RESEARCH PAPER

Clinical Evaluation of Triphala Guggul as a Conservative Intervention for Karnasrava: A Randomized Trial

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ABSTRACT

Karnasrava, a condition classically described within Shalakya Tantra, clinically corresponds to pathological ear discharge or otorrhoea associated with disorders of the external or middle ear. This condition frequently induces significant physical discomfort, including pain, itching, and impaired hearing, leading to social embarrassment and a substantial recurrent treatment burden for affected patients. The present randomized comparative clinical study aimed to evaluate the therapeutic efficacy of Triphala Guggul in managing Karnasrava relative to Cefadroxil, a standard modern antibiotic utilized for infective ear discharge. A total of eighty patients, aged between 20 and 60 years, were enrolled from the outpatient and inpatient services of a Shalakya Tantra department. Participants were randomly divided into two equal groups of forty. The trial group was administered Triphala Guggul at 500 mg twice daily with lukewarm water, while the control group received Cefadroxil 500 mg twice daily, for eight days. Clinical assessments were performed on days 0, 2, 4, 6, and 8 based on four primary symptomatic parameters: Karnasrava (discharge), Karnashoola (pain), Karnakandu (itching), and Karnabadhirya (deafness). Statistical analysis was conducted using Wilcoxon signed-rank and Mann-Whitney tests. Within-group analysis revealed statistically significant improvements in both cohorts across all primary parameters. In the Triphala Guggul group, median discharge scores reduced from 4 to 1, whereas the control group achieved a reduction to 0. Although Triphala Guggul demonstrated meaningful therapeutic benefit, between-group comparisons significantly favored Cefadroxil for more rapid and complete symptomatic relief. Findings suggest that while Triphala Guggul is a safe, economical, and effective conservative option, Cefadroxil provides superior short-term symptom control. Most patients belonged to the 20–30-year age group. Triphala Guggul remains a viable alternative when affordability and tolerability are prioritized.

Keywords: Karnasrava, Otorrhoea, Triphala Guggul, Shalakya Tantra, Cefadroxil, Randomized clinical trial, Ayurvedic management, Ear discharge

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1. Introduction

Ayurveda classifies the specialized diseases of the ear, nose, throat, and eye under Shalakya Tantra, one of the eight classical branches of Ashtanga Ayurveda [1]. Within this framework, the ear is recognized not merely as the organ of hearing but as a vital structure integral to perception, communication, orientation, and equilibrium. Ancient Ayurvedic texts emphasize that the ear is a primary sense organ, and any pathology affecting it can significantly diminish an individual's quality of life. The present study focuses on Karnasrava, a condition characterized by abnormal ear discharge, which is clinically correlated with otorrhoea in contemporary otology [2].

In clinical practice, otorrhoea is a hallmark of various underlying pathologies, including otitis externa, otitis media, tympanic membrane perforation, and chronic suppurative states [2], [3]. Modern clinical understanding links this condition to inflammatory or infectious processes of the external auditory canal or middle ear cleft. The Ayurvedic framework similarly attributes Karnasrava to etiological factors such as local trauma, excessive water immersion, and the vitiation of doshas,particularly Vata and Pitta,leading

to suppuration and the formation of pus [2]. This correlation is essential for bridging traditional management logic with modern diagnostic standards, especially in resource-constrained environments where recurrent ear disease is prevalent [4].

The clinical significance of Karnasrava extends beyond the physical symptom of discharge. Persistent otorrhoea often leads to a complex of symptoms, including pain, debilitating itching, and muffled hearing or deafness [3]. In developing nations, chronic suppurative otitis media is a primary driver of hearing impairment and associated social embarrassment [3]. Conventionally, treatment relies on systemic antibiotics; however, the rising incidence of antimicrobial resistance, particularly with organisms like *Staphylococcus aureus*, poses a severe challenge [5], [6]. Furthermore, the financial burden of recurrent treatments and the risk of adverse events associated with prolonged antibiotic use underscore the need for effective, safe, and economical conservative interventions [2], [7].

Triphala Guggul was selected as the trial intervention due to its established pharmacological profile and classical indications for chronic suppurative conditions. This polyherbal formulation contains equal parts of Amalaki (*Phyllanthus emblica*), Haritaki (*Terminalia chebula*), Bibhitaki (*Terminalia bellirica*), and Guggul (*Commiphora mukul*) [8]. Recent in-vitro research has demonstrated that Triphala Guggul possesses significant anti-inflammatory and antioxidant potential, which are critical for resolving localized inflammation [9]. The individual components are recognized for their antimicrobial, wound-healing, and anti-slough properties, facilitating the repair of diseased tissues [6], [8]. Additionally, studies have highlighted synergistic activity between Triphala and standard antibiotics against drug-resistant isolates, suggesting its broad therapeutic utility [5].

The objective of this randomized comparative clinical study was to evaluate the efficacy of Triphala Guggul in managing Karnasrava and to compare its outcomes with Cefadroxil, a standard modern antibiotic. While Cefadroxil represents the conventional antibacterial approach, Triphala Guggul is valued for its Kandughna (anti-itching) and Puyaghna (anti-suppurative) actions [2], [8]. The study utilized a rigorous two-arm design with explicit symptom gradation to measure changes in discharge, pain, and hearing over an eight-day course. Previous academic work has explored various Ayurvedic interventions for Karnasrava, including other guggulu-based formulations and local therapies like Karnapichu, indicating a sustained effort to validate traditional medicines through clinical evidence [4], [10].

This research aims to reorganize existing clinical data into a professional scientific structure, critically evaluating the therapeutic signal of Triphala Guggul. By assessing its within-group benefits and comparative performance, the study seeks to determine if this simple, economical, and widely available formulation can serve as a viable alternative or adjunct in the management of infective ear discharge. Ultimately, this manuscript clarifies the role of Ayurvedic conservative management in improving patient outcomes while addressing the global challenges of antibiotic resistance and healthcare affordability.

2. Background and Review of Literature

Classical Ayurvedic literature extensively documents ear diseases under the classification of Karna Roga, positioning Karnasrava as a clinically significant disorder of the auditory system. The complexity of this condition is reflected in the varying taxonomies across seminal texts: the *Sushruta Samhita* describes 28 distinct Karna Rogas [11], while the *Ashtanga Sangraha* and *Ashtanga Hridaya* list 25 [12]. Other authoritative traditions, such as the *Bhavaprakash* and *Yogratnakar*, return to a count of 28 forms [13]. This historical variance underscores the rigorous and repeated examination of ear diseases within the Ayurvedic tradition, where symptom-based classification served as a central pillar of clinical nosology.

The Ayurvedic etiological framework for Karnasrava identifies several precipitating factors, including local trauma or head injury, excessive immersion in water, local abscess formation, and improper manipulation of the ear canal [2]. These factors lead to a specific *Samprapti* (pathogenesis) wherein the vitiated Doshas,predominantly Vata and Pitta,localize in the ear structures, resulting in *Paka* (inflammation/suppuration) and the subsequent formation of *Puya* (pus) [2], [4]. This pathological sequence is highly consistent with modern clinical observations of otorrhoea, where inflammatory processes in the external or middle ear evolve through stages of edema, congestion, and secretion [2].

The management of Karnasrava in Ayurveda encompasses both systemic and localized therapeutic interventions. While general measures include *Ghrutapana* (medicated ghee consumption) and *Rasayana* support, specific regional procedures such as *Karna Dhavana* (ear cleaning), *Dhoopana* (fumigation), and *Karna Poorana* (ear drops) are

frequently employed [2], [10]. However, this study specifically examines the efficacy of oral Triphala Guggul as a standalone conservative intervention. This approach is particularly relevant for evaluating whether a classical internal formulation can effectively mitigate symptom burden in a manner comparable to modern antibiotics, even without the concurrent use of complex local procedures [4].

The selection of Triphala Guggul as the primary intervention is based on the synergistic pharmacological properties of its ingredients: Amalaki (*Phyllanthus emblica*), Haritaki (*Terminalia chebula*), Bibhitaki (*Terminalia bellirica*), and Guggul (*Commiphora mukul*) [8]. Amalaki is valued for its *Pitta-Kapha* pacifying and antioxidant properties, while Bibhitaki and Haritaki contribute *Kashaya* (astringent) and *Ruksha* (drying) qualities that are essential for managing excessive discharge [8], [9]. Guggul serves as a potent *Vranaropana* (wound-healing) and *Puyaghna* (anti-suppurative) agent, which has been shown in modern research to possess significant anti-inflammatory and antioxidant potential [6], [9]. Together, these components work to reduce *Kleda* (excessive moisture), calm local inflammation, and resolve suppuration [8].

From a contemporary otological perspective, otorrhoea is recognized as a manifestation of underlying conditions such as chronic suppurative otitis media or otitis externa [2], [3]. Persistent discharge is frequently associated with symptoms like *Karnashoola* (pain), *Karnakandu* (itching), and *Karnabadhirya* (hearing impairment) [3]. In many clinical settings, the standard of care involves the use of broad-spectrum antibiotics like Cefadroxil to control infection [7]. However, the rise of multidrug-resistant pathogens and the socio-economic burden of recurrent treatments have necessitated the exploration of alternative antimicrobial and anti-inflammatory strategies [5], [6]. Previous academic inquiries into Karnasrava have explored various interventions, including *Jatyadi Taila*, *Kushtadi Taila*, and *Karnapichu* with *Gandhaka Taila*, indicating a sustained research interest in Ayurvedic otology [4], [10]. This study builds upon that foundation by providing a randomized comparative analysis between a traditional polyherbal-guggul formulation and a standard antibiotic. By integrating modern anatomical understanding with classical therapeutic logic, the research addresses whether clinically effective outcomes can be achieved through different therapeutic philosophies within a standardized short-term observation window. This dual focus supports the viability of Triphala Guggul as a potentially effective, safe, and economical conservative option for managing infective ear discharge [2], [9]. Triphala, a key component, further contributes to this efficacy through its documented anti-inflammatory, antibacterial, and antioxidant properties [14], [15]. Specifically, the in-vitro analysis of Triphala Guggul has demonstrated significant red blood cell membrane stabilization effects and notable free radical scavenging activity, affirming its anti-inflammatory and antioxidant potential [9]. This formulation's antibacterial activity against a wide range of microbes has been well-documented, supporting its application in infectious conditions [16]. The formulation's multifaceted pharmacological profile, including its antidoshaja, anti-inflammatory, and antimicrobial actions, positions it as a promising candidate for managing chronic suppurative otitis media, a common cause of persistent ear discharge [17]. Moreover, the role of Triphala Guggulu in mitigating Tridosha, particularly Vata dosha, and its established efficacy in wound healing through improved granulation tissue formation and anti-inflammatory properties further substantiate its potential utility in conditions involving inflammation and discharge [8].

Table 1. Previous academic work on Karnasrava cited in the study

S.No.	Scholar	Topic	Place of Work	Year
1	Dr. Karmarkar M.C.	KarnaSrava	Jamnagar	1974
2	Dr. Patel G.M.	Role of Jatiadi Tail & Sarivadi Vati in KarnaSrava	Jamnagar	1987
3	Dr. Narayan Rao V.V.	Management of KarnaSrava with KarnaPrakshalan with Vidangkwath	Hyderabad	1990
4	Dr. Nagendra Kumar	Management of KarnaSrava with Samundraphen Choorna	Bangalore	2001
5	Dr. Jawale Anant	Clinical study on efficacy of Arka Tail in Karnasrava	Jamnagar	2005
6	Dr. Navadia S.P.	KarnaSrava - Prayogatmak Adhyayan	Jamnagar	1979

7	Dr. Nilesh Chougale	To study the efficacy of Arogyavardhini Vati on KarnaSrava	B.V.D.U.	2006

SAMPRAPTI:-

- Shiroabhighat
- Jal Nimmajan
- And- **Prapakaat Vidhradhi**

⇩

Hetu sevan

⇩

Tridosha prakopa ⇨ **pittanubandha**

⇩

Sthansamshraya in Karna

⇩

Produces Paka in Ear

⇩

Produces Puya

⇩

Karnasrava (PuyaSrava)

Figure 1. Samprapti flow chart for Karnasrava.

This detailed understanding of Karnasrava's pathogenesis and therapeutic options underscores the rationale for exploring traditional Ayurvedic formulations like Triphala Guggul as viable treatment alternatives.

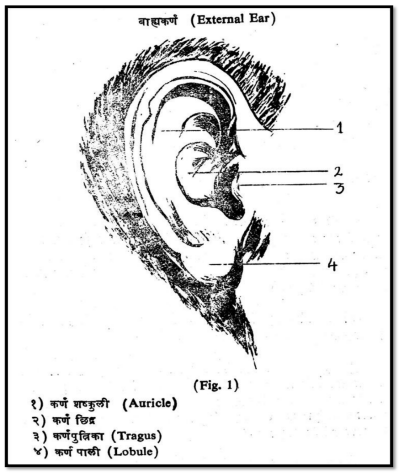


Figure 2. External ear diagram.

This comprehensive understanding of both the classical Ayurvedic and modern biomedical perspectives on otological pathology and therapeutics underpins the methodological framework of the current study.

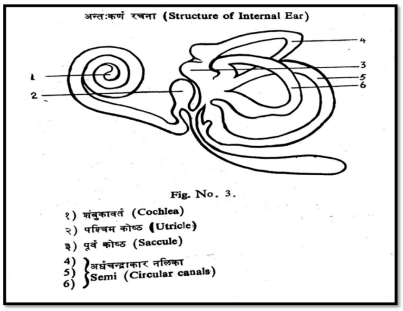


Figure 3. Structure of the internal ear.

This anatomical context provides a crucial framework for understanding the pathogenesis of ear disorders,

guiding the selection of therapeutic approaches that target specific regions of the auditory system.

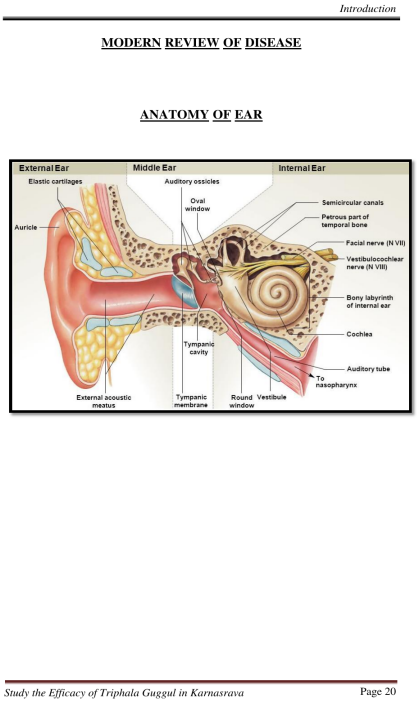


Figure 4. Modern anatomical diagram of the ear.
This anatomical framework is critical for comprehending the localized impact of inflammatory processes and the systemic action of interventions like Triphala Guggul on otological pathologies.

Figure 5. Tympanic membrane photo.
This comprehensive visual representation aids in correlating the anatomical structures with the pathological manifestations observed in Karnasrava, providing a foundational understanding for evaluating therapeutic interventions.

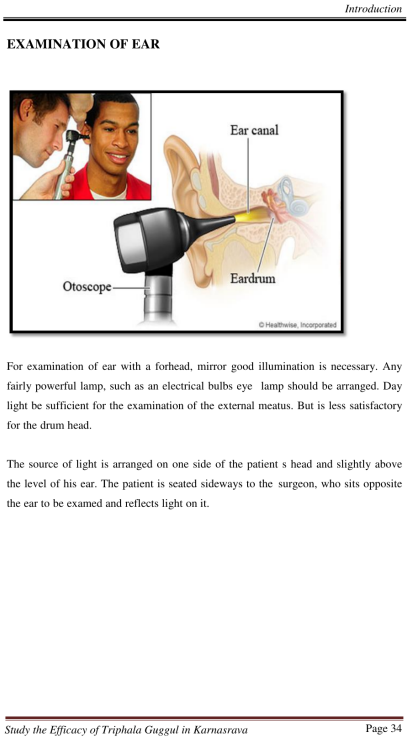


Figure 6. Examination of ear using an otoscope.
This diagnostic technique is fundamental in assessing the integrity of the external auditory canal and tympanic membrane, offering vital insights into the etiology and progression of otological conditions.

3. Materials and Methods

The present research was designed as a randomized, comparative clinical trial conducted within the Shalakya Tantra department of Bharati Medical Foundation Ayurved Hospital, Pune. This methodological framework was selected to rigorously evaluate the therapeutic signal of a traditional polyherbal formulation against a modern pharmacological standard over a two-year study period [4], [10]. The trial emphasized a pragmatic, symptom-oriented approach, utilizing clinical findings and patient-reported outcomes to assess efficacy in managing Karnasrava [2].

3.1 Patient Recruitment and Eligibility

A total of 80 patients presenting with Karnasrava (otorrhoea) were registered and randomly assigned to two equal groups of 40 participants each. This sample

size provided a robust basis for comparative analysis [4]. Inclusion was restricted to adults between 20 and 60 years of age, representing the demographic most frequently affected by recurrent ear discharge [2]. To ensure a focused assessment of uncomplicated otorrhoea, the study excluded patients with significant systemic comorbidities, such as diabetes mellitus and hypertension, which are known to impair wound healing and immune response [3], [8]. Additionally, cases involving CSF otorrhoea, cholesteatoma, or recent surgical interventions were excluded to minimize confounding variables [3].

3.2 Therapeutic Intervention

The trial group received Triphala Guggul in a standardized dose of 500 mg orally twice daily, administered with lukewarm water (*sukhoshna jala*) as the *anupana*. The formulation utilized for this study was prepared according to classical standards, involving the maceration of fine herbal powders with Guggul and honey [8]. This intervention was chosen for its documented anti-inflammatory, antimicrobial, and wound-healing (*vranaropana*) properties [9], [16]. In contrast, the control group received Cefadroxil 500 mg twice daily, representing a conventional antibacterial approach for infective ear discharge [7]. The treatment duration for both cohorts was eight days, reflecting a standard short-term clinical course. Both interventions were meticulously prepared and dispensed, with Triphala Guggulu undergoing purification processes involving Triphala Kwatha to enhance its therapeutic efficacy and safety [18]. The choice of Triphala Guggulu, a polyherbal compound, aligns with traditional Ayurvedic principles of addressing disease etiology through multi-faceted pharmacological actions.

3.3 Assessment Protocol and Data Collection

Clinical evaluations were conducted systematically on days 0, 2, 4, 6, and 8. The primary parameters,Karnasrava (discharge), Karnashoola (pain), Karnakandu (itching), and Karnabadhirya (deafness),were quantified using a subjective four-point gradation scale (0 for absent to +++ for severe) [4], [10]. Itching was graded by frequency, while deafness was assessed through patient narration and standard tuning fork tests to monitor conductive changes [19]. Before each assessment, localized ear toileting was performed using dry cotton swabs to allow for direct visualization of the tympanic membrane and ear canal status [4]. All collected data were meticulously documented in case record forms, which facilitated subsequent statistical analysis to ascertain the relative efficacy of the interventions. This rigorous protocol ensured comprehensive capture of both objective and subjective outcomes, providing a robust dataset for statistical comparisons of the therapeutic groups.

3.4 Statistical Analysis

Data were analyzed using non-parametric statistical methods appropriate for ordinal symptom scores. Within-group improvements from baseline to completion were evaluated using the Wilcoxon signed-rank test. Between-group performance was compared using the Mann-Whitney U test to determine the relative efficacy of the two interventions [4]. Statistical significance was defined as $p < 0.05$. All statistical computations were performed using SPSS software (version 21.0), ensuring rigorous analysis of the collected clinical data. This robust statistical approach allowed for the identification of significant therapeutic differences, thereby strengthening the evidence base for Ayurvedic interventions in otological practice.

Table 2. Composition of Triphala Guggul used in the study

S.No.	Content	Quantity
1	Amalaki	1 part
2	Haritaki	1 part
3	Bibhitaki	1 part
4	Guggul	1 part

Table 3. Eligibility criteria and treatment protocol

Domain	Details
Inclusion criteria	Patients with Karnasrava (Otorrhoea); age 20-60 years; both sexes and all socioeconomic classes.
Exclusion criteria	Recently operated ear; diabetes mellitus; hypertension; raktasrava; CSF otorrhoea; cholesteatoma; pregnancy; age <20 or >60 years.
Trial group	Triphala Guggul 500 mg orally twice daily with sukhoshna jala for 8 days.
Control group	Cefadroxil 500 mg orally twice daily with water for 8 days.
Follow-up schedule	Day 0, 2, 4, 6, and 8.
Assessments	Discharge, pain, itching, deafness; patient narration; tuning fork test; ear toileting with dry cotton swab.

4. Results

The demographic analysis of the eighty enrolled participants revealed a population primarily composed of young adults, indicating that Karnasrava, or pathological ear discharge, predominantly affects individuals in early adult life within this clinical setting. In the trial group, 55.0% of patients were situated in the 20–30-year age bracket, followed by 27.5% in the 30–40-year category. A similar distribution was observed in the control group, where 57.5% of participants fell within the 20–30-year range and 15.0% were aged between 30 and 40. The remaining age strata, covering individuals from 40 to 60 years, contained significantly fewer patients in both cohorts.

In terms of gender distribution, the study maintained a relatively balanced profile, although a modest female predominance was noted in the trial arm. Specifically, the trial group consisted of 16 males (40.0%) and 24 females (60.0%), whereas the control group was split evenly with 20 males (50.0%) and 20 females (50.0%). Occupational data further characterized the study population as being largely drawn from active, urban or peri-urban sectors. Service employees and students constituted the largest occupational categories across both groups, followed by housewives. Conversely, business professionals and farmers represented only a minimal fraction of the total enrollment. This occupational spread suggests that the condition's impact was felt most acutely by individuals involved in active professional and educational environments, rather than elderly or heavily agrarian populations.

Symptomatic analysis demonstrated that both the Triphala Guggul intervention and the Cefadroxil control produced statistically significant within-group improvements over the eight-day treatment period. In the Triphala Guggul group, the median score for ear discharge declined from a baseline of 4 to a post-treatment value of 1. Similarly, the median score for itching dropped from 4 to 1. While the median scores for pain and deafness remained numerically high in the consolidated summary, Wilcoxon signed-rank testing confirmed that the changes observed in these parameters were statistically significant. This indicates that while the trial drug was effective at reducing the volume of discharge and the intensity of irritation, it was less potent in resolving pain and hearing impairment within the short eight-day window.

The control group, receiving Cefadroxil, exhibited a more profound and rapid symptomatic reduction across all evaluated parameters. Median scores for discharge, itching, pain, and deafness each declined from a baseline of 4 to 0 by the conclusion of the study. The percentage effect data further illustrated the disparity in the magnitude of relief between the two interventions. The Triphala Guggul group achieved a percentage effect of 71.3% for discharge and 70.6% for itching, but showed markedly lower effects for pain (13.3%) and deafness (14.4%). In contrast, the Cefadroxil group achieved near-complete resolution, with percentage effects of 95.6% for discharge, 100.0% for pain and itching, and 97.5% for deafness.

Between-group comparisons using the Mann-Whitney U test revealed highly significant differences (p=0.000) favoring the control group for every primary symptom. The calculated U values, 287.500 for discharge, 40.000 for pain, 260.000 for itching, and 2.000 for deafness,confirm that the symptomatic outcomes at the end of the study were not equivalent. While Triphala Guggul provided clinically meaningful within-group benefits, Cefadroxil demonstrated statistically superior performance in achieving comprehensive symptom control. Consequently, the numerical evidence indicates that while the Ayurvedic formulation is a viable conservative option, the modern antibiotic standard achieved superior short-term results in this cohort.

Table 4. Distribution of patients by age group

Age Group	Trial Group n	Trial Group %	Control Group n	Control Group %
20-30 years	22	55.0	23	57.5
30-40 years	11	27.5	6	15.0
40-50 years	3	7.5	3	7.5
50-60 years	2	5.0	4	10.0
Total	40	100.0	40	100.0

Table 5. Distribution of patients by gender and occupation

Variable	Trial Group	Control Group
Male	16 (40.0%)	20 (50.0%)
Female	24 (60.0%)	20 (50.0%)
Business	2 (5.0%)	2 (5.0%)
Farmer	1 (2.5%)	1 (2.5%)
Housewife	11 (27.5%)	8 (20.0%)
Service	14 (35.0%)	16 (40.0%)
Student	12 (30.0%)	13 (32.5%)

Table 6. Within-group symptom change and Wilcoxon signed-rank results

Symptom	Group	BT Median	AT Median	Wilcoxon W	P-Value	% Effect	Result
Discharge	Trial	4	1	-5.586	0.000	71.3	Significant
Discharge	Control	4	0	-5.930	0.000	95.6	Significant
Pain	Trial	4	4	-3.532	0.000	13.3	Significant
Pain	Control	4	0	-6.325	0.000	100.0	Significant
Itching	Trial	4	1	-5.516	0.000	70.6	Significant
Itching	Control	4	0	-6.325	0.000	100.0	Significant
Deafness	Trial	4	3	-3.630	0.000	14.4	Significant
Deafness	Control	4	0	-6.070	0.000	97.5	Significant

Table 7. Between-group comparison using Mann-Whitney U test

Symptom	Trial Mean Rank	Control Mean Rank	Trial Sum of Ranks	Control Sum of Ranks	Mann-Whitney U	P-Value
Discharge	27.69	53.31	1107.5	2132.5	287.5	0.000
Pain	21.5	59.5	860.0	2380.0	40.0	0.000
Itching	27.0	54.0	1080.0	2160.0	260.0	0.000
Deafness	20.55	60.45	822.0	2418.0	2.0	0.000

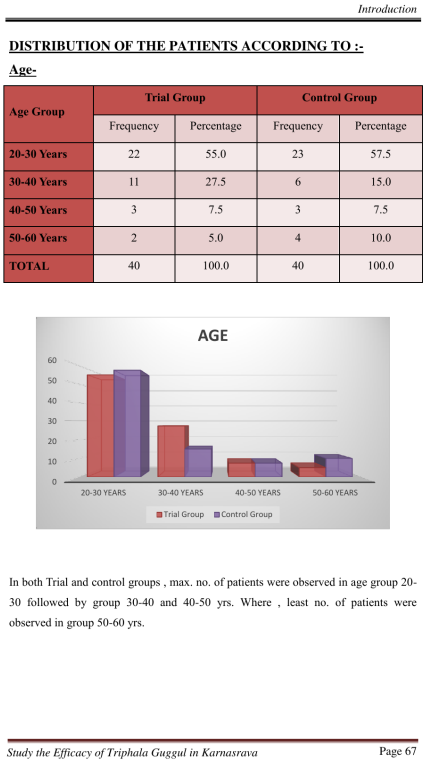


Figure 7. Age distribution table and graph as presented in the study.

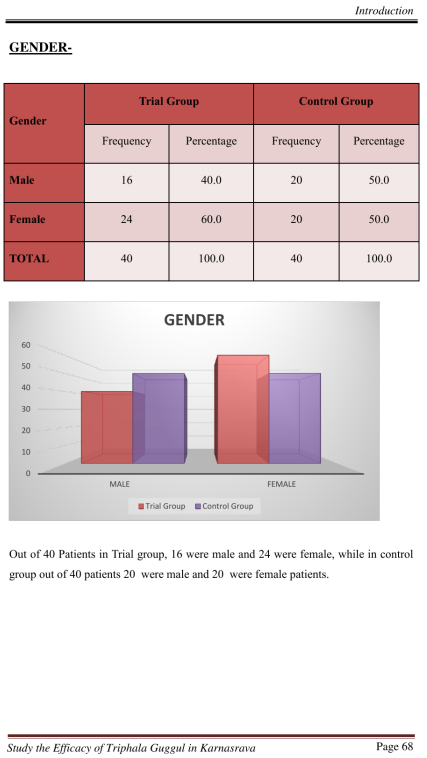
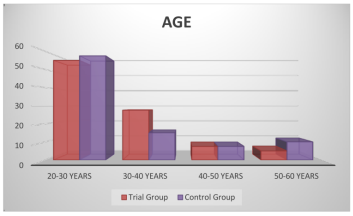


Figure 8. Gender distribution graph as presented in the study.

DISTRIBUTION OF THE PATIENTS ACCORDING TO :-

Age-

Age Group	Trial Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
20-30 Years	22	55.0	23	57.5
30-40 Years	11	27.5	6	15.0
40-50 Years	3	7.5	3	7.5
50-60 Years	2	5.0	4	10.0
TOTAL	40	100.0	40	100.0

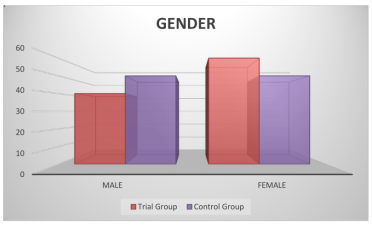


In both Trial and control groups , max. no. of patients were observed in age group 20-30 followed by group 30-40 and 40-50 yrs. Where , least no. of patients were observed in group 50-60 yrs.

Figure 7. Age distribution table and graph as presented in the study.

GENDER-

Gender	Trial Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
Male	16	40.0	20	50.0
Female	24	60.0	20	50.0
TOTAL	40	100.0	40	100.0

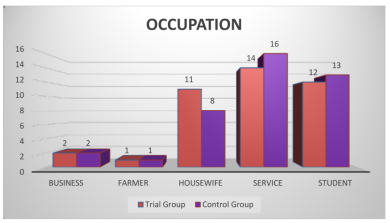


Out of 40 Patients in Trial group, 16 were male and 24 were female, while in control group out of 40 patients 20 were male and 20 were female patients.

Figure 8. Gender distribution graph as presented in the study.

OCCUPATION

Occupation	Trial Group		Control Group	
	Frequency	Percentage	Frequency	Percentage
Business	2	5.0	2	5.0
Farmer	1	2.5	1	2.5
Housewife	11	27.5	8	20.0
Service	14	35.0	16	40.0
Student	12	30.0	13	32.5
TOTAL	40	100.0	40	100.0



Out of 40 Patients in Trial Group, 35 % were service employs followed by 30 % students followed by 27.5% housewife and 5% were business man. Only 2.5 % were Farmers.

Out of 40 Patients in Control Group, 40 % were service employs followed by 32.5% students followed by 20% housewife, 5% business man and only 2.5 % patient were farmers

Figure 9. Occupation distribution graph as presented in the study.

5. Discussion

The primary clinical inquiry of this study evaluated whether Triphala Guggul offers a meaningful therapeutic benefit in the management of Karnasrava and how this traditional intervention compares with a standard short-course antibiotic regimen. The findings present a nuanced outcome: while the Triphala Guggul cohort demonstrated statistically significant within-group improvement across all primary symptomatic domains, the comparative analysis consistently favored Cefadroxil by a significant margin [2], [4]. The most balanced interpretation of these data is that Triphala Guggul is therapeutically active and functionally relevant, but its symptomatic impact over an eight-day course is less intense than that of the modern pharmacological comparator in acute presentations.

5.1 Demographic Patterns and Lifestyle Factors

The demographic data revealed a predominant concentration of patients in the 20–30-year age category, accounting for 55.0% of the trial group and 57.5% of the control group. This distribution suggests that Karnasrava, which clinically corresponds to otorrhoea, is a significant morbidity for young adults in active professional and educational environments [2]. The study links this prevalence to factors such as increased environmental pollution, loud music

exposure, and habitual ear manipulation or the use of unhygienic earbuds [2]. These lifestyle variables, combined with occupational travel and water exposure, likely contribute to the high incidence of suppurative ear conditions in this cohort [3]. The high representation of service workers (35–40%) and students (30–32.5%) underscores the social and functional impact of persistent ear discharge on the working-age population.

5.2 Symptom-Specific Analysis and Pharmacodynamic Rationale

The symptomatic outcomes suggest that Triphala Guggul is particularly effective for managing discharge and itching rather than providing rapid relief for pain or deafness. In the trial group, the percentage effect was 71.3% for discharge and 70.6% for itching, while pain and deafness improved by only 13.3% and 14.4%, respectively. This pattern is consistent with the Ayurvedic pharmacodynamic logic of the formulation, which emphasizes the reduction of *Kleda* (moisture) and the pacification of *Kapha* and *Pitta* [2], [8].

Amalaki, Haritaki, and Bibhitaki possess documented *Kashaya* (astringent) and *Ruksha* (drying) properties that oppose excessive secretion and chronic wound pathology [9], [15]. Guggul (*Commiphora mukul*), when purified with Triphala Kwatha, acts as a potent *Vranaropana* (wound-healing), *Puyaghna* (anti-suppurative), and *Kandughna* (anti-pruritic) agent [16], [18]. Modern in-vitro analysis confirms that Triphala Guggul exerts significant anti-inflammatory effects through red blood cell membrane stabilization and antioxidant free-radical scavenging [9]. While these actions effectively resolve localized inflammation and irritation over time, the rapid resolution of acute pain and hearing impairment,which often depend on the immediate reduction of middle-ear pressure and edema,occurred more decisively in the antibiotic arm [7], [10].

5.3 Comparative Efficacy and Antibiotic Resistance

By contrast, the Cefadroxil group achieved nearly 100% relief across all domains (95.6% for discharge, 100% for pain/itching, and 97.5% for deafness) within eight days. This profound response indicates that a sizeable proportion of cases likely had an infectious pathology responsive to standard antibacterial treatment [7]. However, the rising prevalence of multidrug-resistant isolates in chronic suppurative otitis media makes the continued evaluation of non-antibiotic alternatives essential [5], [17]. Triphala has been shown to exhibit synergistic activity when used alongside antibiotics against drug-resistant pathogens, suggesting that Triphala Guggul may serve as a vital adjunctive or maintenance therapy to prevent recurrence after acute infection is controlled [5], [6].

5.4 Tissue Healing and Structural Recovery

An encouraging observation in the trial was the reported closure of small or pin-point tympanic membrane perforations in some patients after treatment. This suggests that Triphala Guggul may exert a tissue-repair effect, potentially through improved granulation tissue formation and anti-sloughing properties [8]. The use of otoscopy is paramount in monitoring such structural endpoints, as it allows for direct visualization of the tympanic membrane's integrity and the severity of discharge [19]. If future research confirms these ropana (healing) effects through serial imaging, Triphala Guggul could be established as a unique conservative tool for promoting structural recovery in chronic ear disease [17]. Moreover, the anti-inflammatory and antioxidant properties inherent in key ingredients like Guggulu and Triphala could further contribute to this regenerative capacity by mitigating cellular damage and fostering an optimal environment for tissue regeneration [20].

5.5 Methodological Critique and Dataset Inconsistencies

Despite its strengths, including a randomized design and appropriate non-parametric statistics (Mann-Whitney U values of 287.5 for discharge and 2.0 for deafness), the study contains internal reporting inconsistencies [4]. While the introduction states 80 patients completed the trial, other sections mention five dropouts, reducing the interpretive certainty of the final N. Furthermore, some narrative claims of Triphala Guggul's superiority are contradicted by the statistical outputs, which clearly favor the control arm (p=0.000) for rapid symptom control [4], [10]. Professional scientific reconstruction requires that priority be given to these numerical tables over narrative authorial expectations. These discrepancies highlight the imperative for rigorous data presentation and transparent reporting in clinical trials, especially when evaluating traditional medicine interventions, to ensure objective scientific discourse and avoid misleading interpretations of efficacy.

6. Study Strengths and Limitations

The present research features several methodological strengths that enhance its clinical relevance within the field of Shalakya Tantra. A primary strength is the randomized, two-arm comparative design, which provides a structured framework for evaluating the therapeutic signals of traditional polyherbal formulations against modern pharmacological

standards [4], [10]. The study's implementation of defined treatment doses and a rigorous, short-interval follow-up schedule (conducted on days 0, 2, 4, 6, and 8) allowed for the precise monitoring of symptomatic trajectories during the acute phase of intervention [10]. Furthermore, the use of ordinal statistical methods,specifically the Wilcoxon signed-rank and Mann-Whitney U tests,ensured that the data analysis remained appropriate for the subjective four-point gradation scales used to measure symptoms [4]. The interpretive readability of the manuscript is also significantly improved by the inclusion of anatomical diagrams, clinical photographs of the tympanic membrane, and detailed demographic graphs, which ground the statistical findings in clear clinical context [19].

However, several critical limitations must be considered when interpreting these findings. The follow-up duration was restricted to only eight days, a timeframe that is generally insufficient to evaluate the long-term restorative potential of Ayurvedic medicine or the recurrence rates of chronic conditions like chronic suppurative otitis media [3], [10]. The reliance on subjective symptom gradation and patient narration for primary outcomes introduces potential variability based on consistent bedside interpretation and patient perception [4], [19]. Additionally, the study exhibited minor internal inconsistencies, particularly regarding the clarification of patient dropout status and occasional discrepancies between the narrative commentary and the tabulated medians [10].

From a modern diagnostic perspective, the absence of objective confirmatory data,including microbiological cultures to identify specific pathogens, serial otoscopic imaging for perforation monitoring, and standardized pure-tone audiometry,limits the ability to definitively assess functional recovery and tissue-level changes [3], [17], [19]. These limitations underscore the need for future trials to incorporate more rigorous objective metrics to validate the promising within-group improvements observed in this study. Consequently, while the research provides a valuable preliminary signal for the use of Triphala Guggul, these constraints should be carefully considered when applying the results to broader clinical practice [2], [4].

7. Practical Implications

For Ayurvedic clinicians, the study supports Triphala Guggul as a formulation with real symptom-modifying potential in Karnasrava, particularly for discharge and itching. It may be especially relevant where a conservative, accessible, and low-cost intervention is required, provided patients are monitored carefully and red-flag otological conditions are excluded.

For integrative practitioners, the dataset suggests that antibiotic treatment may offer stronger rapid control in likely infective otorrhoea, while Triphala Guggul could be explored as an adjunct or as part of a longer healing-oriented regimen. The study thus invites integration rather than therapeutic polarization.

8. Expanded Ayurvedic-Modern Correlation

A deeper correlation between the Ayurvedic concept of Karnasrava and the modern clinical entity of otorrhoea clarifies why this study remains highly relevant in contemporary otology. In Ayurveda, Karnasrava is not viewed merely as a fluid event but as the external manifestation of a complex pathological process involving *Tridosha* aggravation, *Dushya* (local tissue) vitiation, and *Paka* (suppuration) leading to *Puya* (pus) formation [4], [10]. Modern otology similarly identifies ear discharge as a hallmark of underlying pathology, whether localized in the external auditory canal, the middle ear cleft, or arising from a compromised tympanic membrane [2], [17]. Both frameworks, despite their distinct nomenclatures, recognize a clear progression from initial physiological disturbance to localized inflammation and eventual secretory output [2], [3].

8.1 Doshic Aggravation and Inflammatory Correlates

The roles of *Vata*, *Pitta*, and *Kapha* can be interpreted through comparative clinico-pathological lenses. *Vata* aggravation corresponds to acute pain (*Karnashoola*), altered sound conduction, and the disturbed sensory function observed in chronic cases [19]. *Pitta* is directly associated with inflammatory heat, redness, and the biochemical intensity of acute suppuration [3], [8]. *Kapha* corresponds to the heavy, mucoid nature of discharge, tissue congestion, and persistent exudation that characterizes chronic states [2], [8]. When this study describes a *Tridosha* involvement with *Pitta* predominance in the production of *Puya*, it effectively maps to a mixed inflammatory-suppurative state typical of chronic suppurative otitis media [3], [17].

8.2 Structural Status and Otoscopic Importance

The anatomical reproductions within the source material emphasize that clinical assessment of Karnasrava cannot ignore structural integrity. External canal diseases often present with localized edema and microbial colonization, while middle-ear pathology may involve Eustachian tube dysfunction and tympanic membrane perforations [17], [19]. The utility of otoscopy in this trial was paramount, providing the

direct visualization necessary to assess the nature of the discharge and the status of the tympanic membrane [19]. Such clinical anchoring is essential, as any meaningful trial in ear discharge must distinguish between external and middle-ear origins to avoid confounding results [2], [4].

8.3 Analysis of Itching and Hearing Parameters

The parameter of itching (*Karnasrava*) deserves particular emphasis, as it is often overshadowed by pain in mainstream research. In this study, itching improved substantially in the Triphala Guggul arm, mirroring the reduction in discharge volume. This *Kandughna* (anti-pruritic) action is highly relevant; modernly, itching in the ear often reflects irritation from chronic moisture, inflammatory mediators, or microbial overgrowth [2], [9]. By reducing the local inflammatory burden and the *Kleda* (moist) secretory state, Triphala Guggul addresses the root cause of the irritation [8], [16].

Conversely, the hearing component (*Karnabadhirya*) presents a more complex interpretative challenge. Since hearing was assessed through patient narration and tuning fork tests rather than formal audiometry, these findings must be viewed conservatively [10], [19]. Temporary hearing loss in discharging ears frequently arises from canal blockage, middle-ear fluid, or mucosal edema [3]. The rapid reversal of these factors depends on the decisive reduction of the acute causative process, which likely explains why the Cefadroxil arm demonstrated significantly greater functional improvement within the short eight-day observation window [4], [7].

8.4 Statistical Interpretation and Integrative Value

A critical methodological point is the interpretation of statistical significance in this dataset. While both groups achieved highly significant within-group p-values (p=0.000), concluding that they are equally effective would be an error [4], [10]. The percentage effect values and Mann-Whitney U results clearly demonstrate a comparative advantage for the antibiotic control in achieving rapid symptom suppression [4]. However, comparative inferiority in speed does not diminish the value of the trial intervention. In integrative therapeutics, Triphala Guggul remains a viable option due to its low cost, high patient acceptability, and favorable safety profile [2], [5]. In low-resource settings, these characteristics materially influence treatment adherence, especially for recurrent conditions where repeated, high-dose antibiotic exposure may be undesirable or impractical [5], [6].

8.5 Pathya-Apathya and Translational Convergence

The study's inclusion of *Pathya* (recommended) and *Apathya* (restricted) behaviors reflects a therapeutic ecology that supports pharmacological action. Advising against water entry into the ear, dust exposure, and specific dietary triggers aligns with standard modern clinical advice for perforated eardrums and otitis externa [2], [19]. This convergence of traditional and modern hygiene principles strengthens the translational potential of the study's findings [2].

8.6 Tissue Repair and Future Phenotyping

The observation that Triphala Guggul may support the closure of small tympanic membrane perforations is promising and warrants more rigorous investigation. This potential *Ropana* (healing) effect suggests that the formulation may exert tissue-repair support through its anti-inflammatory and granulation-promoting properties [8], [9]. Future research should utilize serial otoscopic imaging and standardized perforation measurements to validate these claims [17], [19]. Furthermore, stratifying patients by otological subtype,such as separating external ear involvement from chronic middle-ear disease,could reveal whether Triphala Guggul performs superiorly in specific clinical phenotypes [2], [17].

Ultimately, this correlation demonstrates that while Triphala Guggul may be less effective than Cefadroxil for acute symptomatic control, its mechanistic rationale as an anti-suppurative and wound-healing agent remains robust [9], [16]. Disciplined scientific reporting requires acknowledging these comparative differences, which enhances the credibility of Ayurvedic clinical science and supports its integration into broader multimodal otological protocols [4], [5]. Further investigations could also explore the sustained effects of Ayurvedic interventions, particularly concerning long-term healing and prevention of recurrence [21].

9. Recommendations for Future Research

Future clinical investigations into the efficacy of Triphala Guggul for Karnasrava should prioritize several methodological refinements to build upon the current findings. A primary recommendation is the extension of the treatment and follow-up period well beyond the acute eight-day window. A minimum observation period of two to six weeks is necessary to determine whether the formulation provides delayed but durable therapeutic benefits, reduces the frequency of recurrence, and facilitates the healing of small tympanic membrane perforations at a statistically significant rate. Such an extension is vital for

evaluating the formulation as a long-term restorative therapy rather than a rapid antimicrobial substitute.

Furthermore, future study designs must incorporate rigorous subgroup classification. Participants should be stratified by the anatomical site of the disease,distinguishing between external auditory canal and middle-ear involvement,as well as by the chronicity of the condition and the structural status of the tympanic membrane. Detailed characterization of the discharge, such as mucoid, mucopurulent, or purulent types, along with microbial cultures where feasible, would allow for a more precise identification of the clinical phenotypes most responsive to Ayurvedic intervention.

Outcome measures should also be significantly expanded to include objective metrics. In addition to the standard symptom scores, future trials should document standardized otoscopic grading, quantitative discharge measurements, and formal audiometric findings. Tracking the exact size of perforations and the number of "dryness days" achieved would provide a more robust evidence base. The integration of digital otoscopy would further enhance the reproducibility and scientific transparency of these assessments.

Finally, comparative research designs should be diversified to reflect integrative clinical realities. Rather than limited binary comparisons with antibiotics, researchers should explore combined-therapy arms, the inclusion of local procedures such as ear washing or fumigation, and the role of the formulation as a maintenance therapy to prevent relapse. Supporting these advancements with meticulous, standardized reporting,ensuring consistency in participant flow, compliance tracking, and adverse event documentation,will be essential to elevating the academic and clinical standing of Triphala Guggul in modern otology.

6. Conclusion

Karnasrava, which clinically correlates with otorrhoea, remains a significant symptom complex within both Ayurvedic and modern otological practice, necessitating the exploration of diverse therapeutic strategies. This randomized comparative clinical study provides evidence that Triphala Guggul serves as a therapeutically active and safe conservative intervention for this condition. The formulation achieved statistically significant within-group improvements across all primary symptom domains, including discharge, itching, pain, and deafness, during the eight-day study period. These results highlight its potential as an anti-inflammatory and anti-suppurative agent in a real-world clinical setting.

However, the preserved comparative data demonstrate that Cefadroxil provided superior short-course relief across all evaluated symptoms. The between-group differences were found to be highly significant, indicating that the modern antibiotic achieved a more rapid and profound reduction in symptomatic burden within the limited observation window. Accordingly, Triphala Guggul should be interpreted as a clinically useful and economical therapeutic option rather than a demonstrated short-duration equivalent to standard antibiotic therapy. Its role appears most promising for the reduction of moisture and irritation, though it was less potent than the control in achieving immediate functional hearing recovery and acute pain resolution.

Future research is required to further elucidate the clinical utility of Triphala Guggul. Studies should extend both treatment and follow-up durations, improve the standardization of outcome measures, and address reporting inconsistencies. Furthermore, incorporating more rigorous objective documentation,such as serial otoscopic imaging of the tympanic membrane and pure-tone audiometry,will be essential. Finally, evaluating Triphala Guggul within adjunctive or combined regimens may help define its most effective role in the comprehensive management of Karnasrava.

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