IAMJ

INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

Research Article | ISSN: 2320 5091 | Impact Factor: 5.344

OPEN LABEL CLINICAL STUDY TO COMPARE THE EFFECT OF KUSHTADI TAILA PICHU AND CIPROFLOXACIN EAR DROPS IN PUTIKARNA (SAFE CHRONIC SUPPURATIVE OTTITIS MEDIA)

Raju S. N[1], **Veerayya R Hiremath**[2], **Shashikala D K**[3], **Gururaj N**[4]

[1]M.S. (Scholar), [2]M.S, Ph.D., Professor (& Head), [3]M.S, Associate Professor, [4]Assistant Professor
Department of Shalakya Tantra, SJGAMC & Hospital, Koppal, Karnataka, India

Corresponding Author: gonchigarraju@gmail.com

https://doi.org/10.46607/iamj2508102020
(Published online: October 2020)
Open Access

Article Received: 01/10/2020 - **Peer Reviewed:** 03/10/2020 - **Accepted for Publication:** 04/10/2020

Check for updates

ABSTRACT

Putikarna is the most common *Karnaroga* in day to day ENT practice, characterized by pus discharge with or without pain in the ear. It can be correlated to chronic suppurative otitis media (CSOM). Treatment of CSOM includes aural toilet, antibiotic ear drops, and tympanoplasty. *Karna Pramarjana, Prakshalana, Dhupana,* and *Purana* are the line of treatments advocated in the treatment of *Putikrna. Karnapichu* is a convenient method with similar benefits to *Karnapurana.* In this study, *Kushtadi* Ciprofloxacin ear drops were used as a controlled drug. **Aims and Objective**: To study the effect of *Kushtadi Taila Karna Pichu* and ciprofloxacin ear drops in *Putikarna* and compare the efficacy of both. **Methods:** Patients of Group A (n=20) were treated with *Kushtadi Taila Karna Pichu* daily two times for 7 days. Patients of Group A (n=20) were treated with ciprofloxacin ear drops 2-3 drops three times a day for 7 days. Tab. *Nimbadi Guggulu* 500 mg was administered orally twice a day for 7 days in both groups. **Observation** & **Results:** 95 % of patients got complete remission and 5 % of patients got moderate improvement Group A and 50% of patients got complete remission, 25% of patients got marked improvement and 25% of patients got moderate improvement in Group B. **Discussion** & **Conclusion:** The highly significant results were observed in Group A compared to Group B on-ear discharge. *Kushtadi Taila* is *Vrana Ropaka, Vrana Shodhaka, Tridosha Shamaka* which helped to reduce infection and inflammation resulting in relieving of symptoms.

Keywords: CSOM, *Putikarna, Kushtadi Taila, Karna Pichu*, Ciprofloxacin*, Karna Srava*.

INTRODUCTION

Puthikarna[1] is the disease in which pus discharge from the ear associated with or without pain. Chronic suppurative otitis media (CSOM) is a long-standing infection of a part or whole of the middle ear cleft characterized by ear discharge and a permanent Perforation. The incidence of CSOM is higher in developing countries because of poor socioeconomic standards, poor nutrition, and lack of health education.[2] It affects both sexes and all age groups. In India, the overall prevalence[3] rate is 46 and 16 persons per thousand in rural and urban populations, respectively. It is also the single most important cause of hearing impairment in the rural population. The general line of treatment includes frequent aura toileting and administration of anti-inflammatory and antibacterial ear drops. As validating the old facts is one of the aims of research; *Kushtadi Taila* -mentioned in *Bhaishajya Ratnavali* in *Karna Roga Adhikara* has been selected for the present study. Its ingredients are *Kushta*, *Hingu*, *Vacha*, *Shunti*, *Shatahva*, *Devadaru*, *Saindhava Lavana*, *Bastha Moothra,* and *Tila Taila* as a base. Which are very cheap & easily available in their authentic form. The ingredients have *Vatakaphahara*, *Vranaropaka*, *Vrana Shodhaka* properties. Since randomized controlled trials are the most rigorous way of determining whether a cause-effect relation exists between treatment and outcome and for assessing the cost-effectiveness of treatment; in the present study, ciprofloxacin ear drops are used as standard medicine in the control group. The study was performed on 40 sample size and analyzed with suitable statistical methods.

Aim of the Study:

"Open-label clinical study to compare the effect of *Kushtadi Taila Pichu* and ciprofloxacin ear drops in putikarna" (safe chronic suppurative otitis media).

Objectives of the Study:

- To evaluate the efficacy of *Kushtadi Taila Karna Pichu* in the management of *Putikarna*.
- To evaluate the efficacy of ciprofloxacin ear drops in *Putikarna* (CSOM).
- To compare the effect of *Kushtadi Taila Karna Pichu* and ciprofloxacin ear drops in *Putikarna* (CSOM).

Materials & Methods:

Source of Data: OPD of *Shalakaya Tantra*, SJGAM College Hospital Koppal.

Method of Collection of Data: sample size estimation was done using the formula

N= 4PQ/E2 which was 40. Hence 40 patients diagnosed as *Putikarna* in an age group of 07-40-year-old were selected and randomly categorized into Group 'A' (n=20) and Group 'B'(n=20)

Type of study: Open labeled comparative clinical study.

Drug source:

1. The raw drugs needed for preparing Kushtadi Taila were purchased from the standard herb dealer from the market and their authentication was done by the Department of Dravyaguna, RGES's Ayurveda Medical College and Hospital, Rona.

- **Method of drug preparation:** *Kushtadi Taila*[4] was prepared in the *Rasashala* of SJGAMC as per the reference mentioned in *Bhaisajya Ratnavali*.
- **Ingredients**: *Murchita tila taila, bastha moothra, kushta, hingu, Vacha, devadaru, Satava, sunti, and rock salt*.
- **Process of *Taila* preparation**: *Murchita tila taila* 1 liter, *Basta Mootra* 1 liter, and a total of 250 gm of *Kalka Dravyas* was taken and *taila* was prepared according to *Taila Paka Vidhi*.

2. Ciprofloxacin[5] ear drop was procured from the market.
3. Tab *Nimbadiguggulu*[6] was procured from the market.

Ethical Clearance: This study got clearance from institutional ethical comity with vide reference no **SJGAMC & HK /ICEC/2019-20/137** and dated 19/09/2020 and this study was Registered on 12/09/2019 in CTRI with vide reference no **CTRI/2019/09/021197**.

Study Design:

Selection Criteria: The selection of patients was based on clinical features of putikarna mentioned in *Ayurveda* as well as safe chronic suppurative otitis media as in modern otolaryngology

Inclusion Criteria:

- Patients presenting with features of Safe Chronic Suppurative Otitis media for more than 3 months.

Patients in the age group of 6 to 40 years and irrespective of gender.

Exclusion Criteria:

- Ear discharge is associated with complications such as cholesteatoma, polyps, granulation tissue, and purulent discharge with a foul smell.
- Patients with immune-compromised diseases.
- Pregnant and lactating women.
- Attic and total perforations.
- Patients with severe conductive deafness, mixed deafness.
- Patients with blood-stained ear discharge.

Intervention:

- Group A: patients of this group were given *Kushtadi Taila Karna Pichu*[7] daily two times for 7 days.
- Group B: patients of this group were treated with ciprofloxacin ear drops 2-3 drops three times a day for 7 days.
- Both the groups were given Tab. *Nimbadi Guggulu* 500 mg Bid orally for 7 days.

Assessment: The parameters were assessed on,

- Before Treatment (day 1),
- After Treatment (7^{th} Day),

And during the treatment and the Clinical observations were recorded systematically and thoroughly in the Case Record Form prepared for the study.

Follow up: First Follow Up 14^{th} day and Second Follow Up on the 21^{st} Day.

Gradation Parameter:

To assess the effect of therapy, all the signs and symptoms were given scoring depending upon their severity as below:

Grading of parameters	
Ear discharge	0 – Absent 1 – Mild - scanty secretion near Tympanic membrane 2 – Moderate - Secretion irrigating in the ear canal 3 - Severe - secretions coming out of ear canal
Tympanic membrane Perforation	0 – No perforation of the tympanic membrane 1 – small 2 – medium 3 - large
Pure tone audiometry (Hearing loss)	0 – up to 25 dB 1 – 26 to 45dB 2 – 45 to 65dB 3 - more than 65dB

Assessment of overall response:

To evaluate the effect of treatment on individual parameters in Group A and Group B

Good response – Above 75% relief in overall features.

Moderate response – 50%-75% relief in overall features.

Poor response – Below 25% relief in overall features.

Statistical analysis was done using

1. *t-test, 2: Chi-Squared Test, 3: Fisher's Exact Test, 4: Wilcoxon Test*

The result of having a P value less than <0.05 is considered as statistically significant in this study.

Investigations: - pus culture and sensitivity.

Observations & Results:

Demographic Analysis:

Age: CSOM can occur at any age, but more commonly seen in children. In this study slightly a greater number of patients were in the age group of 20-40 years. This may be because of the small sample size.

Sex: It was observed that the number of male patients (60%) suffering from *Puti Karna* was more than female (40%). This may be because the incidence in males is more than in the female. **Religion:** Religion wise distribution of patients showed that the majority of patients (82.5 %) were Hindus. This is probably suggestive of a more local Hindu population. Hence it has no research significance. **Occupation:** housewife (20%) business people (15%) and students (47.5%) were affected more. Exposure to dust, poor nutrition, and poor living standards could be a major reason for more involvement of housewives as they belong to a rural area. The involvement of students could be due to the reason that they come under the age group wherein the incidence of the disease is more. **Socioeconomic status:** Socioeconomic wise distribution of patients in this study showed that putikarna is more prevalent in the poor (27.5%) than in the middle class (70 %) and rich (2 %). It might be because poor living standards, poor nutrition, lack of health education, lack of timely treatment in the lower class and middle class predisposes to chronic suppurative otitis media. **Diet**: Based on the diet it could be noted that the majority of the patients (60%) were from a mixed diet. This may be because the majority of the population in this area is of a mixed diet. This did not have any research significance. **Marital status:** In the present study it is observed that 18(45%) patients were married and 22 patients (55%) were unmarried. No proven reference regarding the relation of CSOM with marital status is available. ***Prakruti*:** *Prakruti* wise distribution showed that the maximum number of patients in this study were of *Kaphavata Prakriti* (70 %). This shows that *Kaphavata Prakruthi* persons are more predisposed to *putikarna* this may be because *Vata* and *Kapha* are the main *Doshas* involved in *Putikarna*.

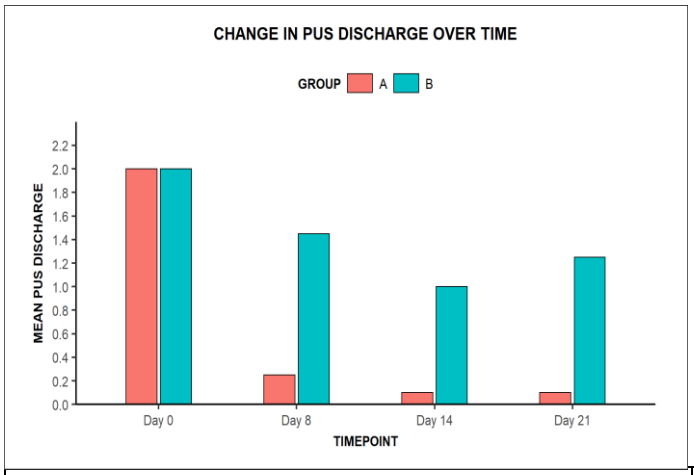
Habitat: Habitat wise distribution showed that the maximum number of patients (70 %) in this study were of the rural area this could be because the disease prevalence is seen more in a rural area. **Laterality:** *Putikarna* can be unilateral or bilateral, in the present study, out of 40 patients all of them had unilateral involvement. **Chronicity:** The bulk of patients were concentrated in the group with the duration of illness for more than three months. It was observed in the present study that patients with a duration of less than 3months had shown faster and stable results compared to the others.

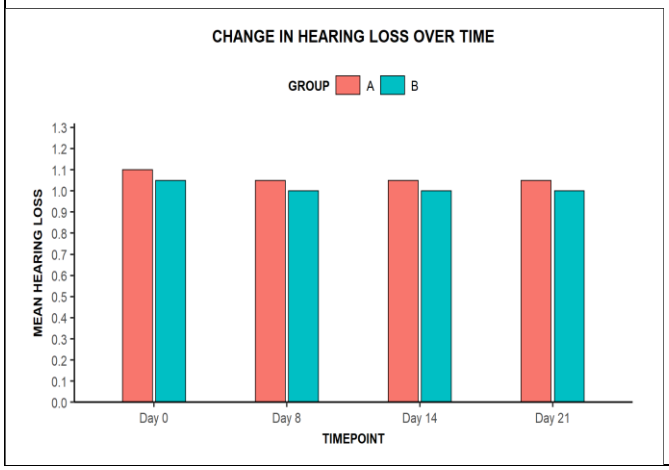
Disease Analysis:

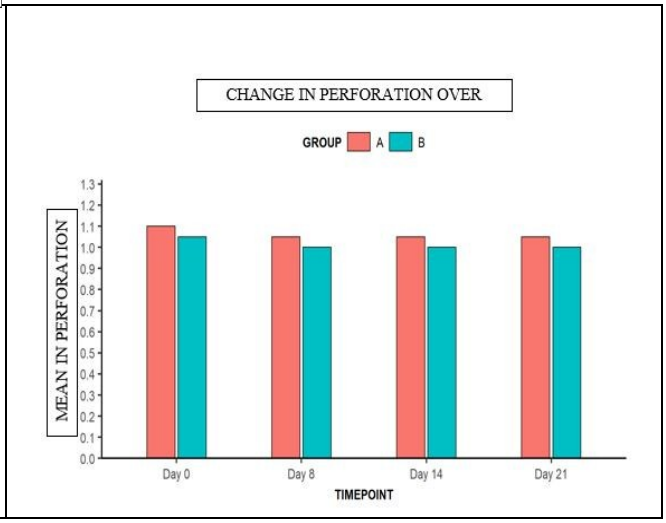
While observing parameters: Out of a total of 40 patients in group A & B, At the end of treatment, 18 patients showed good response in Group A and 2 patients showed good response in Group B. 1 patient showed a moderate response in group A and 8 patients in Group B, 1 patient showed a poor response in Group A and 10 patients in Group B.

Group A: showed **5**% recurrence of ear discharge and 95 % showed no recurrence., **Group B**: **showed 50%** recurrence of ear discharge and 50% no recurrence

There was no change in the other parameters – perforation and hearing loss before and after treatment.







Results: Both *Kushtadi Taila Karna Pichu* and ciprofloxacin ear drops gave symptomatic relief in all subjects. There was a statistically significant difference between group A and group B in-ear discharge. ($p<0.05$). There was no statistically significant difference in other parameters. Comparative analysis within the groups before and after treatment was statistically significant at $p=0.01$. Multiple comparisons result for the effect of varied duration (before, during & after treatment and follow up) on the efficacy of treatment within the two groups (group A and group B) was statistically significant at $p=0.05$.

DISCUSSION

On disease: *Putikarna* is a common *Karna Roga* in tropical regions. Chronic suppurative otitis media is a fairly common infection affecting the mucosa of the middle ear cleft with a prevalence rate is 46 and16 persons per thousand in rural and urban populations respectively.[8] It is also the single most important cause of hearing impairment which can be easily preventable. Though meticulously managed CSOM gets cured gradually but sometimes because of improper medication, resistance to medicine, and lowered immunity cause persistent infection or off and on infection and resultant otorrhea, which affects an individual's quality of life to great extent. The presence of this disease in early childhood can hamper the speech development of the child after lowering the hearing level. In school children, there will also be a hindrance in learning, because of reduced hearing. The infection of tonsils/adenoids/sinuses associated with CSOM may further hamper the development and intellect of a child. So, all these facts leave a scope to find out a better solution for the disease

from the medical heritage of the traditional Indian System of medicine, an effective treatment approach, which is simple and economical, needs serious consideration on drugs and procedure. The ingredients of *Kushtadi Taila are Kushtadi, Vacha, Hingu, Shatapushpa, Saindhava Lavana, Devadaru, Shunti*. These drugs possess *Katu* and *Tikta Rasa*, *Ruksha*, *Laghu*, *Tikshna* Guna*, Ushna Veerya,* and mainly *Kapha-Vata Hara* properties. *Tila Taila* used as a base in *Kushtadi Taila* preparation is considered as a *Shreshta Vatahara*. It alleviates *Vata* and the *Vyavayi*, *Vikas Guna* Of *Tila Taila* helps in better absorption. *Katu* Rasa Has *Shodhana, Krimihara, Kanduhara, Kledahara, Vrana Avasaadaka, Kapha Shaamaka properties, and Tikta Rasa has Shodhana, Kanduhara, Puyashoshanakara Krimihara* properties. Both help to reduce ear discharge and remove debris leading to wound healing. *Ruksha Guna* is having *Shoshana Shakti* which will absorb the discharge in the auditory canal and reduce the *Kapha Dosha*. *Laghu Guna* having *Lekhana* and *Ropana* properties helps in the healing of the wound. *Tikshna* and *Sara Gunas* by *Shighrakaari* property start action very quickly. *By properties of its ingredients, Kushatadi Taila Is Vrana Shodhaka, Vrana Shamaka, Vedanasthapaka, Puyashoshanakara,* thereby reducing *Srava* and other symptoms, the ingredient drugs also have the properties of Antimicrobial anti-inflammatory and astringent which are essential for the treatment of chronic suppurative otitis media, hence *kushtadi taila* by these qualities discourage bacterial growth and helps to reduce local edema, exudation and inflammation. Astringents when applied topically in low concentration stimulate the growth of new tissue. *Pichu* facilitates more tissue contact time and minimal usage of the drug. The local action of Pichu is based on cellular absorption of the medicine. Pichu also helps in the wound healing process by absorbing the secretions from the ear canal. Ciprofloxacin ear drops are a topical antimicrobial agent belongs to the fluoroquinolones group which is composed of Ciprofloxacin 0.3% w/v Benzalkonium Chloride, NF0.01% w/v (Preservative) Sterile aqueous vehicle q.s and it is already proven its antimicrobial activity over both gram-negative and gram-positive organism. *Nimbadi Guggulu* It has *Tridoshagna, Vrana Ropaka*, *Vranashodhaka, Vedanastapaka Guna,* and possesses *Katu Tikta Kashaya* and *Ushna Veerya* helps as bacteriostatic and reduces the discharge by controlling *the* infection of middle ear cleft promoting the healing in CSOM. The *Nimbadi Guggulu* Tablet was given in both groups; the action of these tablets will be the same in both groups.

Discussion on aural toileting

Karnapramarjana in prime treatment modality was mentioned for *Karnasrava* and *Putikaarna Chikitsa*. The current primary treatment modality for CSOM is a combination of aural toilet and topical antimicrobial drops. The term aural toilet refers to keeping the chronically draining ear clean and dry as much as possible. Techniques include in-office mopping with cotton swabs, suctioning to remove discharge and debris, and placing an ear wick. So just by instilling the ear drops without proper cleaning of the ear canal will not help in reducing the ear discharge, due to this there will be a chance of growth of fungus leads to otomycosis. So, the combination of aural toilet and topical medicine is a must for proper healing of the CSOM.

Discussion on Culture Sensitivity:

All the patients were subjected to culture and sensitivity to rule out the microorganism involved causing the CSOM. 20 patient's culture and sensitivity showed E.coli as a causative organism and in the remaining 20 patients, pseudomonas argeunosa was seen. In the above-said organisms, good results were observed in E.coli and pseudomonas aeruginosa, so it suggests that the kushtadi taila is having properties of controlling the infection due to its antimicrobial properties present in it.

Discussion on Analytical Test:

The *Kushtadi Taila* Was Subjected to Analytical Study for Standardization These Are The Tests And Its Values. Specific Gravity 0.88, Viscosity -3.34-3.37 Peroxide Value Negative, Acid Value -5.61, Rancidity –Negative, Saponification Value-185.5 Iodine Value -88.11 Ph Value-7.4, Refractive Index -1.47 Gas Chromatography N-Butanol Extract- RI-2085, 2175, 1285, 1580, 1828, 2169, 2093, 2366, 2274, 1191.

TLC Was Done In Extract Diethyl Ether In Toluene: Ethyl Acetate 9:1 Solvent System the RI in Visible

Light Was 0.37 and in short UV 0.37 and Long UV 0.05, 0.08, 0.13, 0.17, 0.219, 0.255.

Other Observations:

The ciprofloxacin ear drop is the one that is used as an antimicrobial drug in CSOM. After starting the treatment it's observed that there was the presence of fungal mass after 2-3 days and it may be due to the aqueous base or instilling the ear drops without doing aural toileting.

Result

Comparison between Group A and Group B: The comparative statistics were done to evaluate the efficacy of ***Kushtadi Taila Pichu*** **and ciprofloxacin ear drops in** ***Putikarna*****"** The calculated data shows the comparative result is significant ($p< 0.05$) between the groups. The mean value, however, was found higher for Group A (Group A > Group B) in the overall assessment which is suggestive that there was a mean difference between the groups. if we increase the sample size then we might obtain significant results. Therefore, further research is needed with a large sample size.

CONCLUSION

The following conclusions are drawn after considering the clinical aspects and theoretical facts. *Putikarna* can be compared to chronic suppurative otitis media. In both, ear discharge is the chief complaint. Both Groups were found not effective in the healing of perforations of the tympanic membrane and relief of hearing loss. The *Karnapichu* can be used wherein *Karna Purana* is mentioned, in the case of putikarna as there will be tympanic membrane perforation while doing *Karnapurana* the *Taila* may enter into the middle ear through the perforation and may create complications but by doing *Karna Pichu Dharana* it can be avoided. So, it's been advised to use *Karna Pichu* if there is Tympanic membrane perforation. And is not a time-consuming procedure like *Karnapoorana* and its cost-effective, safe, and easy procedure that can be performed at the O.P.D. level without any complications. Still, the further scope for the present study pattern can be contributed to the form of a prospective clinical study with an increased sample size. As the *Kushtadi Taila* shows good sensitivity over E.coli and pseudomonas aeruginosa by controlling the infection in CSOM so the present study can be contributed by doing culture and sensitivity over other gram-positive and gram-negative organism.

REFERENCES

1. *Sushruta; Sushruta Samhita, Uttara Tantra*; English Translation By Prof. Priyavrat Sharma; Published By Chaukambha Visvabharati: Varanasi; Reprint-2014; Vol III; .Cha.No/Sl.No-20/15-16; P.No-237.
2. PL Dhingra S Dhingra; Diseases of Ear, Nose, and Throat. 4th Ed. New Delhi: Elsevier; 2007. Cha.No 11 P. No-67.
3. PL Dhingra S Dhingra; Diseases of Ear, Nose, and Throat. 4th Ed. New Delhi: Elsevier; 2007. Cha.No 11 P. No-68.
4. *Bhaisajyaratnavali Of Shri Govinda Dasji*; Published By Chowkhamba Sanskrit Sansthan, Varanasi; Vol III; Shiroroga Adhikara; Cha. No/Sl. No-62/42 Pg No 239.
5. Https://Www.Ciplamed.Com/Content/Ciplox-Eyeear-Drops
6. *Basavaraja, Shree Govardhana Sharma Chagani: Basavarajeeyam*, Edited By Pandit Shivakarana Sharma Changani: Published By Rasayana Pharmacy: Delhi: Edition: 2014, Pg.: 275.
7. *Vaghbhata; Ashtanga Hrudaya, Uttara Tantra*; English Translation By Prof. K. R. Srikantha Murthy; Published By Chaukambha Krishnadas Academy Varanasi; Reprint-2018; Vol III; Cha.No18/Sl.No-17-19; P.No-164.
8. PL Dhingra S Dhingra; Diseases of Ear, Nose, and Throat. 4th Ed. New Delhi: Elsevier; 2007. Cha. No 11 P. No-68.

Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Open Label Clinical Study To Compare The Effect Of Kushtadi Taila Pichu And Ciprofloxacin Ear Drops In Putikarna (Safe Chronic Suppurative Ottitis Media). International Ayurvedic Medical Journal {online} 2020 {cited October, 2020} Available from: http://www.iamj.in/posts/images/upload/4735_4741.pdf