canal after a swim, when meatal skin is already macerated. Common organisms are *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *B. Proteus* and *Esch. Coli* involved in otitis externa.

HYPOTHESIS OF THE STUDY:

Ho: *Yashtimadhu Ghrita karnapooran* is not significantly effective in *Pittaja karnashoola*.

H1: *Yashtimadhu Ghrita karnapooran* is significantly effective in *Pittaja karnashoola*.

AIM AND OBJECTIVES:

AIM:

Study the efficacy of *YashtimadhuGhrita karnapooran* in the management of *pittajakarnashoola*

OBJECTIVES:

- To review the literature of *pittajakarnashoola* and *yashtimadhughrita*
- To study the etiological factors of *pittajakarnashoola* in *ayurvedic* and modern perspective in present era.
- To review the procedure of *karnapooran* in details.
- To assess changes in signs and symptoms of *pittajakarnashoola* after treatment given in *ayurvedic* Literature.
- To provide safe and effective *Ayurvedic* remedy in *pittajakarnashoola*

MATERIAL:

1. Patient :

Total 70 patients clinically diagnosed of will be *pittaja karnashoolar* randomly selected from OPD & IPD of *Shlakyatantra* Department.

2. Drugs:

ꣳÉÏUuÉꣳꣳÉmÉëuÉÉsÉáwÉÑ qÉkÉÑMäü cÉISiÉá iÉjÉÉ |
MüsMüYuÉÉjÉá mÉUÇ mÉYuÉá zÉMïüUÉqÉkÉÑMæü: xÉUæ: ||
xÉÑ.xÉÇ
E´ÉUíÉÇ\$.20| 30

Yashtimadhughrita was prepared by standard method. Raw drug was collected from genuine source. Authentication and standardization was done by pharmacological and physiochemical methods. *Ghrita* ingredients was prepared and standardized as per *Ayurvedic* pharmacopeia of India standards.

SELECTION CRITERIA:

Inclusion Criteria:

- Patients who give written consent for study.

- Age group 16 to 60 respective of sex, religion and occupation.
- Patients selection will be done on the basis of signs and symptoms of *Pittaja Karnashoola* (otitis Externa) described as per *Ayurvedic* and Modern medical science.

Exclusion Criteria:

- Patients suffering from any other systemic diseases like diabetes, hypertension.
- Patients having *karnashoola* with other ear pathology perforation of tympanic membrane, otitis media, Labyrinthitis, will be excluded from the study.
- Patients having referred pain due to caries, alveolar abscess, Impact last molar, oral cavity malignancy, deviated nasal septum, sinusitis, post tonsillectomy, malignancy of oropharynx, malignancy of larynx, pyriform fossa malignancy, TM joint arthritis.

Criteria adopted for present study as under:

1. *Karnashoola*(Earache)
2. *Daaha*(Burning sensation)
3. *Strava*(Discharge)
4. *Shoth*(Swelling)
5. *Karnapitika* (Blister formation and its spread through the discharge coming out)
6. Local redness
7. *Jwara*(Fever)

8. CRITERIA FOR ASSESMENT

Parameter	Grade 0	Grade I	Grade II	Grade III
<i>Karnashoola</i>	No	Mild, (+).	Moderate, (++)	Severe, (+++).
<i>Daaha</i>	No	Mild, (+).	Moderate, (++)	Severe, (+++).
<i>Strava</i>	No	Scanty (+)	Moderate, (++)	Severe, (+++).
<i>Shoth</i>	No	Mild, (+).	Moderate, (++)	Severe, (+++).
<i>Karnapitika</i>	No	Mild, (+).	Moderate, (++)	Severe, (+++).
<i>Jwara</i>	No	Mild, (+).	Moderate, (++)	Severe, (+++).
Redness	No	Mild, (+).	Moderate, (++)	Severe, (+++).

The efficacy of the therapy will be assessed on the basis of following criteria.

OVERALL ASSESSMENT CRITERIA: Effect of therapy will be assessed as below

1	Cured	100 % relief from signs and symptoms
2	Marked improvement	76 to 99 % relief from signs and symptoms
3	Moderate improvement	51 to 75 % relief from signs and symptoms
4	Slight improvement	26 to 50% relief from signs and symptoms
5	No improvement	Upto 25% relief from signs and symptoms.

OBSERVATIONS AND STATISTICAL ANALYSIS

Data is qualitative in nature and thus one cannot use parametric test e.g. paired t test as data is not normally distributed. Therefore, non-parametric tests are used to test significance of therapy. As grading used for all the signs and symptoms were ordinal in nature, “Wilcoxon Signed Rank test” is used for intra-group comparison. (i.e. before and after treatment of a group). Findings are presented along with appropriate summary statistics and graphs/diagrams and result is interpreted accordingly. The level of significance is kept at 0.05.

Observations:

- Maximum no (77%) of patients seen in 21- 50 years of age group.
- Lower incidence (9%) is seen in age group 16-20 years
- Out of 70 patients 57.14% are Male and 42.86% are Female.
- Maximum patients were housewives (30%) and students (27%) was second in rank.
- Out of 70 patients 31 (30%) was vegetarian and 29 (70%) was taking mixed diet.
- Out of 70 patients most of the patients i.e.(85.71 %) are Hindu, (8.57 %) are muslim and (5.71 %) was christean
- (80.00%) were from middle class and very less (1.67 %) from upper class.

- Disease was seen more in pitta vaat prakruti (41.43 %) patients and very less (8.57)% was kapha-pitta prakruti.
- Family history dosen't seem to be significant
- There was significant reduction in *pittajakarnashool* (80.00%) so medicine *yashtimadhughrita* can be considered effective in reducing the symptom earache.
- There was significant reduction in *karnadaaha* (67.31%) so medicine *yashtimadhughrita* can be considered effective in reducing the symptom burning sensation in the ear.
- There was significant reduction in *karnastrava*(60.87%) so medicine *yashtimadhughrita* can be considered effective in reducing the symptom ear discharge.
- There was significant reduction in *karnashoth* (71.07%) so medicine *yashtimadhughrita* can be considered effective in reducing the symptom swelling of external auditory canal.
- There was significant reduction in *karnapitika* (76.75%) so medicine *yashtimadhughrita* can be considered effective in reducing the symptom blister formation and discharge coming out.
- There was significant reduction in *jwara* (87.50%) so medicine *yashtimadhughrita* can be considered effective in reducing the symptom *jwara*.
- There was significant reduction in Redness (90.06%) so medicine *yashtimadhughrita* can be considered effective in reducing the symptom redness.

Mean percent improvement in various signs and symptoms:-

Parameters	Mean % Improvement	Remark
Karnashoola	80.00%	Significant
Daaha	67.31%	Significant
Strava	60.87%	Significant
Shoth	71.07%	Significant
Karnapitika	76.75%	Significant
Jwara	87.50%	Significant
Redness	90.06%	Significant
Average Mean %	76.22%	

improvement	
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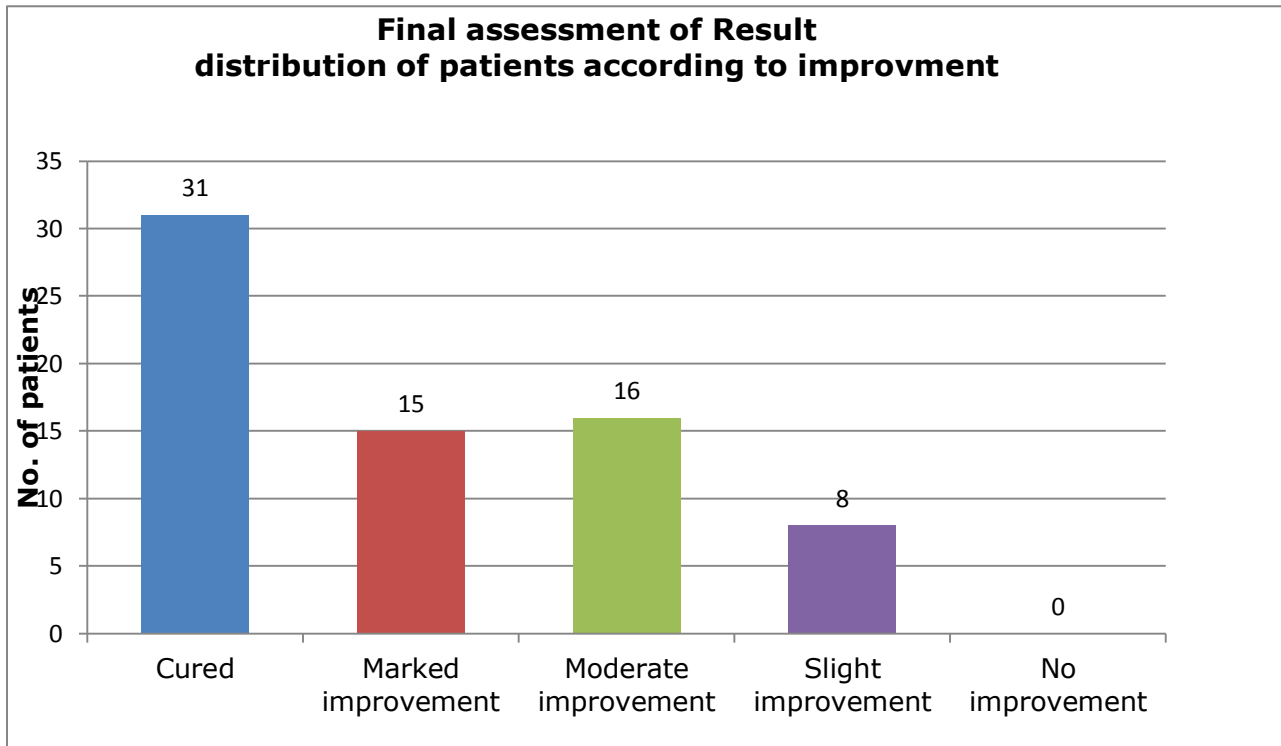
Final assessment of results:-

For assessment of final result, following criteria was used.

Sr. No.	Remark	criteria
1	Cured	100 % relief from signs and symptoms
2	Marked improvement	76 to 99 % relief from signs and symptoms
3	Moderate improvement	51 to 75 % relief from signs and symptoms
4	Slight improvement	26 to 50% relief from signs and symptoms
5	No improvement	Upto 25% relief from signs and symptoms.

Distribution of patients according to relief:

Final assessment (patient wise)	No. of patients	
	Count	%
Cured	31	44.29
Marked improvement	15	21.43
Moderate improvement	16	22.86
Slight improvement	8	11.43
No improvement	0	0



DISCUSSION ON CLINICAL STUDY:

The discussion notes on the data obtained from observation are presented as follows:

Total Registered: In the clinical study, a total of 76 patients were registered; out of which 6 patients discontinued treatment. Total 70 patients were studied with a single drug *Yashtimadughrita*.

The clinical study has involved 70 patients of *pittajakarnashoola* (Otitis externa). Their age ranged from 16 to 60 yrs. It was noted that higher incidence of Otitis externa is (10 %) seen in 16 – 20 years followed by (25.71%) were in the age groups of 21-30, (25.71%), were in the age groups of 31-40, followed by 41-50 years of age (24.29%) and 51-60 years of age (14.29%). of age group. Here higher incidence is seen in younger patients mostly due to swimming and habitual ear pricking with wrong instruments. Involvement of this young age group patients is in *pittakala* of human being as per *ayurvedic* texts.

Out of 70 patients 57.14% are male and 42.86% are Female.It is seen that the incidence ratio in both the sex doesn't seem to be significant.

Out of 70 patients most of the patients i.e.(84.29%) are Hindu and (10%) are muslim and (5.71%) from christian community. This shows that the religion being Hindu dominant there were more hindu patients.

Out of 70 patients 20 (28.57%) were vegetarian and 50 (71.43%) were taking mixed diet.As majority of patients are mixed diet, there may be pitta dushti due to *ushanatikshnaguna* of dietary habits.Out of 70 patients, 34 patients (48.57%) had good appetite, 14 patients (20%) are with moderate appetite while 22 patients (31.43%) are with poor appetite. As most of the patients are young age group appetite of patient is good in majority of patients.

Out of 70 patients, 39 patients (55.71%) were not addicted, 8 patients (11.43%) were alcoholic, 6 patients (8.57%) were Masher user, 16 patients (22.86%) were tobacco user while 1 patient (1.43%) was tobacco user as well as alcoholic.

Out of 70 patients It was noted that the disease was seen more in *pitta -vataprakruti* (41.42 %) and *vata-pitta* was(21.43%).Lowest in *Kapha-pittaprakruti* (8.57 %) this shows that *pitta-vataprakruti* people are more susceptible to the disease *pittajakarnashoola*.Out of 70, no patients had family history.In this disease family history dosen't seem to be significant.Out of 70 patients, 17 patients (24%) were illiterate, 13 patients (19%) were educated up to primary secondary school, 10 patients (14%) went to higher secondary school, 26 patients (37%) were undergraduate while 4 patients (6%) were post graduate.There is no specific incidence found in education.

Out of 70 patient incidence of disease is seen in housewives (22.86%) and students (15.71%). There are (21.4%) are farmers and (11.43%)are labour. Incidence of 24.29% is service peoples and (4.29%) was business people.There is no specific incidence found in occupation.It was seen that most of the patients (57.14%) were from middle class and (38.57%) were from lower class and very less (4.29 %) from upper class.This shows that the usual flow of patients to hospital is of middle class people.

Out of 70 patients all had unilateral disease. Due to localized reason the incidence of disease is mostly unilateral. In this study there was 31 pts (44.29%) was of left earache and 39pts(55.71%) was of right earache complaints.

Out of 70 patients (24.29%) 17 patients causative factors was water entering may be due to swimming and (45.71%) 32 was due to scratching the ear canal and (11.43%) 8 with wrong instrumentation in the ear. Unknown reason(18.57%) were seen as causative factors. Thus majority of patients reported the aetiology as mentioned in the *hetu* of *Karnarogas* in *Ayurvedic* classics.

OVERALL EFFECT OF THERAPY

Out of 70 patients.

31 patients (44.29%) were cured

15 patients (21.43%) showed marked improvement,

16 patients (22.86%) were having moderate improvement.

8 patients (11.43%) were with mild improvement.

PROBABLE MODE OF ACTION OF *KARNAPOORANA*:

Drug administration through *Karnapoorana* is the natural choice for the treatment of local ear disorders. Among the most common examples are antibiotics and steroid agents for otitis externa. In these cases, local measures are the primary option for drug delivery because in lower dose it allows a rapid symptom of relief.

A more detailed description regarding the mode of action of *Karnapoorana* is not available in *Ayurvedic* classics. But as *Karna Tarpanana* is mentioned as *SnehaPravicharana* (ch.su.13/25). Its mode of action can be understood as *SthanikaSnehana*, if *SnehaDravaya* is used for it.

In *PurvaKarma* gentle massage is done with Luke warm medicated oil around the ear and pinna for a short duration of time (Approx.5-7 min). Massage also cover lateral portion of neck inferior to ear. This causes increase of blood circulation in ear.

After this heat is applied is *hasttaapswed* by waving, touching and pressing for some time (Approx.10 min.). This cause vasodilation and thus increase permeability of capillaries. As a result of both *Abhyanga* and *Swedana* facilitates more absorption of drug. As the efferent

vasodilator nerves are spread out on the superficial surface of the face, receives stimulation by fomentation and it may increase blood flow to the brain.

Instilled medicine in ear canal gets absorbed by skin lining external auditory meatus and tympanic membrane and reaches systemic blood flow, according to Ayurveda, drugs gets absorbed by *BhrajakaPitta* present in skin and shows its effect on body and local tissue.(A.S su 20/7).Patient's tragus is gently pressed by figure 5-6 times to facilitate more drug absorption.The drug instilled in the form of oil, *swaras* etc. is used luke warm it helps in relieving inflammation thus it reduces ear ache, and by counter effect of heat it also relives pain of near by structures like mandible or neck.In this way *Karnapoorana* eliminates disease of ear.In addition to this medicine is used Luke warm so *Vata* is eliminated also by *UshnaGuna*.As medicine for *Karnapoorana* is made by *Snehapaka* method all fat soluble active ingredients of drug get enclosed.Fat soluble active principle can be easily assimilated through nerve endings.

As a combine effect of all these *Karnapoorana* is useful in *karnashoola*.*Karnapoorana* is indicated in *Karnaroga* by all *Acharyas*.*Acharya* has advised to do *Poorana* after *Pramarjana*.In the present study *Karnapoorana* was advocated only after making ear reasonable dry by mopping with *Pichuvarti* (ear wick) or microscopic suctioning.

CONCLUSION

On detailed analysis of classics it is observed that clinical anatomical description of Karna is explained in a scattered manner in classics.

- In *Ayurvedic* classics, the term *Karnashool* suggested a symptom and also covers a broad spectrum of disease.On the basis of similarity between the etiological factors, symptoms, complications, prognosis, and treatment modalities, otitis externa can be correlated with *PittajaKarnashool*.
- *Karnapoorana* is mentioned as a line of treatment in *ayurved* classics not only for ear diseases but also for other *urdhvajatrugata* diseases.
- Water entry in the ear, scratching of the ear by unsterile instrument such as, matchstick, hair pin, key and finger nails are main cause of bacterial invasion.
- For *Karnapoorana*, *sneha* should be prepared till the stage of *Kharapaaka*.

- *Karnapoorana* is very effective local procedure in *KarnagataRoga*.
- Prevalence of *PittajaKarnashoola* (Bacterial Otitis Externa) is found to be more in 20 - 40 yearsage group.
- Percentage of *PittajaKarnashoola*(Otitis Externa) is same irrespective of sex.
- *PittajaKarnashoola* has no relation with particular occupation but among female patients, housewives are more prone.
- *Pitta – vaataPrakriti* people are more prone for this disease.
- Study shows middle class people are mostly affected with this disease.
- It usually affects one ear.
- Genetic factor has no role with this disease as no any family history found in studied patients.
- During the treatment period *Pathyapathya* should be followed especially head bath and swimming, Scratchingshould be prohibited.
- Clinically and statistically in the cases of studied sample size of 70 patients significant result is seen in the parameters, *karnashool*, *karnastrava*, *Karnadaaha* etc.

In the studied sample size statistically significant effect of *YashtimadhuGhritakarnapooran* in *PittajaKarnashoola* was found.

No adverse reaction was noted in any of the patient during the study.

Patients of all the age group tolerated the study well.In the treatment of all types of wounds and inflammations *Yashtimadhu* is considered the drug of choice. In inflammatory conditions of the eye and various types of Varna, *Chakradutta* has advocated the use of this drug.

AcharyaCharaka has advocated the use of this drug in *Vataja* and *Raktaja* diseases at various places. In *Sushruta* Samhita also described its use in pain in various surgical and medical diseases.

Yastimadhu has *madhurarasa*, *sheetavirya*, *madhuravipakaha*. It is *vata-pittashamaka*.It is healing, anti-ulcer, anti inflamotary and skin regenerative properties.sodium, glycyrrhizate possesses anti-ulcer activity and stimulation of regeneration of skin.

Yashtimadhughrita is *Madhur*, *Madhur*, *Sheeta* and *guru*, and *snigdha*, all the properties of trial drug are antagonistic to *pittavata*, which is the main cause of the disease.This trial drug is *shothaghna*, *Vedanasthapana*, *Viranashodhana*, *Vranaropana*, *pittaghna* properties.Due to these properties, the trial drug cures the disease “*pittajaKarnashoola*” successfully.

Ghrita is *Samskaranuvartanum* (Cha. Su.13/13) it means that it imbibe the qualities of drug processed with it. It is *yogavahi*, *Rasayan* and *bruhana*. So it carries active principles of the drugsto increase the potency of the compound drug.

Lipophilic action of *ghrita* facilitates transportation to a target organ and final delivery inside the cell, because cell membrane also contains lipid. When *ghrita* is processed with *yashtimadhu*, its activity and utility is increased. So the pathology of Acute Otitis Externa, absence of skin lipid to protect the external meatus is broken and lipid contents in *yashtimadhughrita* helps to protect the skin of external auditory meatus

There were no sides of the trial drug and it was well tolerated by the patents through the study. In this study Glycyrrhizin, Glabridin, Sodium glycyrrhizate, Glycyrrhetic acid, the active components of *Yashtimadhu* (*glycyrrhiza glabra*) exhibited antibacterial activity against bacteria in Acute Otitis Externa.

The emergence of drug resistant bacteria has become a major problem. There is a continuous effort by the pharmaceutical industries to develop new antimicrobial agents for the treatment of the infections. Due to the increase of resistance to antibiotics, there is a pressing need to develop new and innovative antimicrobial agents. One approach is to screen local medicinal plants which represent a rich source of novel antimicrobial agents. *Yashtimadhu* (*Glycyrrhizaglabra*) is one such plant which has shown remarkable activity against large number of organisms, such as bacteria, fungi, viruses, parasites etc. This review has tried to give an account of multifold activity of various bioactive molecules of *Yashtimadhu* (*Glycyrrhiza glabra*) against various microorganisms.

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