VER
Vascular & Endovascular Review

Evaluation Of Virechana Efficacy Using Nimbaamritadi Erand Tailam And Gandharvahastadi Erand Tailam In Vatarakta: A Pilot Clinical Trial

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ABSTRACT

Background: Gout, a chronic inflammatory arthritis marked by acute joint pain, redness, and swelling, results from the accumulation of monosodium urate crystals due to hyperuricemia. In Ayurveda, it correlates with Vatarakta, a condition arising from the vitiation of Vata dosha and Rakta dhatu. Though modern treatments offer symptomatic relief, they are often accompanied by side effects. Ayurveda advocates Virechana Karma (therapeutic purgation) for Vatarakta, with formulations like Nimbaamritadi Erand Tailam and Gandharvahastadi Erand Tailam being traditionally used. However, clinical evidence comparing their efficacy is limited.

Materials and Methods: A pilot, open-label, comparative clinical trial was conducted on 20 patients diagnosed with Vatarakta, divided into two groups (n=10 each). Group A received Nimbaamritadi Erand Tailam, and Group B received Gandharvahastadi Erand Tailam as Virechana drugs. Patients were assessed on subjective parameters (pain, burning sensation, tenderness, swelling, walking ability) and objective parameters (ESR, serum uric acid) at baseline and on the 1st, 15th, and 30th days post-treatment. Ethical approval was obtained, and informed consent was taken.

Results: Both groups showed symptomatic and biochemical improvements. Group A showed greater relief in pain (39.28%), burning sensation (42.85%), swelling (41.66%), and walking ability (44%) compared to Group B. Group B showed slightly better relief in tenderness (42.30% vs. 38.46%). ESR and serum uric acid levels declined more in Group A (19.13% and 7.31%) than in Group B (13.07% and 3.74%), with the reduction in serum uric acid being statistically significant in both groups ($p < 0.05$).

Conclusion: Both formulations were effective for Vatarakta, but Nimbaamritadi Erand Tailam provided superior clinical and biochemical outcomes. It can be recommended as a potent Ayurvedic intervention for gouty arthritis. Further large-scale, long-term studies are warranted to substantiate these preliminary findings.

KEYWORDS: Vatarakta, Gouty arthritis, Nimbaamritadi Erand Tailam, Gandharvahastadi Erand Tailam, Virechana Karma

How to Cite: Sandip S. Deore, Santosh Chavan., (2025) Evaluation Of Virechana Efficacy Using Nimbaamritadi Erand Tailam And Gandharvahastadi Erand Tailam In Vatarakta: A Pilot Clinical Trial, Vascular and Endovascular Review, Vol.8, No.19s, 264-272

INTRODUCTION

Gout is a common form of inflammatory arthritis characterized by recurrent episodes of acute joint pain, redness, swelling, and tenderness, most commonly affecting the first metatarsophalangeal joint (Grassi & De Angelis, 2011; Stewart et al., 2016) [1,2]. It results from the deposition of monosodium urate crystals in joints and soft tissues due to persistent hyperuricemia (Ragab et al., 2017) [3]. The condition is more prevalent in males and is often associated with metabolic syndromes like obesity, diabetes, hypertension, and chronic kidney disease (Singh & Gaffo, 2020) [12]. The incidence of gout has increased globally due to sedentary lifestyles, dietary changes, alcohol consumption, and the growing prevalence of associated comorbidities (Kuo et al., 2015) [18].

From the Ayurvedic perspective, Vatarakta is a disease caused by the vitiation of Vata dosha and Rakta dhatu, leading to their obstruction and mutual aggravation. The classical features of Vatarakta include *Ruja* (pain), *Daha* (burning sensation), *Sparshasahatva* (tenderness), *Shotha* (swelling), *Twak Vaivarnya* (discoloration), and joint deformities in chronic stages. Ancient Ayurvedic scholars (Acharyas) have classified Vatarakta as *Uttana* (superficial) and *Gambhira* (deep-seated) based on its progression and tissue involvement (Charaka Samhita, n.d.; Sushruta Samhita, n.d.) [7,15]. Gout and Vatarakta share many symptomatic similarities, making Vatarakta an Ayurvedic correlate of gouty arthritis.

The prevalence of gout is estimated to be around 1–4% worldwide, with increasing trends in urban and industrialized regions (Wijnands et al., 2015) [4]. Despite the availability of modern pharmacological agents like NSAIDs, corticosteroids, and uric acid-lowering drugs, their long-term use often results in adverse effects or limited disease-modifying action (Richette & Bardin, 2010) [19]. Hence, there is a growing need to explore safe, effective, and holistic alternatives. Ayurveda offers a unique approach to metabolic and inflammatory disorders through *Shodhana* (bio-purification) and *Shamana* (palliative) therapies (Patil et al., 2018) [24].

Among the five major purification therapies, *Virechana* Karma (purgation therapy) is specifically indicated for diseases involving Pitta dosha and Rakta dhatu, and is thus considered a prime treatment for Vatarakta. Classical Ayurvedic texts recommend the use of medicated *Eranda Taila* (castor oil) in various forms for Virechana due to its deep-acting, Vata-Pitta–alleviating properties (Thakar, 2012) [28].

In this context, two classical Ayurvedic formulations—*Nimbaamritadi Erand Tailam* and *Gandharvahastadi Erand Tailam*—are frequently used in clinical practice for Virechana in Vatarakta. Nimbaamritadi Erand Tailam contains bitter, blood-purifying herbs like *Nimba* (Azadirachta indica, neem) and *Amrita* (Tinospora cordifolia, guduchi), while Gandharvahastadi Erand Tailam is known for its gentle purgative and *tridosha*-balancing effects. However, clinical evidence comparing their efficacy is limited (Raghunathan et al., 2015; Deep & Sharma, 2023) [5,8].

Need of the Study: Although both formulations are well-documented in Ayurvedic literature, there is a lack of comparative clinical evidence highlighting their individual efficacy in Vatarakta. With increasing cases of gout and a growing demand for integrative treatment approaches, it becomes imperative to evaluate and compare these two formulations for Virechana in a scientific manner. This pilot study aims to generate preliminary data that can guide larger controlled clinical trials in the future.

The aim of the study is to compare the clinical efficacy of Nimbaamritadi Erand Tailam and Gandharvahastadi Erand Tailam as Virechana drugs in the management of Vatarakta (gouty arthritis).

MATERIALS AND METHODS

2.1 Study Design

Type of Study: Pilot Comparative Clinical Trial

Place of Study: Department of Panchakarma, G.S. Gune Ayurveda College, Maliwada, Ahmednagar – 4140025; Bharati Vidyapeeth (Deemed to be University), College of Ayurved and Hospital, Pune – 411043

2.2 Participants

Sample Size: 20 patients (10 in each group)

Inclusion Criteria:

- Patients of either sex, aged 20–60 years.
- Patients presenting with the classical signs and symptoms of *Gambhira Vatarakta* (acute gouty arthritis).
- Patients willing to give informed consent and deemed fit for Virechana karma.

Exclusion Criteria:

- Patients with complications like deformity of joints or loss of joint function.

- Patients with comorbidities such as uncontrolled diabetes mellitus.

- Patients on regular corticosteroid therapy.

- Pregnant or lactating women.

Withdrawal Criteria:

- Occurrence of any serious adverse effects, which was to be reported to the concerned authority.
- Violation of the study protocol or if the patient became uncooperative

- Patient's unwillingness to continue in the trial or to adhere to the assessment schedule.

- Evidence of any other illness that could interfere with the efficacy evaluation of the trial drugs.

2.3 Ethical Consideration

Ethical approval for the trial was obtained from the Institutional Ethics Committee of Bharati Vidyapeeth (Deemed to be University) College of Ayurved and Hospital, Pune (Approval No. BVDUCOA/EC/103/2022-23). Written informed consent was taken from all participants prior to inclusion in the study.

2.4 Interventions

Group A: 10 patients received Nimbaamritadi Erand Tailam as the Virechana (purgative) drug.
Group B: 10 patients received Gandharvahastadi Erand Tailam as the Virechana drug.

Table 1: Grouping and posology

Parameter	**Group A**	**Group B**
Sample size	**10 patients**	**10 patients**
Shodhanang Snehapan (internal oleation)	Go-Ghrita (cow ghee) until *Samyak Siddhi* (proper oleation signs)	Go-Ghrita until *Samyak Siddhi* (proper oleation signs)
Sarvanga Bahya Snehana–Swedana (external oleation & sudation)	2 days on *Snehaviram dina* (post-oleation rest days); 1 day on Virechana day	2 days on *Snehaviram dina*; 1 day on Virechana day
Virechana drug (*Erand Taila*)	Nimbaamritadi Erand Tailam	Gandharvahastadi Erand Tailam
Snehaviram dina (gap days before purgation)	2 days	2 days
Procedure (Virechana)	Therapeutic purgation performed	Therapeutic purgation performed
Dose (based on *koshta*, bowel tendency)	Mridu (mild): 40 ml; Madhyama (moderate): 50 ml; Krura (strong): 60 ml	Mridu: 40 ml; Madhyama: 50 ml; Krura: 60 ml
Follow-up	1st, 15th, 30th day post-treatment	1st, 15th, 30th day post-treatment

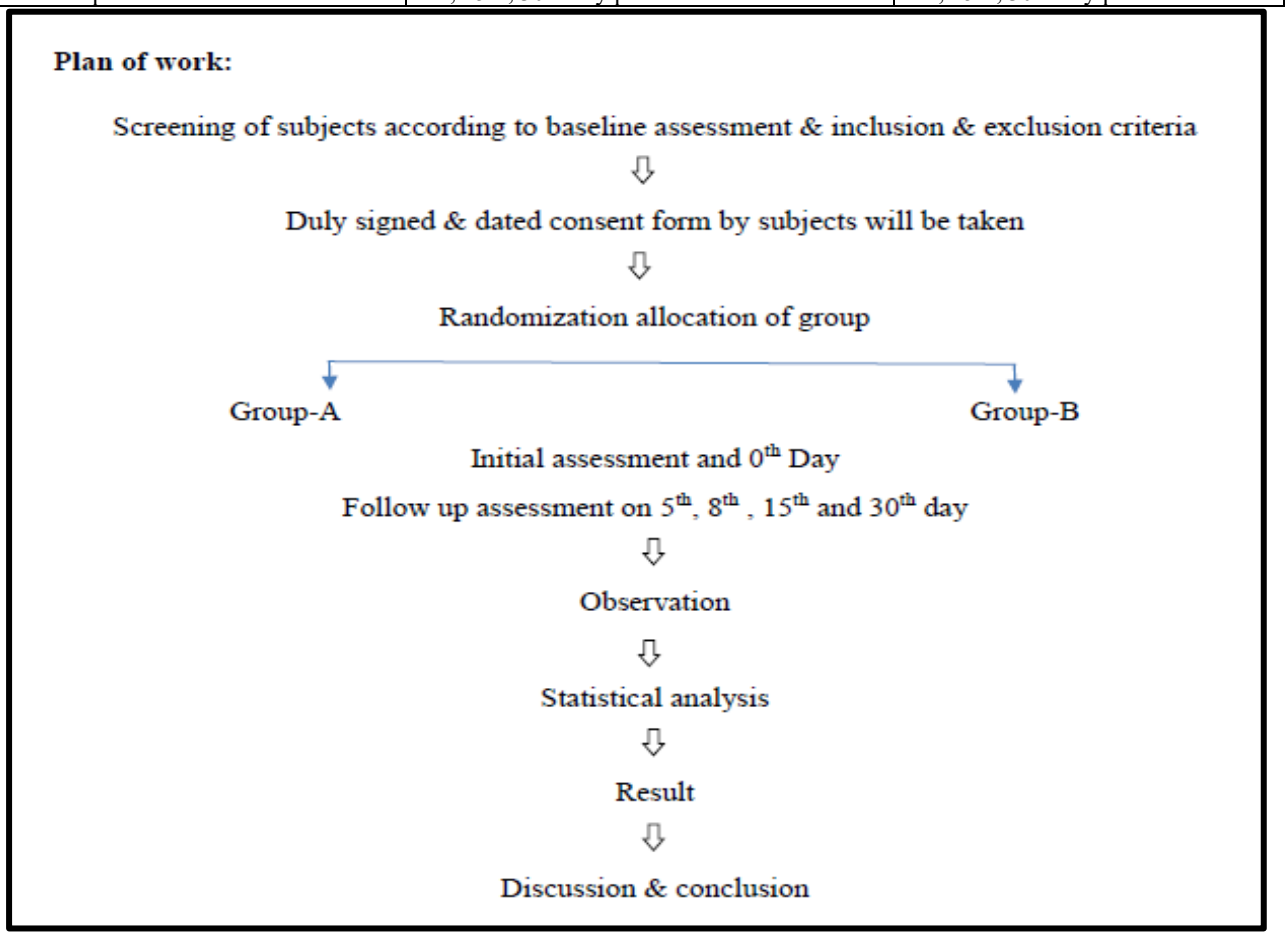


Figure 1: Plan of work. **(Flowchart depicting the study procedure)**

2.5 Plan of Work

(Refer to Figure 1 for the schematic plan of the trial.)

2.6 Criteria of Assessment

Subjective Parameters: *Ruja* (pain), *Daha* (burning sensation), *Sparshasahatva* (tenderness), *Shotha* (swelling), and walking ability. All of these were assessed using a graded scoring system before and after treatment.

Table 2: Assessment scale of subjective parameters

Symptom	**Score 0 (Absent)**	**Score 1 (Mild)**	**Score 2 (Moderate)**	**Score 3 (Severe)**
Ruja (Pain)	No pain	Mild pain; able to continue routine work; relieves on rest	Moderate, frequent pain; interferes with routine work; relieved after taking analgesics	Severe pain; intolerable; not fully relieved even after analgesics
Daha (Burning sensation)	No burning sensation	Mild burning sensation	Moderate burning sensation	Severe burning sensation
Sparshasahatva (Tenderness)	No tenderness	Complains of pain on touch	Complains of pain and winces	Complains of pain and withdraws (upon touch)

Symptom	Score 0 (Absent)	Score 1 (Mild)	Score 2 (Moderate)	Score 3 (Severe)
Shotha (Swelling)	No swelling	Mild swelling	Moderate swelling	Severe swelling
Walking ability	Walks easily	Walks with mild difficulty	Walks with moderate difficulty	Unable to walk without support

Objective Parameters: Erythrocyte Sedimentation Rate (ESR) and serum uric acid levels.

2.7 Data Management and Statistical Analysis
Data were entered and managed using Microsoft Excel 2010.
Analysis was performed using STAT software, Version 10.1 (2011).

Descriptive statistics: Frequency and percentage were used for demographic variables.

Inferential statistics: Within-group comparisons for subjective parameters were done using the Wilcoxon Signed-Rank Test (pre- vs post-treatment). Between-group comparisons were done using the Mann-Whitney U Test for non-parametric data, and an unpaired Student t-test was used for continuous variables.

A p-value < 0.05 was considered statistically significant.

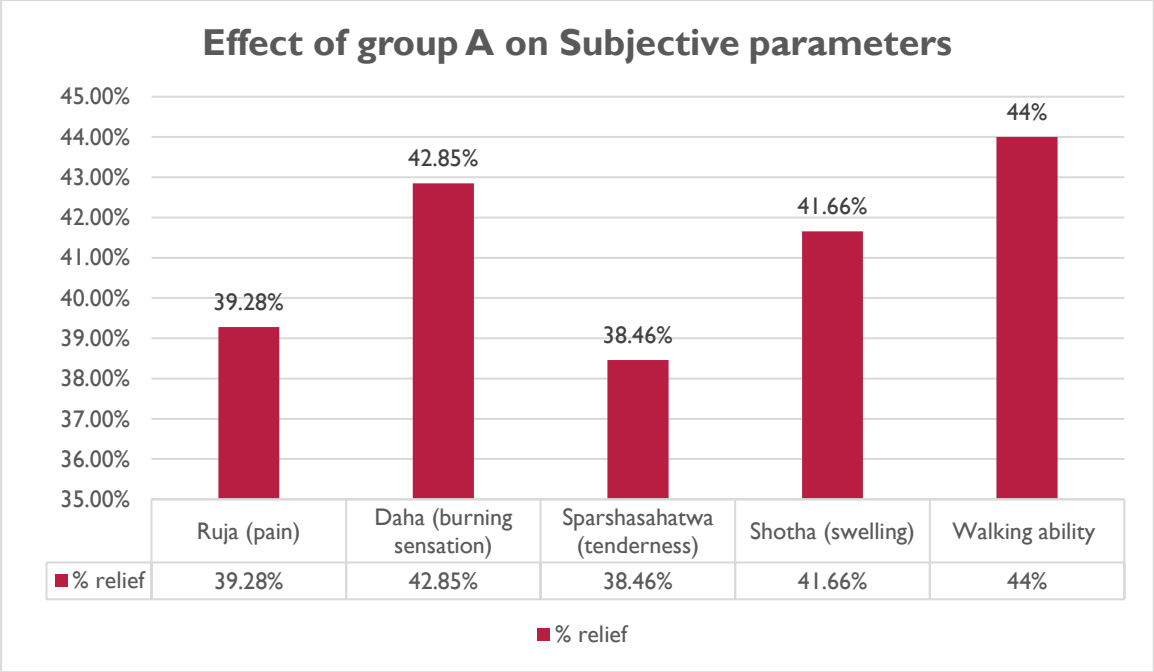
RESULTS

Demographic Distribution: The baseline demographic characteristics of patients in both groups were comparable (no significant inter-group differences in age, sex, etc.).

Table 3: Effect of Group A (Nimbaamritadi Erand Tailam) on subjective parameters (pre- and post-treatment within Group A)

Parameter	Mean (BT) ± SD	Mean (AT) ± SD	% Relief	t-value	p-value
Ruja (Pain)	2.8 ± 0.69	1.7 ± 0.69	39.28%	1.60	> 0.05 (NS)
Daha (Burning)	2.8 ± 0.74	1.6 ± 0.74	42.85%	8.50	> 0.05 (NS)
Sparshasahatva (Tenderness)	2.6 ± 0.70	1.6 ± 0.70	38.46%	8.70	> 0.05 (NS)
Shotha (Swelling)	2.1 ± 0.76	1.4 ± 0.76	41.66%	8.77	> 0.05 (NS)
Walking ability	2.5 ± 0.73	1.4 ± 0.73	44.00%	0.00	> 0.05 (NS)

BT: Before Treatment; AT: After Treatment; SD: Standard Deviation; NS: Not significant.



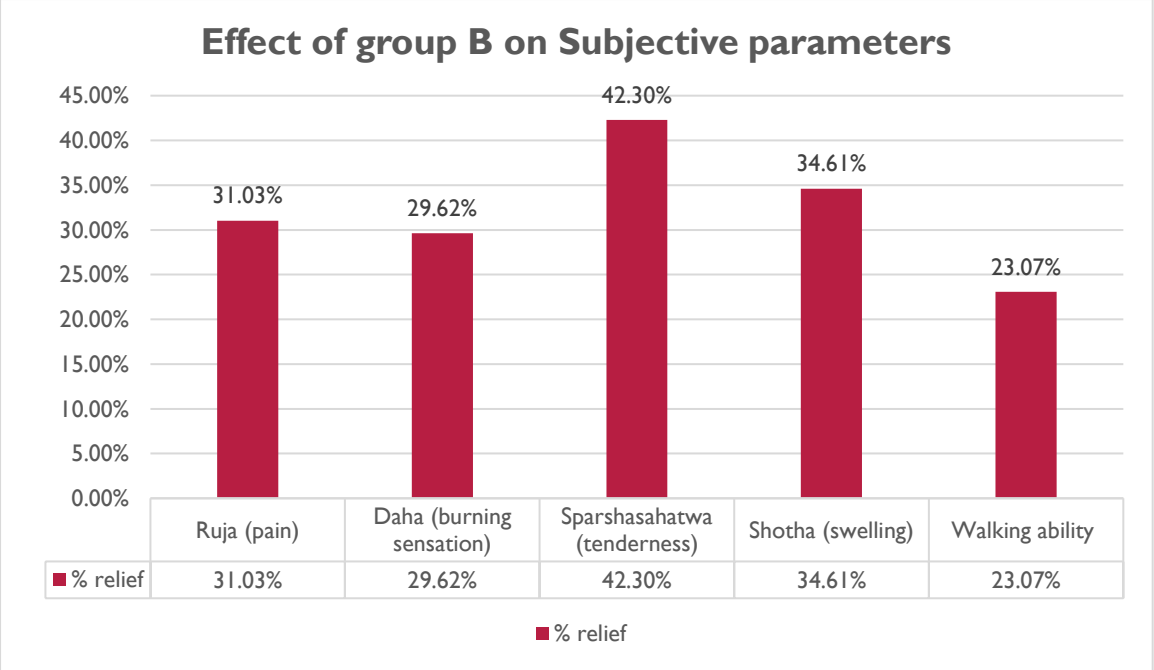
In Group A (treated with Nimbaamritadi Erand Tailam), all subjective symptoms of Vatarakta showed meaningful improvement. The mean score for *ruja* (pain) decreased from 2.8 to 1.7, yielding a 39.28% relief, indicative of a substantial analgesic effect. Similarly, *daha* (burning sensation) and *shotha* (swelling) were reduced by 42.85% and 41.66% respectively, reflecting a clear anti-inflammatory action of the formulation. *Sparshasahatva* (tenderness) reduced by 38.46%, and walking ability improved by 44%, indicating enhanced joint functionality. Although the p-values for these improvements were > 0.05 (statistically non-significant), the degree of symptomatic relief is clinically significant and suggests that Nimbaamritadi Erand Tailam has strong

potential in managing the subjective symptoms of Vatarakta.

Table 4: Effect of Group B (Gandharvahastadi Erand Tailam) on subjective parameters (pre- and post-treatment within Group B)

Parameter	Mean (BT) ± SD	Mean (AT) ± SD	% Relief	t-value	p-value
Ruja (Pain)	2.9 ± 0.58	2.0 ± 0.58	31.03%	8.53	> 0.05 (NS)
Daha (Burning)	2.7 ± 0.64	1.9 ± 0.64	29.62%	0.00	> 0.05 (NS)
Sparshasahatva (Tenderness)	2.6 ± 0.73	1.5 ± 0.73	42.30%	0.00	> 0.05 (NS)
Shotha (Swelling)	2.6 ± 0.65	1.7 ± 0.65	34.61%	8.50	> 0.05 (NS)
Walking ability	2.6 ± 0.55	2.0 ± 0.55	23.07%	0.00	> 0.05 (NS)

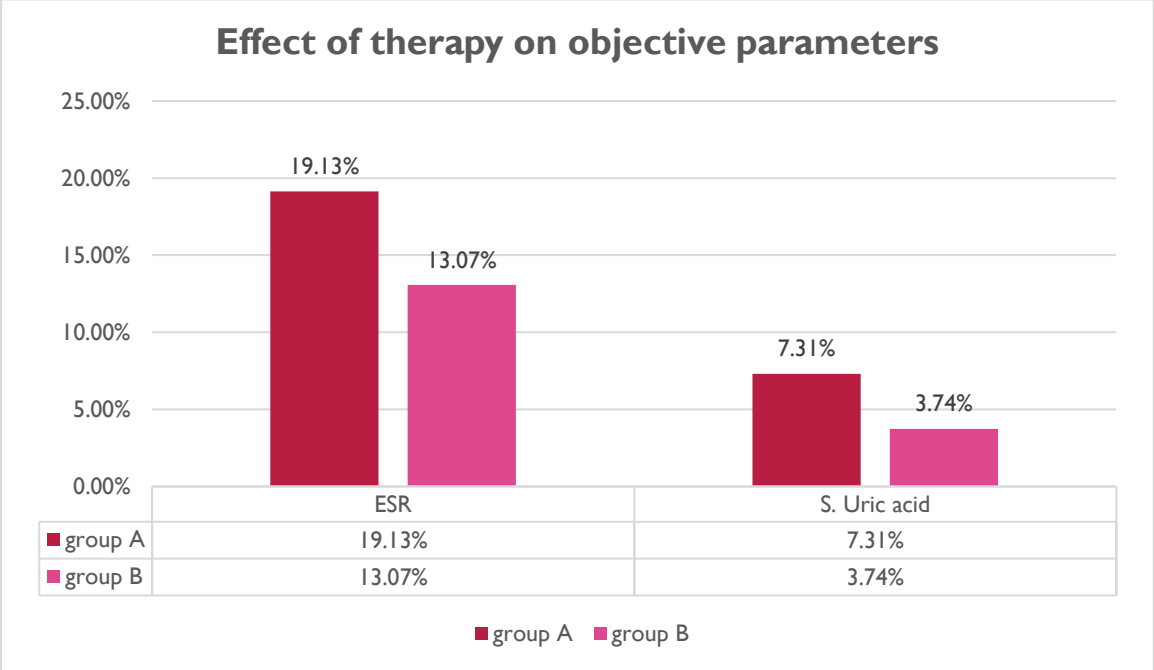
Group B (treated with Gandharvahastadi Erand Tailam) also demonstrated symptomatic improvements, although to a comparatively lesser extent than Group A. *Ruja* (pain) showed a 31.03% relief and *daha* (burning sensation) reduced by 29.62%. The highest



improvement in this group was observed in *sparshasahatva* (tenderness) at 42.30%, which slightly exceeded the tenderness relief in Group A. *Shotha* (swelling) showed 34.61% relief, and walking ability improved by 23.07%. These results suggest that Gandharvahastadi Erand Tailam is effective, particularly in reducing joint tenderness and pain, though its overall improvements in other parameters were more moderate compared to Group A.

Table 5: Effect of therapy on objective parameters (Group A vs Group B)

Parameter	Group A BT ± SD	Group A AT ± SD	% Change (A)	Group B BT ± SD	Group B AT ± SD	% Change (B)	p-value
ESR (mm/hr)	32.4 ± 4.34	26.2 ± 4.34	–19.13%	30.6 ± 2.98	26.6 ± 2.98	–13.07%	> 0.05 (NS)
Serum uric acid (mg/dL)	7.79 ± 0.34	7.22 ± 0.34	–7.31%	7.74 ± 0.19	7.45 ± 0.19	–3.74%	< 0.05 (Sig)

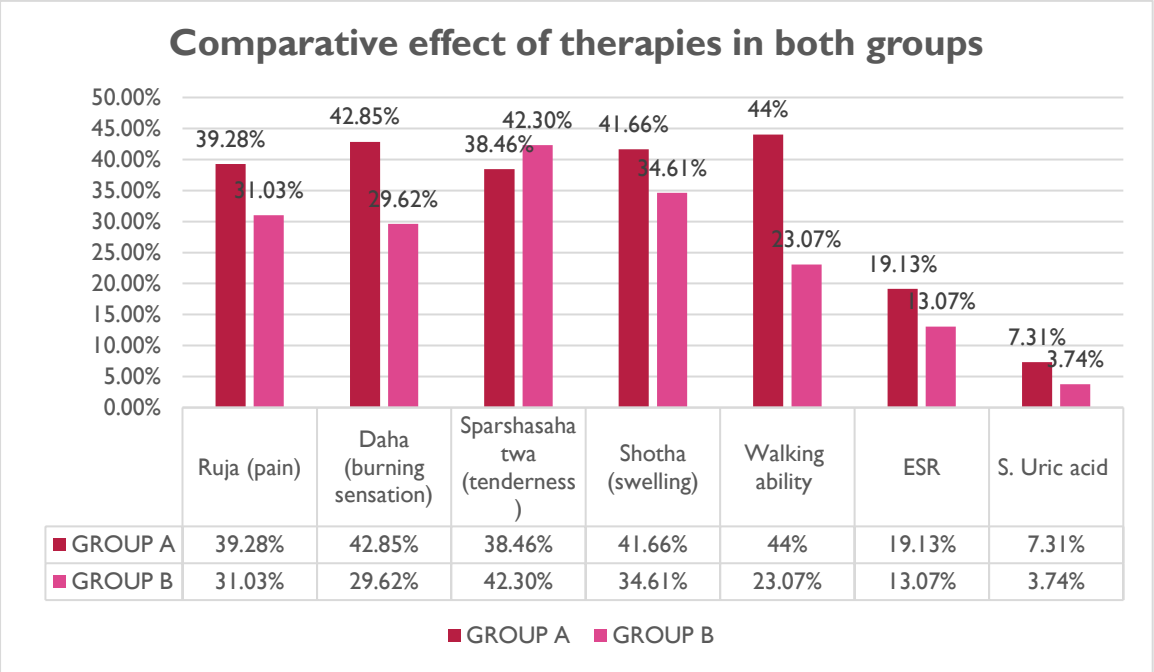


Both groups showed reductions in the objective parameters (ESR and serum uric acid) after treatment. In Group A, ESR dropped from 32.4 to 26.2 mm/hr (19.13% reduction) and serum uric acid from 7.79 to 7.22 mg/dL (7.31% reduction), indicating a favorable biochemical response. Group B showed a reduction in ESR from 30.6 to 26.6 mm/hr (13.07%) and serum uric acid from 7.74 to 7.45 mg/dL (3.74%). While both therapies improved these parameters, Group A achieved greater reductions in both ESR and uric acid. Notably, the decrease in serum uric acid was statistically significant in both groups ($p < 0.05$), whereas the change in ESR was not significant ($p > 0.05$).

Table 6: Comparative effect of therapies in Group A vs Group B

Parameter	% Relief (Group A)	% Relief (Group B)	Difference (A–B)	Better Result	p-value
Ruja (Pain)	39.28%	31.03%	+8.25%	Group A	< 0.05 (Sig)
Daha (Burning)	42.85%	29.62%	+13.23%	Group A	> 0.05 (NS)
Sparshasahatva (Tenderness)	38.46%	42.30%	–3.84%	Group B	< 0.05 (Sig)
Shotha (Swelling)	41.66%	34.61%	+7.05%	Group A	< 0.05 (Sig)
Walking ability	44.00%	23.07%	+20.93%	Group A	> 0.05 (NS)
ESR	–19.13%	–13.07%	+6.06%	Group A	< 0.05 (Sig)
Serum uric acid	–7.31%	–3.74%	+3.57%	Group A	< 0.05 (Sig)

When comparing Group A and Group B directly, Group A showed superior outcomes in most subjective and objective



parameters. For instance, Group A achieved ~8.25% more pain relief, ~13.23% more reduction in burning sensation, and ~7.05% more reduction in swelling than Group B. Group B had a slight edge in tenderness relief (42.30% vs. 38.46% in Group A). In terms of functional improvement, Group A's patients had a markedly higher improvement in walking ability (44% vs. 23% in Group B).

Objective measures reinforced these trends: Group A demonstrated a greater reduction in ESR (19.13% vs. 13.07%) and serum uric acid (7.31% vs. 3.74%) compared to Group B. The inter-group difference in serum uric acid reduction (about 3.57% more in Group A) was statistically significant ($p < 0.05$), as was the difference in ESR reduction (about 6.06% more in Group A, $p < 0.05$). Overall, the comparative analysis confirms the more potent anti-inflammatory and metabolic corrective properties of Nimbaamritadi Erand Tailam (Group A) over Gandharvahastadi Erand Tailam (Group B).

DISCUSSION

The present study aimed to evaluate and compare the efficacy of Nimbaamritadi Erand Tailam (Group A) and Gandharvahastadi Erand Tailam (Group B) in the management of Vatarakta (gouty arthritis). The findings from the subjective assessments indicate significant clinical improvements in both groups, with Group A generally outperforming Group B across most domains. In Group A, the greatest relief was observed in walking ability (44% improvement), followed by burning sensation (42.85%), swelling (41.66%), and pain (39.28%). This pattern suggests that the formulation not only reduced inflammation and pain but also improved functional mobility. The pronounced anti-inflammatory and analgesic effects of Group A can be attributed to its key ingredients – *Nimba* (Azadirachta indica), *Guduchi* (Tinospora cordifolia), and *Eranda* (Ricinus communis, castor oil) – which are known in Ayurvedic literature for alleviating Vata–Rakta disorders through both *Shodhana* (purificatory) and *Shamana* (palliative) actions (Chauhan et al., 2015; Jaiswal & Williams, 2016; Gupta et al., 2019) [21,22,29].

Group B also showed improvements, though to a lesser degree. Tenderness showed the highest relief in Group B (42.30%, slightly higher than in Group A), suggesting that Gandharvahastadi Erand Tailam – with its pronounced *Vata-hara* (vata-alleviating) and *Shoolahara* (pain-relieving) properties – may have a targeted effect on pain perception and local tenderness (Raghunathan et al., 2015) [5]. However, improvements in parameters like walking ability (23.07%) and burning sensation (29.62%) were notably lower in Group B, reflecting a more moderate overall therapeutic response. Moreover, while both groups benefited metabolically, Group B's formulation lacked the broader metabolic corrective impact seen with Group A. This indicates that although Gandharvahastadi Erand Tailam is beneficial for symptomatic relief (particularly pain and tenderness), Nimbaamritadi Erand Tailam offers a more holistic treatment effect by addressing both the inflammatory symptoms and the underlying metabolic disturbance (hyperuricemia) of Vatarakta.

The objective outcomes further support the superior efficacy of Nimbaamritadi Erand Tailam. Group A achieved greater reductions in ESR and, importantly, in serum uric acid levels compared to Group B, aligning with the notion that Group A's formulation better rectifies the underlying urate metabolic imbalance. The statistically significant greater drop in uric acid in Group A versus Group B ($p < 0.05$) consolidates the view that Nimbaamritadi Erand Tailam has a stronger disease-modifying effect in gout/Vatarakta. These findings are consistent with a recent pilot study by Deep and Sharma (2023) [8], which also reported significant improvements in gouty arthritis symptoms using Nimbaamritadi Erand Tailam as a Virechana agent.

In summary, while both Ayurvedic formulations provided therapeutic benefit in Vatarakta, Nimbaamritadi Erand Tailam demonstrated a more comprehensive efficacy profile – yielding superior clinical relief and better biochemical improvement – compared to Gandharvahastadi Erand Tailam.

CONCLUSION

This comparative clinical trial demonstrated that both Nimbaamritadi Erand Tailam and Gandharvahastadi Erand Tailam are effective in the management of Vatarakta (gouty arthritis). However, Nimbaamritadi Erand Tailam (Group A) was found to be more efficacious in terms of both subjective symptom relief and objective parameter improvement.

Group A treatment significantly reduced pain, swelling, burning sensation, and functional ability, and more importantly, reduced serum uric acid to a greater extent. Group B showed notable improvement in tenderness, but overall therapeutic benefits were relatively lower.

The objective assessments confirmed the superior metabolic corrective effect of Nimbaamritadi Erand Tailam, suggesting it is more effective for long-term management and for preventing recurrences of Vatarakta. Thus, Nimbaamritadi Erand Tailam may be recommended as a potent Ayurvedic intervention for the treatment of Vatarakta, especially in cases where both inflammatory symptoms and metabolic derangements (like hyperuricemia) are present. Future research with a larger sample size and longer follow-up is warranted to further validate these findings.

Acknowledgements
The authors express their gratitude to the patients, institutional staff, and research advisors for their support during the study.

Conflicts of Interest
None declared.

Funding
No external funding was received for this study.

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