



Research Article

Efficacy of *Vidanga Arka* in *Karnashoola* with special reference to Otomycosis - A Randomized controlled clinical study

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Abstract

Introduction: *Karnashoola* is one among the *Karna Rogas*, characterized by *Shoola*, *Kandu* and *Srava*. Among the type of *Karnashoola*, *Vata-kaphaja Karnashoola* can be correlated to Otomycosis and also it being the commonest in occurrence has been selected for the present study. *Madhu* has *Tridoshaghna*, *Lekhana*, *Ropana* and *Vranashodhana* property also indicated in *Karnashoola*. This was taken as control drug. *Vidanga Arka* mentioned in the *Arkaprakasha* is useful in the management of *Krimi*, also *Vidanga* is known for its *Vedaanahara* property. **Objectives:** To evaluate the efficacy of *Vidanga Arka* in the management of *Karnashoola* (Otomycosis). **Materials and methods:** After securing ethical clearance and registering the trial with the CTRI, 30 subjects satisfying the inclusion criteria and diagnosed with *Karnashoola* were randomized into two groups (15 in each group). Group A and Group B was treated with *Vidanga arka* and *Madhu* ear drop for 7 days respectively. Objective [parameters were assessed using Aural endoscopy and recorded on the baseline, 7th, 14th, 21st and 28th day. The data related to the within the group response at different time intervals in Group A & B were assessed by Friedman's test for repeated measures. To evaluate the difference between the groups with regards to parameters, Mann Whitney rank sum test was carried out. **Result:** Study indicates that *Vidanga arka* and *Madhu* are equally effective in the management of *Karnashoola* (Otomycosis) ($p < 0.05$). **Conclusion:** The study concludes that both *Vidanga Arka* and *Madhu* Ear drop has beneficial effect in the management of *Karnashoola* (Otomycosis).

Keywords: *Karnashoola*, *Otomycosis*, *Vidanga arka*

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Introduction

Karnashoola is one among the *Karna Rogas*, mentioned in the *Ayurveda* classics characterized by *Shoola*, *Kandu* and *Srava*. (1) Twenty eight *Karnarogas* are explained in classical literature of *Ayurveda* where *Karnashoola* is one among them. *Karnashoola* is mentioned in both *Bruhatrayi* and *Laghutrayi*.

Karnashoola is characterized by *Shoola*, *Kandu* and *Srava* which are similar to Otomycosis. Otomycosis is one of the most frequently encountered aural diseases seen in all age groups, races and gender. (2) Its prevalence has been quoted to range from 9% to 27.2% among patients who present with signs and symptoms of otitis externa and up to 30% in patients with discharging ears. It is worldwide in distribution with a higher prevalence in the hot, humid and dusty areas of the tropics and subtropics. (3)

Otomycosis is a fungal infection affecting the external ear. *Aspergillus niger* is the commonest fungus to cause otomycosis. (3) The other fungi encountered are *Candida albicans*, *Aspergillus fumigatus* and *Candida tropicalis*. Diabetes and other immunocompromised states are predisposed to otomycosis.

This condition is characterized by symptoms like itching in the external auditory canal, pain, otorrhoea, ear blockage and presence of fungal mass. The fungal mass may appear white, brown or black. Pinna is usually not affected, but in extensive cases skin may be infected and blebs may be seen. External canal may be congested, ulcerated and the fungal mass will be seen and tympanic membrane may be congested occasionally. (4)

Management of Otomycosis includes thorough cleaning of the fungal flakes from the external auditory canal by syringing or suction cleaning. Antifungal ear drops like Nystatin, Clotrimazole, are advised. Painting of the canal with either 2% salicylic acid or 1% gentian violet can also be done. For prevention of Otomycosis infection, the ear should be kept dry. (5)

Even though these drops are very effective in Otomycosis, regular cleaning plays an important role in recovery of disease. This antifungal therapy is contraindicated in Children < 3 years, pregnancy, lactation period and membrane perforation. Special care should be taken in patients of hypersensitivity and also avoid contact with eyes upon topical application.

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Madhu has *Tridoshaghna*, *Lekhana*, *Ropana* and *Vranashodhana* property also indicated in *Karnashoola*. This was taken as control drug.

Vidanga arka mentioned in the *Arka prakasha* is quoted to be useful in the management of *Krimi*, also *Vidanga* is known for its *Vedanahara* property. (6) Thus it can be beneficial in the management of both *Karnashoola* and *Ostomycosis*.

With this evidence, a present study was planned to evaluate the efficacy of *Vidanga Arka* in Otomycosis.

Objectives

The Objective of the study was to compare the efficacy of *Vidanga Arka* with *Madhu* in *Karnashoola* with special reference to Otomycosis

Materials and Methods

The study included participants from Shalakya tantra department (OPD and IPD) of Sri Sri College Ayurvedic Science and Research, Bengaluru, Karnataka.

Drugs

Raw drug for the preparation of *Vidanga Arka* was collected from authentic sources after proper identification from the department of *Dravyaguna*, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. *Vidanga Arka* for the treatment was prepared in teaching pharmacy of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, under the guidance of Department of *Rasashastra* and *Bhaishajya Kalpana*.

Madhu was procured from GMP certified pharmacy.

Method of Preparation of Drugs

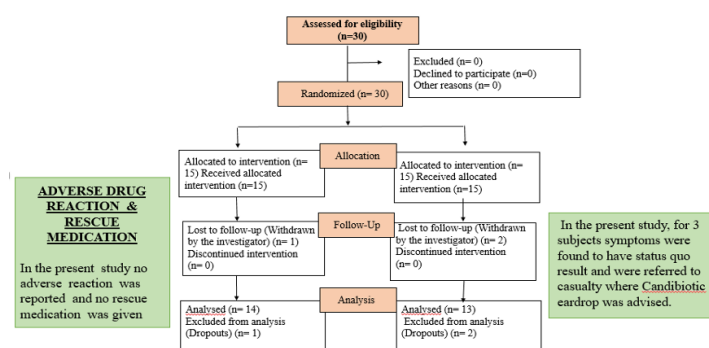
Vidanga Arka

Vidanga Arka was prepared according to *Arka Kalpana Vidhi* explained in *Arkaprakasa*. 50 gm of *Vidanga phala* were procured from authentic source and crushed into coarse powder. Then soaked in 500 ml of water for whole night. Next day it was subjected for distillation. The process of distillation was started at 10:45am at 50 degree Celsius. 60% of distillate was collected, cooled and transferred to sterile amber container, which was later transferred to sterile droppers.

Research Study Design

The clinical trial consists of two groups with 15 participants in each group.

Figure 1 Depicts the CONSORT flow diagram of the study



Participants

A total of 30 subjects diagnosed with *Karnashoola* were recruited from the Shalakya tantra OPD and IPD of the Sri Sri College Ayurvedic Science and Research, Bengaluru, Karnataka.

Inclusion criteria

The Subjects aged 21 to 60 years and fulfilling the diagnostic criteria were included in the study irrespective of gender, occupation, religion, socio- economic status and duration of illness.

Exclusion criteria

The Subjects having perforated tympanic membrane and other aural pathologies (external, middle and inner ear pathologies) were excluded from the study.

Intervention

The trial commenced after obtaining approval from the Institutional Ethics Committee, (Protocol ID SSIEC/205/2021) and CTRI registration ((CTRI/2022/09/045405, dated: 12/09/2022).

Treatment Protocol

Table 1: The detailed study protocol

Group	Treatment	Dose	Duration	Follow up Period	Study Period
A (trial)	<i>Vidanga Arka</i>	1 drop (Thrice a day)	Continuously for 7 days	14 th , 21 st and 28 th day	28days
B (control)	<i>Madhu</i> ⁸	1 drop (Thrice a day)	Continuously for 7 days	14 th , 21 st and 28 th day	28days

Outcomes

Subjective parameters (7)

1. *Karnakandu* (Ear Itching)

- No itching – 0
- Mild (2-3 times/day) - 1
- Moderate (3-10 times) - 2
- Severe (continuous whole day) – 3

2. *Karnashoola* (Earache)

- No pain - 0
- Patient is not restless/pain is tolerable - 1
- Patient is restless but controlled - 2
- Pain disturbs patient's routine work - 3

3. *Karnapratinaha* (Blockage of ear)

- No feeling of ear blockage - 0
- Occasionally feeling of ear blockage - 1
- Day/night time feeling of ear blockage - 2
- Whole day feeling of ear blockage – 3

4. *Karnasrava* (Aural discharge)

- No discharge - 0
- Scanty- discharge can be seen during fungal mass removal - 1
- Moderate – feeling of discharge inside ear, needs mopping - 2
- Profuse – discharge itself comes outside – 3

Objective parameters (7)**5. Aural endoscopy**

No fungal mass present - 0

Scanty to Half packed EAC with fungal mass - 1

More than half to full packed EAC with fungal mass – 2

Randomisation

Lottery method used to generate the random allocation sequence

Head of the department generated the allocation sequence, Principal investigator enrolled participants, and who assigned participants to interventions.

Statistical methods

To carry out statistical analysis, data was recorded on 0th day, 7th day, 14th day, 21st day and 28th day. Statistical analysis was performed using Sigma Stat version 3.1 and IBM SPSS Version 26. The data were analyzed initially to ascertain whether they pass normality test or not with Shapiro-Wilk test -if normality test was passed then analysis for parametric data was employed if not non-parametric test were employed to determine the level of significance. For non- parametric, within group analysis was done using Friedman Repeated Measures Analysis of Variance on Ranks when there were more than 2 assessments within the group. Parametric, within group analysis was done with one way repeated measures analysis of variance. Between group analysis

was done with Mann-Whitney Rank Sum test. After the statistical analysis, interpretation of the results were done based on the p value. The corresponding p value was noted and obtained results were interpreted as Non significant: >0.05; Significant : <0.05; Highly significant : <0.001.

Chi Square test used to analyze the overall assessment. Effect size difference (ESD) on Friedman Test for repeated measures was calculated using $W = Q/n(k-1)$ and was interpreted as 0.1 - small; 0.3 - medium; 0.5 – large. Effect size difference (ESD) on Mann Whitney test with 95% of confidence limit was calculated using

$$r = \frac{|Z|}{\sqrt{nA+nB}}$$

and was interpreted as Small ≤ 0.2 ; Medium $> 0.2 \leq 0.5$; Large > 0.5 ; Very large > 0.8

Results

The research adhered to the guidelines outlined in the CONSORT statement for recording and documenting the study results.

Recruitment

The informed consent was taken from all the participants and data collection was done between May 2022 and June 2023, throughout the trial, participants were required to visit the outpatient department (OPD) for assessment and documentation. Additionally, participants were instructed to inform the investigator promptly if they experienced any adverse effects.

Table 2: Karnashoola

Group	Karnashoola at different points of time (Data : Median, 25 th and 75 th percentile)									
	Right ear					Left ear				
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 0	Day 7	Day 14	Day 21	Day 28
A	1.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00
	(1.00-1.00)	(0.00-0.50)*	(0.00-0.00)*	(0.00-0.00)*	(0.00-0.00)*Nil	(1.00-1.00)	(0.00-0.00)*	(0.00-0.00)*	(0.00-0.00)*	(0.00-0.00)* Nil
B	1.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00
	(1.00-2.00)	(0.00-0.75)*	(0.00-0.00)*	(0.00-0.00)*	(0.00-0.00)*Nil	(1.00-1.00)	(0.00-0.00)*	(0.00-0.00)*	(0.00-0.00)*	(0.00-0.00)*Nil

***p<0.05 in comparison to the D0 values. Nil- no pain score (complete relief) (Friedman's test)**

Group A and Group B both showed statistically significant decrease in *Karnashoola* with $p < 0.05$ in Friedman RM Analysis of Variance on Ranks.

Between the groups with regards to *Karnashoola*, Mann Whitney rank sum test was carried out. Comparison shows that the difference between the groups was statistically non - significant on all points of time with $p > 0.0$.

Table 3: Karnakandu

Group	Karnakandu at different points of time (Data : Median, 25 th and 75 th percentile)									
	Right ear					Left ear				
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 0	Day 7	Day 14	Day 21	Day 28
A	1.00	0.00	0.00	0.00	0.00	1.00	1.00	1.00	0.50	1.00
	(0.50-1.00)	(0.00-0.50)	(0.00-1.00)	(0.00-0.50)	(0.00-1.00)	(0.50-1.00)	(0.00-1.00)	(0.00-1.00)	(0.00-1.00)	(0.00-1.00)
B	1.00	0.00	0.00	0.00	0.00	1.00	0.50	0.50	0.00	0.00
	(0.00-1.00)	(0.00-1.00)	(0.00-1.00)	(0.00-0.00)	(0.00-0.75)	(0.50-1.00)	(0.00-1.00)	(0.00-1.00)	(0.00-1.00)	(0.00-1.00)

Group A and Group B – No change could be observed in *Karnakandu* with $p > 0.05$ in Friedman RM Analysis of Variance on Ranks.

Between the groups with regards to *Karnakandu*, Mann Whitney rank sum test was carried out. Comparison shows that the difference between the groups was statistically non - significant on all points of time with $p > 0.05$

Table 4: Karnapratinaha

Group	Karnapratinaha at different points of time (Data : Median, 25th and 75th percentile)									
	Right ear					Left ear				
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 0	Day 7	Day 14	Day 21	Day 28
A	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	(0.00-1.00)	(0.00-0.50)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-1.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)
B	2.00	0.00	0.00	1.00	1.00	0.50	0.00	0.00	0.00	0.00
	(0.25-2.75)	(0.00-1.00)	(0.00-1.00)	(0.00-1.00)	(0.00-1.00)	(0.00-2.50)	(0.00-0.50)	(0.00-0.50)	(0.00-1.00)	(0.00-1.00)

Group A and Group B – No change could be observed in *Karnapratinaha* with $p > 0.05$ in Friedman RM Analysis of Variance on Ranks.

Between the groups with regards to *Karnapratinaha*, Mann Whitney rank sum test was carried out. Comparison shows that the difference between the groups was statistically non - significant on all points of time with $p > 0.05$.

Table 5: Karnasrava

Group	Karnasrava at different points of time (Data : Median, 25th and 75th percentile)									
	Right ear					Left ear				
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 0	Day 7	Day 14	Day 21	Day 28
A	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	(0.00-1.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.50)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)
B	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	(0.00-0.75)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)	(0.00-0.00)

Group A and Group B – No change could be observed in *Karnasrava* with $p > 0.05$ in Friedman RM Analysis of Variance on Ranks.

Between the groups with regards to *Karnasrava*, Mann Whitney rank sum test was carried out. Comparison shows that the difference between the groups was statistically non - significant on all points of time with $p > 0.05$.

Table 6: Fungal mass

Group	Fungal mass at different points of time (Data : Median, 25th and 75th percentile)									
	Right ear					Left ear				
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 0	Day 7	Day 14	Day 21	Day 28
A	1.00	0.00	0.00	0.50	1.00	1.00	0.00	0.00	0.50	0.50
	(1.00-1.50)	(0.00-0.50)*	(0.00-1.00)*	(0.00-1.00)	(0.00-1.00)	(1.00-1.00)	(0.00-0.00)**	(0.00-0.50)**	(0.00-1.00)**	(0.00-1.00)
B	2.00	0.00	0.00	1.00	1.00	1.50	0.00	0.50	0.50	1.00
	(1.00-2.00)	(0.00-0.75)*	(0.00-1.00)*	(0.00-1.00)*	(0.00-1.00)*	(1.00-2.00)	(0.00-0.00)*	(0.00-1.00)*	(0.00-1.00)*	(0.00-1.00)*
*P< 0.05 in comparison to the D0 values ((Friedman's test)										
**P=0.001 in comparison to the D0 values (One way repeated measure ANOVA)										

Group A - RE showed statistically significant decrease in fungal mass with $p < 0.05$ in Friedman RM Analysis of Variance on Ranks and LE showed statistically highly significant decrease in fungal mass with $p = 0.001$ in One way repeated measure ANOVA.

Group B both showed statistically significant decrease in fungal mass with $p < 0.05$ in Friedman RM Analysis of Variance on Ranks.

Between the groups with regards to fungal mass, Mann Whitney rank sum test was carried out. Comparison shows that the difference between the groups was statistically non - significant on all points of time with $p > 0.05$.

Table 7: Effect size difference

Effect size difference (ESD) on Friedman Test for repeated measures was calculated using $W = Q/n (k-1)$

Parameters	Group	Laterality	Day 0-7 ESD	Day 0-14 ESD	Day 0-21ESD	Day 0-28 ESD
Karnashoola	A	RE	0.85 -Large	1.02 -Large	1.02 -Large	1.11 -Large
		LE	0.78 -Large	0.89 -Large	0.89 -Large	0.89 -Large
	B	RE	1.01 -Large	1.21 -Large	1.21 -Large	1.29 -Large
		LE	0.90 -Large	0.90 -Large	0.90 -Large	0.90 -Large
Karnakandu	A	RE	0.60 -Large	0.52 -Large	0.62 -Large	0.43 -Medium
	B	RE	0.37 -Medium	0.46 -Medium	0.68 -Large	0.57 -Large
		LE	0.38 -Medium	0.38 -Medium	0.51 -Medium	0.51 -Medium

Karna pratinaha	A	RE	0.49 -Medium	0.65 -Large	0.74 -Large	0.65 -Large
		LE	0.26 -Small	0.35 -Medium	0.35 -Medium	0.35 -Medium
	B	RE	0.74 -Large	0.70 -Large	0.48 -Medium	0.48 -Medium
Karnasrava	A	RE	0.27 -Small	0.27 -Small	0.36 -Medium	0.36 -Medium
Fungal mass	A	RE	0.02-Very small	0.91 -Large	0.73 -Large	0.54 -Large
	B	RE	1.21 -Large	1.10 -Large	0.92 -Large	0.92 -Large

Table 8: Effect size difference (ESD) on Mann Whitney test with 95% of confidence limit was calculated using $r = Z/\sqrt{N} \pm 1.96/\sqrt{N}$

Parameters	ESD with 95% CL on Day 7 (AT)	ESD with 95% CL on Day 14 (F 1)	ESD with 95% CL on Day 21 (F 2)	ESD with 95% CL on Day 28 (F 3)	Comment
Karnashoola RE	0.36 - Medium	0.37 - Medium	0.37 - Medium	0 - No	Group A is higher than Group B
Karnashoola LE	0 - No	1.364 - Very Large	0.54 - Medium	0.5 - Medium	Group A is higher than Group B
Karnakandu RE	0.54 - Medium	0.39 - Medium	0.43 - Medium	0.5 - Medium	Group A is higher than Group B On 7 th and 14 th day
Karnakandu LE	0.44 - Medium	0.44 - Medium	0.44 - Medium	0.54 - Medium	Group B is higher than Group A
Karnapratinaha RE	0.54 - Medium	0.65 - Large	0.88 - Very large	0.8 - Very large	Group A is higher than Group B
Karnapratinaha LE	0.47 - Medium	0.62 - Large	0.69 - Large	0.69 - Large	Group A is higher than Group B
Karnasrava RE	0.49 - Medium	0.49 - Medium	0.63 - Large	0.63 - Large	Group A is higher than Group B
Karnasrava LE	0 - No	0 - No	0 - No	0 - No	Both group has equal effect
Fungal mass RE	0.40 - Medium	0.46 - Medium	0.47 - Medium	0.38 - Medium	Group A is higher than Group B
Fungal mass LE	0 - No	0.54 - Large	0 - No	0.45 - Medium	Group A is higher than Group B on 14 th and 28 th day

Table 9: Overall assessment

Parameter	Group A	Group B
	Percentage relief	Percentage relief
Karnashoola	83.33	86.17
Karnakandu	41.66	39.28
Karnapratinaha	82.29	76.04
Karnasrava	87.50	100
Fungal mass	92.70	87.75
TOTAL	77.49%	77.84%

Though difference existed between the group it did not reach statistically significant level ($p = 0.220$) (Chi square = 20.00 at 16 degree of freedom at $p=0.220$).

ESD calculation for the above (chi-square based test)- by calculating Cramer's $V = \sqrt{X^2/n} \times \sqrt{df} = \sqrt{20/30} \times \sqrt{16} = \sqrt{20/480} = \sqrt{0.04} = 0.2$. "Effect size is found to be small which is clinically significant in favour of Group B".

Figure 2: Day wise changes in Otomycosis during treatment

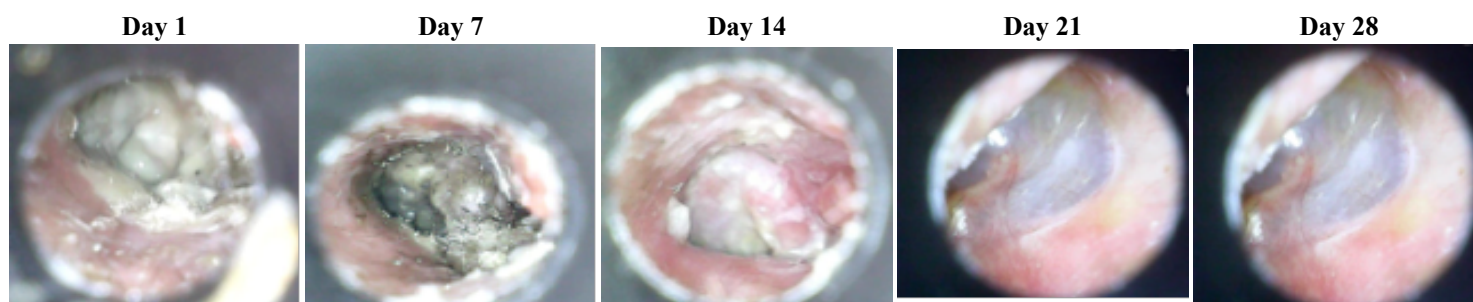


Figure 3: Preparation of Vidanga Arka

Discussion

This randomized clinical study evaluated the efficacy of *Vidanga Arka* (Group A) and *Madhu* (Group B) in the management of *Karnashoola* (earache) associated with fungal infection of the external auditory canal. Both interventions demonstrated a reduction in inflammation and associated symptoms, which can be attributed to their pharmacological properties described in Ayurvedic literature and supported by known phytochemical constituents.

Vidanga (*Embelia ribes* Burm.) contains Embelin and the alkaloid Christembine, which possess analgesic, antifungal, anti-inflammatory, and antioxidant properties. These bioactivities align with the observed *Shoolaghna* (pain-relieving)(8) effect in Group A. Similarly, *Madhu* (honey), characterized by *Kashaya anurasa*, *Ruksha* and *Teekshna guna*, and *Katu vipaka*, exerts *Lekhana* (scraping), *Shoshana* (drying), and *Ropana* (healing) effects. These attributes likely contributed to the reduction in inflammatory symptoms (*Karnashoola*) in both groups.

Although both interventions have *Krimighna* (antimicrobial) and *Lekhana-Shoshana* properties that likely reduced fungal burden, a statistically non-significant change in *Karnakandu* (itching) was observed in both groups. This may be due to the *Ruksha guna* and *Kashaya rasa*, which could lead to dryness (*Rukshata*) of the external auditory canal, potentially exacerbating or maintaining itching sensations.

Persistence of *Karnapratinaha* (ear blockage) in both groups may be explained by the *Sthambana* (obstructive) properties of *Kashaya rasa*. In Group A, the aqueous nature of *Vidanga Arka*, combined with its *Kashaya rasa*, may have contributed to this effect. Similarly, in Group B, *Madhu's Madhura rasa*, *Kashaya anurasa*, and *Sheeta veerya*, all known for their *Sthambhana* action, could be responsible for the continued symptom.

It is noteworthy that *Srava* (discharge) was absent during the study period, likely due to pre-intervention removal of fungal mass, which may have prevented further supuration.

The antifungal activity of *Vidanga* through its *Krimighna*, *Shoolaghna*, *Lekhana*, and *Shoshana* properties, and that of *Madhu* through its *Lekhana* and *Shoshana* actions, are plausible mechanisms for the reduction in fungal mass observed across both groups.

Limitations

- The study relied on classical Ayurvedic diagnostic criteria, and symptom assessment was subjective in nature.
- Lack of fungal culture confirmation post-treatment limits the objective measurement of antifungal efficacy.
- A relatively short follow-up period may not capture recurrence or long-term outcomes.
- The sample size may not have been sufficient to detect subtle differences in some secondary outcomes (e.g., *Karnakandu*).

Implications for Clinical Practice and Future Research

This study highlights the potential of *Vidanga Arka* and *Madhu* as alternative or adjunct therapies for managing fungal ear infections with symptoms of *Karnashoola*. Further large-scale studies with objective diagnostic tools (e.g., mycological culture, otoscopic imaging) and longer follow-up are warranted to validate these findings and assess recurrence rates.

Conclusion

Both *Vidanga Arka* and *Madhu* were found to be equally effective in the management of *Karnashoola* with special reference to Otomycosis. The comparative analysis revealed no statistically significant difference between the two interventions across multiple time points, supporting the conclusion that both treatments have equivalent therapeutic potential. Further studies with larger sample sizes and objective fungal assessments are recommended.

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Conflict of interest – None declared

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