



Management of Otitis externa with Ayurvedic formulation *Gandhak Rasayana*- A case report

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ABSTRACT

Otitis externa is an inflammatory and infectious disease that affects the external auditory canal. The term otorrhea refers to the outflow of discharge from the ear which is one of the main symptoms of otitis externa along with inflammation. External ear canal pathology or middle ear illness with tympanic membrane perforation is the etiological factor of otorrhea. Otorrhea is an indication of infection. Antimicrobial agents are the conventional treatment of various bacterial and fungal infections, but they have impediments such as resistance development, side effects, patient affordability, etc. The *Gandhak Rasayana* formulation mentioned in the *Ayurvedic* text can be a good option for the treatment of various infectious diseases. *Karnasrava* is a type of ear disease referred to as *Vata* predominant *Tridosha* disease and it is curable. The term *Karnasrava* signifies discharge from ear and is self-explanatory. *Karnasrava* consists of a wide spectrum of diseases and can have a near correlation with otitis externa as per signs and symptoms. *Gandhak Rasayana* exhibited significant antibacterial, antifungal and anti-inflammatory activity in otitis externa. Evaluating its antibacterial and antifungal activity can provide scientific evidence for the study through the present case report.

A 31-year-old male patient registered in OPD at Sane Guruji Hospital, Hadapsar, Pune was clinically diagnosed as *Karnasrava* (Otitis externa) and pus culture positive for *Klebsiella* species.

We started the treatment with *Gandhak Rasayana*-an *Ayurvedic* formulation of 250mg two tablets in the morning and evening with lukewarm water for 21 days. The outcome of the treatment was observed as a reduction in *Karnashula* (otalgia), *Karnasrava* (ear discharge), *Karnakandu* (itching), ear blockage and inflammatory changes. Post-treatment culture was negative for the organism. The improvement was noted in Brighton grading scale from grade III to grade I.

Gandhak Rasayana showed significant antibacterial activity in the present case. Evaluating its antibacterial, antifungal and anti-inflammatory activity can provide scientific evidence for the study.

1. Introduction

Otitis externa (ICD- H60.5) is an inflammatory and infectious condition that affects the external auditory canal and causes otorrhea, hearing loss, otalgia, and pruritus, many a time associated with a history of water exposure or local trauma. In terms of aetiology, Otitis externa is mainly caused by fungal overgrowth. Swimming, regular instrumentation, dermatitis, immune-challenged patients, unsanitary habits, and pre-existing ear illness are all predisposing factors for ear disease [1]. The most often isolated species are *Pseudomonas aeruginosa* and *Staphylococcus aureus*. *Proteus* species, *Staphylococcus epidermidis*, diphtheroid, and *Escherichia coli* are among the less usually isolated

microbes. Symptoms of Otitis externa may vary on the basis of the stage and severity of the condition. The presence of otalgia, otorrhea, auditory fullness, pruritus, pain to tenderness, and varying degrees of external auditory canal blockage imply a clinical diagnosis [2]. In the vast world of drugs, antibacterial agents are among the most widely used and abused drugs access to the medical profession. In the old days, magic bullets for their great contribution to curing infections, but recently these bullets also backfired causing resistance, and reducing their effectiveness with side effects [3]. Different studies have shown that the common pathogens causing ear discharge are *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *E. coli*, *proteus vulgaris*, *klebsiella pneumoniae* and *candida albicans* [4,5].

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Management strategies are limited as one of the basic and safe measures to treat wet ear. Medical and surgical alternatives come with potential side effects and risks, and in certain cases, they may not be entirely effective in eradicating the disease. Additionally, surgery may increase the risk of hearing loss and possibly facial nerve injury, limiting its use. Topical antibiotics are the first line of treatment. However, it is important to use antibiotics that are unlikely to cause ototoxicity. Topical sensitivity is a common feature, especially in cases that are resistant or recurring. Additionally, burning or stinging sensations are frequent side effects of ear drops, which might impact a patient's willingness to comply with the treatment [6]. Systemic antibiotics are used in localised and/or systemic diseases. In contemporary medical science, the treatment for otorrhea involves cleansing and removing debris from the external auditory canal (EAC). There has been a rise in the incidence of otorrhea in recent years. This increase is linked to the resistance that occurs to bacteria due to the prevalent usage of antibiotic ear drops, steroids, broad-spectrum antibiotics, and various other medications. In order to mitigate the adverse effects associated with these medications, it is important to identify the most efficient and safe treatment for Otitis externa. Using natural source compounds in the development of new and improved antibacterial or antifungal drugs, alongside conventional treatments, may offer a promising approach to enhance effectiveness and safety.

The *Gandhak Rasayana* formulation mentioned in the Ayurvedic text can be an ideal medicine for the treatment of various infectious diseases. *Gandhak Rasayana* can be used both internally and externally for the disorders described in the Ayurvedic classics. The *Acharyas* were fully aware of *Gandhaka's* restorative properties, as mentioned in *Kustha* (skin disease), *Krimi* (parasite infestations), and other literature. According to reported studies, *Gandhak Rasayana* is safe and does not have any toxicity potential at therapeutic levels. Some of the alterations were identified at higher dose levels that are unlikely to be used in clinical settings [7]. As per *Acharya Sushruta*, the management of *Karnasrava* (J-14) involves various treatment such as *Shirovirechana* (*Nasya*), *Dhoopan* (medicated fumes), *Poorana* (filling the ear with medicated decoctions or oil), *Pramarjana* (cleansing ear with medicated decoction), *Dhaavana* (aural toileting), and oral medication therapy [8]. In light of these considerations, a secure, effective, and easily available treatment for otitis externa is necessary. The literature about treating these types of ear diseases with single Ayurvedic medicine is silent, making this case unique.

Karnasrava is described by *Acharya Sushruta* in chapters on ear diseases among the twenty-eight ear disorders [9]. *Karnasrava* consists of a wide spectrum of diseases and can have a near correlation with otitis externa as per signs and symptoms. Due to *Shiroabhogata* (head trauma), *Jala Nimmajjana* (splashing in water on head), *Karnapaka* (yellowish ear discharge), *Karna Vidradhi* (ear abscess), *Vata* vitiates other *Dosha* and ear canal become stagnated by *Vata* and results in *Karnasrava* [10]. In terms of disease prognosis, *Acharya Vagbhata* suggests that wounds/ulcerations in the skin and muscular tissue, as well as wounds/ulcerations in the ear, are treatable with appropriate medical intervention [11]. *Karnasrava* was regarded as curable disease by *Acharya Vagbhata* described in the *Uttaratantra*. *Gandhak Rasayana* showed significant antibacterial and antifungal activity in otitis externa, but the antibacterial activity was significant compared to antifungal activity. Evaluating its antibacterial and antifungal activity can provide scientific evidence for the study through the present case report.

1.1. Patient information

A 31-year-old male patient complaining of sudden onset of *Karnasrava* (ear pain), *Karnasrava* (otorrhea/purulent ear discharge), *Karnakandu* (itching), and ear obstruction since three days, occurring after exposure to river water (swimming). The patient also had a habit of using headphones and earbuds regularly. The pain and itchiness increased day by day with discharge from the ear and the intensity of the

pain and itching increases at night and in cold weather. So, he consulted *Shalakyatantra* OPD of Sane Gururji Hospital, Hadapsar, Pune for further management.

2. Findings

2.1. General & systemic examination

The patient was of average height, weight 68 kg and belongs to a low socio-economic category. Professionally, he is a security guard. No significant family history was identified and personal history suggested poor sleeping and eating habits. The patient does not have a history of Diabetes Mellitus or hypertension. All vital signs were within normal limits. Physical examination revealed no signs of pallor, jaundice, oedematous limbs, oedema, or lymphadenopathy. There were no abnormalities noted in the cardiovascular system, respiratory system, and central nervous system during the examination.

2.2. Investigation

Pus Culture – S/o *Klebsiella* species.

2.3. Clinical findings

The clinical examination of the ear is shown in Table 1.

2.4. Diagnostic assessment

The diagnostic assessment included a thorough examination based on specific assessment points, and a comprehensive differential diagnosis was conducted to eliminate the possibility of other ear canal ailments. The assessment points include otoscopic examination, endoscopic examination, pus culture, and pre-treatment/post-treatment photographs.

The differential diagnosis for otitis externa took into account disease conditions such as acute otitis media, psoriasis, furunculosis, Herpes Zoster Oticus (Ramsay-Hunt syndrome), contact dermatitis of the ear canal, Temporo-mandibular joint syndrome, foreign body, carcinoma of

Table 1
Clinical examination of ear with findings.

	Examination of ear	Right ear	Left ear
1	External ear and surrounding area		
	Shape and size of pinna	Normal	Normal
	Position	Normal	Normal
	Colour	Reddish	Normal
	Tenderness	^b Present++	No any tenderness
	Swelling	^b Present+	Absent
	Local temperature	Raised	Normal
2	External auditory canal		
	Meatal skin	Hyperaemic	Normal
	Fungal Moulds	Absent	Absent
	Wax	Absent	Absent
	Discharge	Present- Thick, mild greenish	Absent
3	Tympanic membrane		
	Position	^b Retracted ++	Normal
	Colour	Hyperaemic	Normal
	Cone of light	Absent	Present
4	Examination of middle ear	Not seen	Handle of malleus seen
5	Mastoid	Non tender	Non tender
6	Eustachian tube	Normal	Normal
7	Tuning fork test		
	Rinne's test	^a BC>AC	AC > BC
	Weber's test	Lateralized to right ear	No lateralized

^a BC- Bone conduction, AC- Air conduction.
^b Where + as mild, ++ as moderate and +++ as severe.

the ear canal. However, on the basis of otorrhea, inflammatory changes and canal wall obstruction the diagnosis was confirmed as otitis externa.

The Brighton Grading Scheme was adopted to quantify the severity of otitis externa as shown in Table 2.

3. Therapeutic intervention

The drug formulation i.e. *Gandhak Rasayana* (*Dhootapapeshwar* pharma) was prescribed to the patient [12]. The ingredients and composition of *Gandhak Rasayana* are mentioned in Table .3.

3.1. Follow up and timeline

The treatment timeline and follow up are mentioned in Table .4. No any concomitant treatment was administered during the treatment period.

3.2. Result

Following the five days of treatment, the patient experienced relief from symptoms. Within a week, substantial improvements in both signs and symptoms became evident. By the end of 14th day of the prescribed course of treatment, the patient reported relief from ear pain and heaviness, accompanied by a reduction in other associated signs and symptoms(see Fig. 1). Subsequent follow-up revealed no remaining symptoms, complaints or recurrences. No adverse events related to the medication were observed throughout the treatment period.

4. Discussion

About 25% of individuals with acute otitis externa experience daily life disruption. Acute otitis externa has the potential to progress into chronic otitis externa, resulting in canal stenosis that may adversely affect hearing. Common side effects of otitis externa include periauricular cellulitis and malignant otitis externa. Additionally, myringitis, perichondritis, facial cellulitis, necrotizing otitis externa, and osteomyelitis of the temporal bone are among the further complications associated with this condition [13]. The presence of watery and purulent discharge (otorrhea) in Otitis externa indicates the presence of *Paka* (inflammatory changes). Ulceration may occur during the cleaning of the ear canal. The external auditory canal is likely to get damaged. Taking this into consideration otitis externa can be treated in a variety of ways. In the *Uttaratantra*, *Acharya Vagbhata* described *Karnasrava* to be a curable ear disease [11]. In the treatment of otitis externa, *Gandhak Rasayana Vati* proved to be successful as a single formulation regimen. *Gandhak Rasayana Vati* enters all *Sukshma Strotasa* (microcirculatory channels) with *Anupana* (compliant) and acts on *Dosha, Dhatu*, and *Mala*. In *Gandhak Rasayana*, certain *Bhavanadravyas* (trituration medicine) work as bactericidal agents. *Guduchi* (*Tinospora cordifolia*), *Bhringaraj* (*Eclipta alba*), *Dalchini* (*Cinnamomum verum*), *Tamalpatra* (*Cinnamomum tamala*), *Nagkeshar* (*Mesua ferrea*), *Haritaki* (*Terminalia chebula*), *Shunthi* (*Zingiber officinale*), and *Bibhitak* (*Terminalia belerica*) are the herbs used for trituration having *Katukashay Rasa* (pungent and

Table 2
The Brighton Grading Scheme for otitis externa.

Brighton Grade	Description
Grade I	Localised canal inflammation with mild pain, no hearing loss and tympanic membrane visible
Grade II	Debris in ear canal (not completely occluded) and erythematous ear canal, tympanic membrane may be partially obscured
Grade III	The ear canal is oedematous, erythematous, and occluded (often completely closed), and the tympanic membrane cannot be seen
Grade IV	The tympanic membrane is obscured, perichondritis and pinna cellulitis, and signs of systemic involvement.

Table 3
Ingredient and composition.

Ingredient	Binomial name
Gandhak	Purified sulphur
Godugdha	Cow Milk
Twak	<i>Cinnamomum zeylanicum</i> J.Presl
Ela	<i>Elettaria cardamomum</i> (L.) Maton
Patra	<i>Cinnamomum tamala</i> (Buch. -Ham.) T.Nees & C.H.Eberm.
Nagakeshar	<i>Mesua ferrea</i> L.
Guduchi	<i>Tinospora cordifolia</i> (Thunb.) Miers.
Haritaki	<i>Terminalia chebula</i> Retz.
Amalaki	<i>Emblica officinalis</i> L.
Bibhitaki	<i>Terminalia bellirica</i> (Gaertn.) Roxb.
Shunti	<i>Zingiber officinalis</i> Roscoe.
Bhringaraja	<i>Eclipta alba</i> L.
Sita	Sugar

Table 4
Treatment details and follow up.

Duration	Brighton Grade	Treatment Given	Result
1st sitting (From 28/02/2022 to 06/03/2022)	Grade III	Mopping of EAC with the help of sterile cotton applied on the Jobson-Horne probe. <i>Gandhak Rasayana</i> Vati 250mg two tab bid with Luke warm water	Tenderness reduced; Ear discharge cleaned completely on 5th day. Pain – Reduced up to 70% Itching – reduced Ringing sound - Reduced Ear blockage- cleared Redness of EAC & TM was present
2nd sitting (From 07/03/2022 to 13/03/2022)	Grade II	Mopping of external auditory canal with the help of sterile cotton applied on Jobson-Horne probe. <i>Gandhak Rasayana</i> Vati 250mg two tab bid with Luke warm water	Ear Discharge – Absent Pain in right ear- Completely reduced Itching - Absent Ringing sound –Absent Ear blockage -Absent Redness of external auditory canal & Tympanic Membrane- Mild present
3rd sitting (From 14/03/2022 to 20/03/2022)	Grade I But not having any ear canal inflammation	<i>Gandhak Rasayana</i> Vati 250mg two tab bid with Luke warm water	In Follow up patient didn't have any complaints. On oto-endoscopic examination there was no ear discharge.
Observation Follow up		No treatment was administered.	Culture sensitivity done and found no growth in external auditory canal.

astringent taste) and *Ushna Virya* (hot potency) characteristics. As a result, it performs *Deepana* (digestion and metabolism enhancing activity), *Pachana* (appetizer), and *Kaphaghna* (alleviates *Kapha*) *Kledaghna* (alleviates moisture) activity. In this study, *Gandhak Rasayana Vati* aids to cure disease by acting as *Agnideepak*, *Pachak*, *Kaphaghna*, *Kledaghna*, *Raktaprasadak*, *Krimighna*, and *Kushthaghna*. *Gandhak Rasayana* is beneficial in treating the ailments associated with *Kapha*, *Rakta* and *Tvak Dushti* (~skin ailments). Microorganisms are increasingly developing resistance to existing antibiotics. Therefore, instead of employing a localized modern treatment, the authors opted to administer *Gandhak Rasayana* orally.

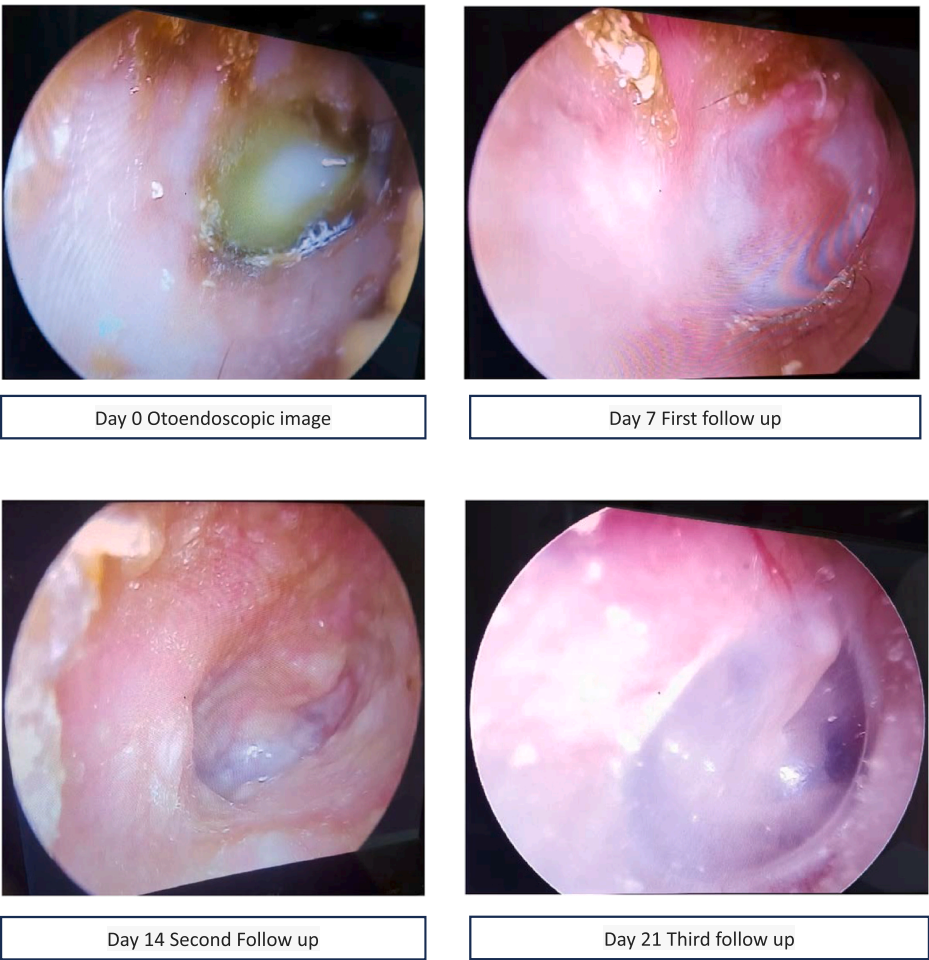


Fig. 1. Otoendoscopic image.

Looking at the *Gandhaka Rasayana* in chronological order from the sources, in *Ayurveda Prakash*, it is clear that they deliberately structured it for the correction of *Agni* (digestive fire) at all levels, from *Koshta* to *Dhatu*. These can also be utilised to cure diseases caused by the disruption of the seven *Dhatus*, ranging from *Rasa* to *Shukra*. *Gandhak Rasayana* is a highly effective *Ayurvedic* medicine with a mineral foundation of purified or detoxified sulphur. Sulphur has undergone detoxification in *Gandhaka Rasayana* through an ancient method outlined in *Rasashastra* literature, diminishing the irritating and toxic properties of sulphur. Herbal juice is used as the main element in the processing.

In ancient Ayurvedic scriptures, *Gandhaka* is referred to as *Krimighna* (anthelmintic). Sulphur has been linked to the antibacterial agent sulphonamides. These medications have been shown to work by preventing the growth of sensitive bacteria by inhibiting their folic acid metabolism [14]. As a result, Sulphur in *Gandhaka Rasayana* could have the same antibacterial mechanism. Because one of sulphur's metabolites, penta thionic acid, was thought to promote cuticle lysis, sulphur ointment was commonly used topically as a scabicide and pediculocide. This demonstrates that sulphur works as a microbicidal agent both systemically and topically [15]. The detailed pharmacological properties of the ingredients of *Gandhak Rasayana* are shown in Table 5. Single-drug therapy is always a challenging part of the *Ayurveda* stream because of the non-availability of standardized herbo-mineral preparations. *Gandhak Rasayana* was reported to be safe and non-toxic if prepared properly [7]. It is also a cost-effective solution if used as a single drug therapy in ear canal diseases having purulent discharge as a hallmark symptom. A sterile cotton probe was used to clean the purulent ear discharge from external auditory canal during each follow up. Mopping

Table 5 Pharmacological properties of individual drug in <i>Gandhak Rasayana</i> .		
Sr. No.	Ingredients	Properties
1	<i>Gandhak Rasayana</i>	Antibacterial, Antiviral, Antimicrobial, broad-spectrum effect [16,17]
2	<i>Pippali</i>	Antioxidant and Anti-inflammatory [18]
3	<i>Triphala Churna</i>	Antioxidant, Immunomodulatory and Antibacterial effect against <i>Klebsiella pneumonia</i> [17,19]
4	<i>Haritaki Churna</i>	Mild antibacterial agent against <i>Klebsiella pneumonia</i> . Antibacterial and Antifungal [20]
5	<i>Amalaki</i>	Antibacterial, Antimicrobial[21] [Page 220]
6	<i>Bibhitaki</i>	Antibacterial and Antifungal [21] [Page 216]
7	<i>Nagakeshar</i>	Antibacterial activity against <i>Staphylococcus aureus</i> [21] [Page 67]
8	<i>Guduchi</i>	Antitubercular, Antidiabetic, Hepatoprotective, Lowering cholesterol [21] [Page 33]
9	<i>Bhringaraja</i>	Antiviral and Hepatoprotective [21] [Page 294]
10	<i>Shunthi</i>	Antibacterial, Antitubercular, Improves gastrointestinal functions [21] [Page 871]
11	<i>Tamala</i>	Anti-diabetic [21] [Page 618]

of the ear canal also leads to quick healing of tissue.

Furthermore, many medications listed have been shown to have antibacterial efficacy against microorganisms that are more commonly isolated from ear discharge in Otitis externa patients. Their antibacterial effect inhibits the growth of these pathogens in the external ear, keeping it free of infection and dry. Based on the findings of this study, it may be assumed that *Gandhaka Rasayana* orally has the same pharmacokinetics as any other antibiotics and antifungals researched in modern

pharmacology, and more research is needed to validate these results.

5. Conclusion

Karnasrava (Otitis externa) is a disease that can lead to serious consequences such as necrotizing otitis externa. The implementation of an *Ayurvedic* treatment plan can effectively manage *Karnasrava* by improving overall health. The provided treatment is not only cost-effective but also safe and easy to administer. Combining the treatment with proper *Pathyahaar* (wholesome diet), a course of *Gandhak Rasayana*, is effective for addressing *Karnasrava*. In cases where *Karnasrava* is associated with *Vrana*, *Dushtavrana Chikitsa* can be employed to regulate its occurrence. *Gandhak Rasayana* has demonstrated enhanced outcomes in the treatment of Otitis externa with anti-fungal, anti-inflammatory and anti-bacterial property. The present case study highlights the significance of *Rasoushadhi* (herbomineral preparations) in *Ayurveda*, showcasing its ability to deliver results in a short time-frame. However, this is a single case study, it is imperative to conduct more extensive and prolonged trials to substantiate the results obtained in this case study. The intriguing results of the study can be replicated on a larger cohort of patients over an extended duration for a comprehensive review and analysis of the findings.

Informed consent

The informed consent of the patient was taken.

Patient's perspective

Initially when the patient came to OPD was annoyed with thick discharge and fullness of ear after swimming and splashing in river water. But once started with treatment with *Gandhak Rasayana* and mopping of ear on every follow up he relieved from symptoms and had no recurrence in otitis externa.

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Conflicts of interest

None disclosed.

Author contribution-

1. Dr Sandip Patil – Treatment design, collection of data, writing the manuscript, collection of references.

2. Dr Pravin Bhat- *Ayurveda* thought process, Concept and Design, writing the manuscript, collection of references, supervision, final approval.

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Declaration

Authors have used Chapt GPT version 3.5 AI tool for language editing

purposes only and we declare hereby that no authoritative statements/sentences were generated from Chat GPT/AI tool.

Declaration of competing interest

None disclosed.

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