Original Article

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Ayurveda Section

Efficacy and Safety of Ayurvedic Interventions in the Management of Rheumatoid Arthritis: A Systematic Review

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ABSTRACT

Introduction: Ayurveda offers a wide range of therapeutic approaches for Rheumatoid Arthritis (RA), including Panchakarma and oral medications. Although many studies are available on Ayurvedic approaches to RA, the efficacy and safety of oral medications haven't been thoroughly reviewed. This gap highlights the necessity of a comprehensive assessment of these interventions.

Aim: The present review evaluates the efficacy and safety of Ayurveda interventions for the management of RA.

Materials and Methods: In the present systematic review, Databases like PubMed, Science direct, Web of Science, Cochrane, Google Scholar, Ayush Research Portal, DHARA (Digital Helpline for Ayurveda Research Abstracts), Shodhganga@ INFLIBNET, and The Clinical Trial Registry of India (CTRI) were searched. All comparative clinical trials on RA (Amavata) published in English, from 2010 to 2024, were considered for the review. Studies administering Ayurvedic interventions involving Shamana Chikitsa intended for oral use for any duration in patients diagnosed with RA- clinically, or confirmed through laboratory and radiological investigations, or based on American College of Rheumatology Diagnostic Criteria- or with Amavata as defined in Ayurveda, were included regardless of age or gender. Data were analysed qualitatively including the Risk of Bias (RoB) assessment. Meta analysis was not possible due to heterogeneity in studies.

Results: A total of 448 articles were identified, with 21 studies meeting inclusion criteria, 15 randomised and six non-randomised trials. None compared Ayurvedic interventions with placebo. Most studies had a high Risk of Bias (RoB) due to weak methodology; randomisation, allocation concealment, and, blinding were poorly described or missing. Even though some studies employed standardised outcome measures, the subjective parameters used by the most studies lacked validated scoring tools. The major concern regarding the studies was selective reporting, with underreporting of adverse events and safety markers.

Conclusion: Despite Ayurvedic medications are widely used in the management of RA, the supporting evidence remains limited due to lack of methodological rigor and inadequate safety assessments. This review highlights the critical need for well-designed randomised controlled trials using standardised outcome measures and safety parameters.

Keywords: *Amavata*, Disease-modifying anti-rheumatic drugs, Randomised controlled trials, *Shamana chikitsa*, Traditional medicine

INTRODUCTION

The RA is a systemic autoimmune disease that causes progressive inflammation, often with phases of remission and relapse. It mainly affects the joints but can involve extra-articular areas too [1]. Over time, RA can lead to severe disability and loss of functionality. RA, is the most common clinical condition encountered by rheumatologists in the modern era. The prevalence of RA is 0.8% of the population (0.3-2.1%) [2]. RA is the most common type of persistent inflammatory arthritis. It affects people all over the world and is found in all ethnic groups. It most often affects middle-aged individuals but can occur at any age, and women are affected three times more than male [3]. If left untreated or poorly managed, RA can lead to significant disability and have a major impact on the quality of life of affected individuals. The main goals of treatment are to alleviate pain and inflammation, prevent joint damage, enhance joint function, and control systemic involvement [4].

The management of RA involves five primary strategies. The first line of treatment includes the administration of analgesics and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), while low-dose glucocorticoids are used as second-line therapy. Third-line treatment involves Disease-Modifying Anti-Rheumatic Drugs (DMARDs), followed by biologics and immunosuppressive agents as the fourth and fifth options [5,6].

Although these treatments are effective in managing the disease to some extent, they are often associated with a range of adverse effects; e.g., NSAIDs, commonly used for symptomatic relief, can lead to complications affecting the gastrointestinal, renal, cardiovascular, hepatic, and hematologic systems [7]. DMARDs, prescribed to alter the disease progression, are associated with the suppression of bone marrow, hepatic, and renal functions [8]. These limitations underscore the urgent need for exploring safer and holistic therapeutic alternatives. Traditional medical systems, such as Ayurveda, offer promising solutions in this context.

In Ayurveda, *Amavata* is often correlated with RA due to its similar clinical presentation and underlying pathology. *Amavata,* however covers a broader range of autoimmune and rheumatological disorders [9,10]. The pathology of *Amavata* basically comprises two components: the formation of *Ama* (toxic by-products of impaired digestion) and the vitiation of *Vata* (the dosha that governs movement and nervous system). The excessively vitiated *Vata* combines with *Ama* and spreads throughout the body. It settles down in *Sandhis* (joints), manifesting as *Amavata* [11]. The management of *Amavata* focuses on addressing the underlying pathologies by eliminating *Ama* and pacifying the vitiated *Vata*. The therapeutic approach is tailored to the specific stage of the disease (*Avastha*), and the associated clinical manifestations. Key strategies include *Langhana* (Fasting or Light Diet), the use of medications that are *Tikta-Katu-Deepana*

(Bitter and Pungent Digestive Stimulants), and procedures such as *Swedana* (Sudation), *Virechana* (Therapeutic Purgation), and *Basti* (Medicated Enemas) [12]. These treatment principles, which have been widely practiced by Ayurvedic practitioners for centuries, provide a broad spectrum of therapeutic options for managing RA. Although numerous studies have evaluated the Ayurvedic management of *Amavata*, a comprehensive review specifically evaluating the efficacy and safety of oral medications- *Shamana Chikitsa* (pacifying or palliative therapy) for the treatment of RA is still lacking. The current review attempts to address this gap by evaluating the efficacy and safety of internal medications administered under *Shamana Chikitsa* for the management of RA. The present study aimed to provide more precise estimates of the effects and safety of various Ayurveda interventions in managing *Amavata* (RA), whether used as a stand-alone or as an add-on to conventional management.

MATERIALS AND METHODS

The present review was carried out using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards. A systematic search for relevant articles was conducted on PubMed, Science Direct, Web of Science, Cochrane, Google Scholar, Ayush Research Portal, DHARA (Digital Helpline for Ayurveda Research Abstracts), Shodhganga@INFLIBNET, and The Clinical Trial Registry of India (CTRI) using controlled vocabulary and free text keywords. Core search string used was ("Rheumatoid arthritis" OR "RA") AND ("Amavata" OR "Amvat" OR "Sanshamana chikitsa"). The reference lists of systematic and other related review articles were hand-searched additionally. The eligibility criteria are included in [Table/Fig-1].

Population	Intervention/ Exposure	Comparison	Time frame	Study design
Patients diagnosed with RA (either clinically, or confirmed through laboratory and radiological investigations, or based on American College of Rheumatology diagnostic criteria), or with *Amavata* as defined in Ayurveda, regardless of age or gender.	Ayurvedic oral interventions (*Shamana Chikitsa*-internal pacifying or palliative therapy), either as a stand-alone or add-on therapy with any dose, dosage form, either alone or in combination, with or without *Pathya-Apathya* (diet and lifestyle regimen), administered over any duration were included. Studies employing external applications were excluded from the review	Studies with non-Ayurvedic (conventional) oral interventions, placebo treatments, other Ayurvedic oral *ShamanaChikitsa*, and combinations of Ayurvedic and non-Ayurvedic (conventional) oral interventions as comparator(s)/control were included.	Articles published between 2010 and 2024 were included in the review.	All comparative clinical trials, including Randomised Controlled Trials (RCTs), quasi-randomised controlled trials, non-Randomised Trials (nRCTs), multiple arms clinical trials, published in English, were included.

[Table/Fig-1]: Eligibility criteria for Population, Intervention, Comparison, Time frame and Study design (PICOTS).

Study Procedure

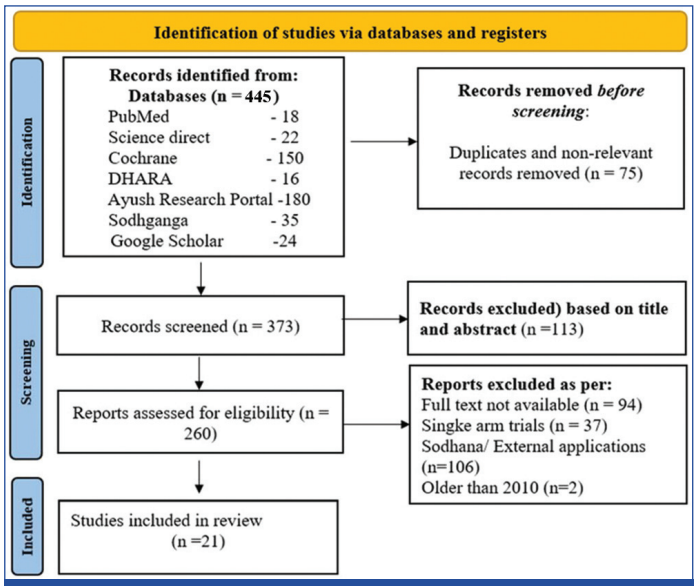
Study selection/ Study screening: The search results from databases were initially downloaded and transferred into Microsoft Excel. Duplicate entries were identified and removed. Two independent reviewers evaluated the eligibility of the studies based on the predefined inclusion and exclusion criteria. First, the titles and abstracts of the articles were screened. Full texts were obtained for articles when insufficient information available from the title or abstract to determine eligibility, or when the article appeared relevant based on its title or abstract. Any disagreements regarding the inclusion of full-text studies were resolved through discussion with a third reviewer. The complete study selection process is presented in the PRISMA flow diagram [Table/Fig-2].

Data extraction: The data was extracted independently by two reviewers and cross-checked for accuracy. Any discrepancies were resolved through discussion with a third reviewer. Data from each included trial were extracted using a pre-designed form for subsequent analysis and predefined outcomes of interest. The main outcomes of interest of the present review included the response in terms of improvement in pain, tenderness, stiffness, and swelling of joints, remission in disease activity assessed using validated tool, reduction in disability, reduction in bio-markers like Erythrocyte Sedimentation Rate (ESR), C-Reactive Protein (CRP) and Rheumatoid factor (RA factor), and incidence of Serious Adverse Events (SAE) resulting in death, disability or incapacity, life-threatening complications, that required hospitalisation. Additional outcome(s) such as change in quality of life, withdrawals of the participant from the study due to Adverse Events (AE)/Adverse Drug Reaction (ADR), non-response to treatment, Incidence of AEs/ADRs reported throughout the study, safety assessment based on laboratory parameters, and the incidence of AEs reported throughout the study.

The information extracted from each study included: title, authorship, publication related information, diagnosis, study design and methodology, participant characteristics (age, sex, disease duration), intervention details (dose, dosage form, frequency, and duration), comparator details (placebo, standard care, or other Ayurvedic oral *Shamana Chikitsa* with dose, dosage form, frequency, and duration), efficacy and safety outcome measures, AEs or ADR, and details of withdrawals and dropouts throughout the study.

Risk of Bias (RoB) quality assessment: Two reviewers independently assessed the RoB for each study. Bias was assessed at the study level for general methodological quality and at the outcome level for specific key outcomes. The assessment considered several methodological aspects, including randomisation, allocation concealment, blinding of participants, completeness of outcome data, selective reporting, and other potential sources of bias.

For RCTs, the Cochrane RoB-2 tool was used. It contains five domains to assess bias arising from the randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. The first domain assesses whether the random allocation of participants was truly random and concealed. In the second domain, deviations from intended interventions is assessed to know if participants remained in their assigned groups or if the study accounted for any deviations from the planned interventions. Third domain assesses if the data for the primary outcome is complete and balanced across groups in terms of missing data and how they are reported and balanced across groups if present. Fourth domain



[Table/Fig-2]: PRISMA flow diagram showing steps followed for the selection of articles for the review.

evaluates appropriateness and consistency of the measurement of outcomes, and also analyses whether the knowledge of the intervention influence outcome assessment. Fifth domain assesses if the outcomes are reported as specified in the protocol or is there any evidence of selective reporting of positive and significant outcomes. Each domain is rated as low risk, some concerns and high RoB and overall RoB is decided based on the assessment of each domain.

For non-randomised studies, the RoB in Non-randomised studies of Interventions (ROBINS-I) tool was applied. It has seven domains, grouped into three stages of a study such as pre-intervention stage, intervention stage and post-intervention stage. In the pre-intervention stage, the RoB due to confounding and selection is analysed. At the intervention stage, bias in classification of interventions is assessed to evaluate whether the interventions were clearly defined and correctly classified. Post-intervention, four domains are evaluated by assessing deviations from intended interventions, missing data, outcome selection and selection of the reported result. Each domain is rated as low, moderate and serious risks and overall RoB will be determined based on the highest RoB in each domain.

RESULTS

A total of 448 relevant studies were identified through an electronic database search. After removing duplicates and non-relevant records, 373 trials remained. These articles were screened based on title and abstract, and 113 articles were excluded. The remaining 260 were checked based on inclusion and exclusion criteria, and the availability of full-text articles; 239 trials were excluded, and 21 studies were included in the review [Table/Fig-3] [13-33].

Description of studies

Out of the 21 studies, 6 were non-randomised (Study no. 1,8,13,15,16,19 as per [Table/Fig-3]), while the remaining 15 were randomised. Among the randomised studies, two (study no. 5,11) included a control arm for conventional intervention, and two (study no. 18,21) had a control arm for Ayurvedic intervention. The remaining 11 were parallel-arm trials, of which three (study no. 10,12,17) were three-arm trials, and the rest were two-arm trials. The two-arm studies primarily evaluated the efficacy of individual drugs or simple formulations, while the three-arm studies included a third arm combining the treatments from the first two arms.

Among the included studies, nine studies diagnosed patients based on the classical features of *Amavata* as described in Ayurvedic texts (study no. 2,3,7,9,10,12,16,18,21), while three studies employed modern diagnostic criteria (study no. 6,14,20). Seven studies utilised a combination of clinical features of *Amavata* along with the 1987 American College of Rheumatology (ACR) criteria for RA (study no. 4,5,11,13,15,17,19). Two studies did not specify any diagnostic criteria (study no. 1,8).

The sample sizes across studies ranged from 30 to 101 participants. However, none of the studies provided a justification for the chosen sample size. The characteristics of the included studies are summarised in [Table/Fig-3] [13-33].

Risk of Bias (RoB) in included studies

The overall RoB in the included studies was high, primarily due to poor methodological reporting. Methods of randomisation were not clearly described in most studies, with only two (study no. 2,17) explicitly stating the use of a coin toss technique. Details regarding allocation concealment were entirely absent. Blinding procedures were reported in only two studies- one single-blind (study no. 20) and one double-blind (study no. 7); however, the validity of blinding in both cases is uncertain due to the use of different dosage forms, which could have revealed treatment allocation. The remaining studies were conducted as open-label trials, with no blinding measures reported.

Reporting of baseline characteristics was inadequate, with no study performing a statistical comparison of baseline variables such as age or disease severity between intervention groups, making it difficult to assess group equivalence at baseline. Outcome data were poorly documented: the number of participants who completed the study, those who were analysed, and those who dropped out were generally not reported. The reason for dropouts was reported only in one study (study no. 21), citing aggravation of symptoms and the need for emergency medication. It was unclear whether analyses were conducted on an intention-to-treat or per-protocol basis, and participants who dropped out were not included in the outcome analysis in any of the studies [Table/Fig-4,5].

Assessment Criteria for RA, and Effect of Ayurveda Interventions

The studies included in the review had different analysis methods and outcome measures. Due to the heterogeneity in the studies, quantitative synthesis of the study was not feasible. So, the studies were reviewed using qualitative synthesis and the findings were organised and presented in tabular format. Assessment criteria varied considerably across studies. Four studies (study no. 4,6,8,21) used subjective and functional parameters, seven (study no. 1,2,7,9,12,14,18) included both subjective and objective measures, and nine (study no. 3,5,10,11,13,15-17,20) employed comprehensive approach, incorporating subjective, functional, and objective parameters in their assessment.

Subjective parameters: The studies utilised a diverse set of cardinal and associated symptoms to assess subjective outcomes, resulting in considerable heterogeneity. Therefore, this review selected the most reported signs and symptoms-namely joint pain (*Sandhishula*), tenderness *Sandhisparshasahvata*), stiffness (*Sandhistabdhta*), and swelling (*Sandhishotha*)-as the primary subjective outcome parameters. Although grading systems were used to evaluate these subjective measures, there was a lack of uniformity in their application, raising concerns regarding the reliability and validation of these tools. All studies reported significant improvement in subjective parameters after treatment.

Functional parameters: Metrics like hand grip strength, foot press strength, and walking time, with variability in grading methods were used for the functional assessment before and after treatment.

Objective parameters: The ESR, CRP, and RA factor were commonly used. Two studies (study no. 4,6) used American Rheumatism Association (ARA) 1967 criteria; one (study no. 18) used Disease Activity Score-28 (DAS-28); and one (study no. 13) used the Indian-adapted Health Assessment Questionnaire.

- **ESR:** A significant reduction in ESR was reported in 14 studies (study no. 1-6,9-12,14,17,19,20); it was not assessed in five studies (study no. 7,8,13,18,21); and no significant change was observed in three studies.
- **CRP:** A significant reduction was reported in four studies (study no. 5,7,13,20); it was listed but not reported in two studies (study no. 12,17).
- **RA Factor:** It was evaluated in 11 studies- eight studies (study no. 1,5,7,10,11,13,17,19) reported significant reductions, while in three studies (study no. 9,15,20), the outcome was not significant; three other studies (study no. 3,12,14) mentioned RA Factor among the parameters but did not report specific outcomes.

RCT Studies: Out of the two RCTs with conventional controls, one (study no. 5) reported greater improvement in RA factor and CRP with Ayurvedic treatment, and while the other (study no. 11) showed better pain relief with the conventional approach, without any significant differences in ESR or RA factor between the groups.

Study no.	Study (Year)	Study design	Sample Size (Group A/ Group B)	Age (years)	Diagnostic criteria: Convention-al/Ayurveda/ Both	Intervention (name; dosage)	Outcome Assessment parameters	Findings of the study	Remarks
1	Rohit R et al., (2014) [13]	Non-Randomised	60 (30/30)	Not mentioned	Not mentioned	Trial group: *Punarnavadi churna* 3 to 6 g with *Rasnasaptak Kwatha*- 30 to 50 mL, and *Eranda taila* 10 to 20 mL BD for 2 months Standard group: *Singhanada guggulu* 1 BD with trial drugs for 2 months	Subjective: *Sandhishotha* (Joint Swelling), *Sandhishoola* (Joint pain) Objective: ESR, RA Factor	Subjective parameters improved significantly (p <0.001) in both groups. Moderate improvement (46.15% and 22.22%) in both groups. Marked improvement (53.85% and 77.78%) in both groups. ESR and RA Factor- Significant improvement in both groups. Standard drug is more effective than trial drug.	Analytical data comparing groups- not available. Reasons for 7 LAMA patients - not mentioned
2	Gupta A and Patni K (2021) [14]	Randomised	40 (20/20)	15 to 65	Both	Group A: *Khanda Shunthi* 10 g BD with lukewarm water - 60 days. Group B: *Prasarni Avaleha*, 10 g BD with lukewarm water for 60 days	Subjective: Pain Index (*Shoola*), Swelling Index (*Shotha*), Stiffness Index (*Jadya*) Objective: ESR, Walking time and grip strength	Subjective parameters improved significantly in both groups: Pain (82.8% and 66.7%) Swelling (75.4% and 67.8%), Stiffness (82.8% and 63.9%). Walking time (83.3% and 68.6%). Grip strength (87.3% and 70%). ESR significantly reduced (81.5% and 64.7%). Group A is more effective than Group B.	
3	Bansode Sandip D and Deshpande Deepak A (2015) [15]	Open Randomised	43	15 to 65	Ayurveda	A:*Trivrutadi Churna* B: *Haritaki Prayog*- 5 g BD with *Kanji* for 1 Month.	Subjective: pain, swelling, stiffness, and tenderness of the joint. Objective: RA Factor, ESR, grip strength, walking time, general functional capacity.	Significant relief in subjective parameters. Improvement in grip strength, walking time, and general functional capacity in both groups. Significant improvement in ESR in Group B. *Trivrutadi Churna* provided better relief than *Haritaki Prayog.*	Groups -not defined, sample size in each group- not mentioned. Analysis done for 35 patients only. Reasons for dropouts- not provided. Results and discussion lack clarity. Effect on RA factor- not addressed. Inter-group comparison- not provided.
4	Mahto RR et al., (2011) [16]	Randomised	101 (51/ 50)	18 to 60	Both American Rheumatism Association (ARA) – 1988 Criteria	A: *Rason-arasnadi Ghanavati* (250 mg)- 2 *Vati* TDS with *Koshna-jala* and *Rasona-rasnadi Lepa*- locally BD for 3 months B: *Simhanada Guggulu* (500 mg)- 2 *vati* TDS with *Koshna-jala, Rasona Rasnadi lepa*-locally BD for 3 months.	Subjective: *Roga Bala* (Strength of disease), *Deha Bala* (Physical strength), *Agni Bala* (Strength of digestive fire), *Chetasa Bala* (Mental strength), Degree of disease activity as per ARA (1967) criteria.	Complete remission- 13.95% in Group A and 4.87% in Group B. Moderate improvement- 34.88% in Group A and 58.53% in Group B. Degree of disease activity: 18.05% improvement in (Group A), 21.91% improvement (Group B). ESR: 8.80% reduction in Group A, 14.32% reduction in Group B. Group A therapy is more effective than Group B.	Dropouts- 8(Group A) and 9 (Group B); reasons unspecified. No SE observed.
5	Singh JP et al., (2010) [17]	Randomised Controlled	63 (33/ 30)	16 to 65	Both ARA 2000 revision.	A: *Rasona Pinda* 50–60 mg/kg bodyweight, three divided doses for 3 months. B: Tab. Etoriocoxib-90 (Nucoxia) 1 OD for 3 months	Subjective: Pain, Tenderness, Stiffness, Swelling, Objective: Haemoglobin (Hb), Total leucocyte count, Differential leucocyte Count (DLC), ESR, RA factor and CRP. LFT & KFT Functional: walking time, pressing power, grip power.	Significant reduction in the time duration of morning stiffness, joint pain, swelling, tenderness, RA titer, CRP and ESR. Grip strength and foot pressure were significantly increased. Complete remission – 29.6% (Group A) and 13% (Group B) Major improvement- 59.3% (Group A) and 21.7% (Group B) Minor improvement in 11.1% (Group A) and 39.1% (Group B) Unchanged in 26.9% (Group B).	Dropouts - 7 (Group A) and 6 (Group B): group; reasons unspecified. No change in LFT, serum creatinine and blood urea value in intervention group Group A - one reported nausea & 3 had loose stools. However, these side effects (SE) did not necessitate discontinuation of drug therapy.

6	Pandey SA et al., (2012) [18]	Randomised, comparative	24 (12/12)	18 to 60	ARA, 1988	A: *Shiva Guggulu* 6 g OD with lukewarm water for 8 weeks B: *Simhanada Guggulu* 6 g OD with lukewarm water for 8 weeks	Subjective: Pain, Tenderness, Stiffness, Swelling, Functional: Walking time, Grip strength, Foot pressure, General functional capacity Degree of disease activity- ARA, 1967	Relief in *Sandhishoola*- 68.53% (Group A) and 71.23% (Group B), *Sandhishotha* - 68.35% (Group A) and 71% (Group B), *Sandhigraha* - 68.11% (Group A) and 70.87% (Group B) *Sparshasahyata* - 66.02% (Group A) and 68.01% (Group B) In *Sandhishoola, Sandhigraha* and *Sparshasahyata*, Significant improvement in Group B than Group A. The mean disease activity score decreased significantly from 1.75 to 1 after treatment (42.85% relief) in Group A and from 1.5 to 0.75 (50% relief) in Group B. Mean ESR reduced from 54.5 to 45.3 in Group A and from 55.2 to 40.1 in Group B post treatment Marked improvement- 30% (Group A) and 40% (Group B) Moderate improvement- 70% (Group A) 60% (Group B)	Analysis of 4 patients is not included; reasons unspecified..
7	Shukla SS and Sharma A (2017) [19]	Double blind, Randomised	60 (30/ 30)	20 to 60	Ayurveda	A-*Bhallatakadi Churna* 2.5 g with *Guda* BD for 3 months B- *Bhallatak Guggulu* 500mg TDS for 3 months	Subjective: Pain, Tenderness, Stiffness, Swelling, Objective: RA factor, ASO titer and CRP.	*Sandhishoola, Sandhigraha, Shoonta Anganam, and Sparshasahayata* improved significantly in both groups ($p<0.001$). RA factor, CRP, and ASO titre showed significant improvement ($p<0.001$).	
8	Kumar PP et al., (2021) [20]	Non Randomised	30 (15/15)	>50	Not mentioned	A: *Vatari Guggulu* and *Brihat Simhanada* B: *Guggulu*, dose and duration not mentioned) for 12-weeks	Subjective: pain, stiffness, swelling Objective Grip strength, Foot pressure ACR / EULAR 2010, Simple Disease Activity Index Score (SDAI).	Subjective & objective parameters: Both drugs showed significant improvement ($p<0.0001$). No significant difference between groups. Moderate relief- 46.67% (Group A) and 66.67% (Group B). Mild relief- 53.33% (Group A) and 33.33% (Group B) ACR / EULAR-2010 & SDAI scores improved significantly in both groups.	Not in IMRAD format. No methodology or discussion sections in the article.
9	Chingale AA and Wali DS (2015) [21]	Open randomised Comparative	60 (30/ 30)	Irrespective of age	Ayurveda	A: *Dhatri Bhallataka Vati* 120 mg BD after food with *Goghruta* for 3 months B: *Dhatri Bhallataka Vati* 120 mg BD after food with *Sukhoshna Jala* for 3 months.	Subjective: Pain, Tenderness, Stiffness, Swelling, & others Objective: RA factor & ESR ACR criteria	Significant results ($p<0.0001$) in severity of Pain (52.1% improvement in Group A, 37.7% in Group B), Stiffness (44.7% in Group A and 30% in Group B), Swelling (62.7% in Group A and 48.8% in Group B), Tenderness (57% in Group A and 43% in Group B) ESR improved significantly in both groups. No change is seen in the RA factor. The study showed no significant difference between Group A and Group B.	

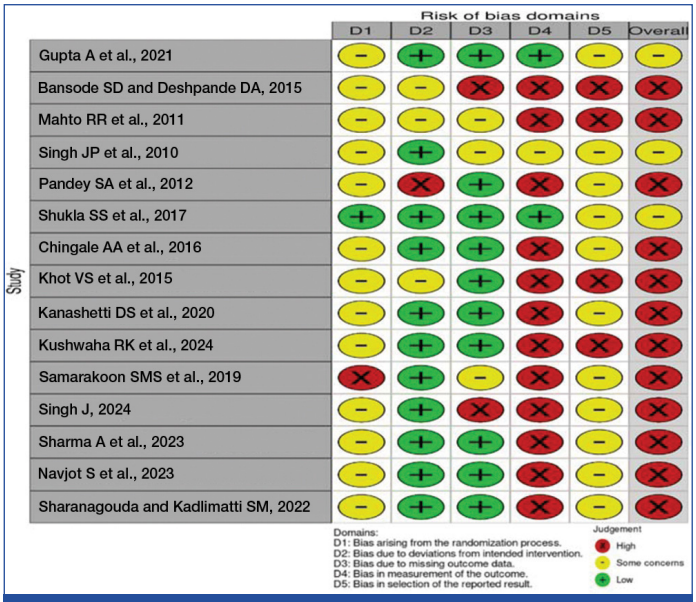
10	Khot VS et al., (2015) [22]	Randomised, comparative	60 (20/20/20)	20- 65	Ayurveda	A: *Bhallatakadi Churna* 1 g BD for 30 days B: *Eranda tail* 10 mL OD for 30 days C: Both for 30 days	Subjective: Pain, Tenderness, Stiffness, Swelling, & others Objective: RA Factor, ESR, CRP, DLC. Functional: walking time, grip strength, general functional capacity and fatigue, improvement in general health.	*Sandhishoola* - 50 %, 55 %, & 85 % Relief (Groups A, B and C). *Sandhishotha*- 60%, 85% & 90%. *Sandhisthabdhata* - 60%, 65% & 75% *Sparshaasahatva*- 75 %, 75% & 80%. respectively. A significant reduction in RA Factor level- 60 %, 60 % & 75 %. ESR- significant improvement in Groups A ($p<0.001$) and C ($P<0.01$). CRP- significant ($P<0.05$) in groups A and C. Significant improvement in grip strength, general functional capacity in all groups. Significant improvement in walking time and fatigue in groups A and C. Marked improvement- 65 % (Group A), 80 % (Group B), 85 % (Group-C). Improvement - 35 % (Group A), 20% (Group B), and 15% (Group-C). Group-C showed better results than A and B.	
11	Kanashetti DS et al., (2020) [23]	Open-randomised controlled	90 (30/30/30)	20 to 60	Both ACR, 1987	A: *Guduchi* and *Shunthi Kwatha*, 45-50 mL BD for 3 months B: Indomethacin 75 mg BD for 3 months C: Both for 3 months	Subjective: pain, swelling, stiffness of the joints Laboratory: ESR, CRP, RA titre.	Pain relief -66.7% (Group A), 96.3% (Group B) and 88.9% (Group-C). Reduction in swelling- 88.9% (Group A), 88.9% (Group B), 85.2% (group 3). Relief in stiffness 66.7% (Groups A, B), 88.9% (Group-C). Mean decrease in ESR after treatment was 8.148, 10.370 & 16.519 in groups A, B and C, respectively. Mean decrease in RA factor after treatment was 11.029, 12.673 & 16.632 in groups A, B and C, respectively. Mean decrease of CRP in after treatment was 12.778, 18.593 & 20.407 in Group A, B and C, respectively.	9 dropouts (3 from each group); reasons unspecified.
12	Kushwah RK et al., (2019) [24]	Randomised, comparative	45 (15/15/15)	18 to 70	Ayurveda	A: *Mritasanjivan Rasa* 125 mg.BD with lukewarm water, after food for 45 days. B: *Sunthyadi Kwath* 40 mL in morning for 45 days. C: Both for 45 days.	Subjective: pain, swelling, stiffness of the joints & others Objective: Hb, serum uric acid, ESR, TLC, DLC, CRP, RA factor	Pain reduced significantly in all groups with ($p<0.001$). Reduction in *Gatrastabdhata* -significant in groups B and C ($p<0.001$), non-significant in Group A ($p>0.001$). Reduction in *Shunataanganam*- significant in groups B and C ($p<0.001$), non-significant in Group A ($p>0.001$). ESR- significantly reduced in groups A and B, non- significant in Group-C.	No statistical inter-group comparison reported.

13	Mishra G and Pandya DH (2017) [25]	Non Randomised Comparative	61(31 in Group A and 30 in Group B)	20 to 60	Both Revised ARA 1987.	A: *Eranda Sneha* (10 mL) & *Shunti* Decoction (20 mL), morning, empty stomach, for 15 days B: *Eranda Sneha*- 10 mL with lukewarm water, morning, empty stomach for 15 days	Subjective: *Sandhishoola*, *Sandhishotha*, *Sandhigraha, Sparshasahatva etc* Objective: RA factor, CRP, ASO titer Functional: Disability index (the Indian health assessment questionnaire), hand grip, foot pressure and walking time.	Both groups provided symptomatic improvement in: *Sandhishoola*-37% (Group A) and 45.97% (Group B). *Sandhishotha*- 50.97% (Group A) and 48.79% (Group B). *Sandhigraha* - 60.03% (Group A) and 66.66% (Group B). *Sparshasahatva*- 50.87% (Group A) and 50% (Group B). Disability index- 40.46% (Group A) and 47.26% (Group B). RA Factor- 3.70% (Group A) and 7.40% (Group B). CRP- 43.16% (Group A) and 12.44% (Group B). ASO - 12.97% (Group A) and 25.91% (Group B). Overall efficacy- 35.71% (Group A) and 20% (Group B)	Dropouts- 8 (Group A- 3 and Group B-5) Reasons not mentioned. Although LFT, serum creatinine and Bl. Urea tests were done, no mention of assessment before and after intervention.
14	Samarakoon SMS et al., (2019) [26]	Randomised, comparative	40 (20 in each group)	20 to 50	Conventional	A: *Erandadi Kwatha*- 120 mL BD, before meals, for 1 month B: *Rasonadi Kwatha*- 120 mL BD, before meals, for 1 month	Subjective: Pain, tenderness, morning stiffness, etc., Objective: ESR, swelling,	Significant improvement in subjective parameters in both groups, no significant difference between groups. ESR- In Group A, Mean value reduced from 23.10 ±11.53 to 17.05 ±08.25, and in Group B, from 38.05 ±22.21 to 23.25 ±15.39. *Rasonadi* decoction is more effective than *Erandadi Kwatha.*	
15	Late SD et al., (2019) [27]	Non Randomised	40 (20 in each group)	18- to 60	Both ACR-EULAR, 2010.	A: *Ramban Rasa* 125mg BD with *Eranda Sneha* 10 mL for 21 days. B: *Ramban Rasa* 125mg BD without *Eranda Sneha* for 21 days.	Subjective: *Sandhi Shoola*, *Sandhishotha*, *Sandhistabdhata*, *Sparsasahatvam etc.,* Objective: RA factor, ESR ACR 2010 walking time, foot pressure, grip strength.	Significant improvement in both subjective and objective parameters in both groups. No significant difference between groups, but Group A have more significant result than Group B. Improvement in: *Sandhishoola*- 73.90% (Group A) and 37% (Group B). *Sandhishotha*- 76.30% (Group A) and 64.10% (Group B). *Sandhistabdhata*- 72.50% (Group A) and 51.20% (Group B). *Sparshasahatva* - 67.60% (Group A) and 46.30% (Group B). ESR- No significant difference in between groups	Intra-Group-Analysis not done. Methods for mean values determination- not reported. No reported ADR/AE.
16	Jagadale VA et al., (2020) [28]	Non-Randomised Comparative	40 (20 in each group)	30 to 65	Ayurveda	A: *Amavatavidhwansa Rasa* 250 mg BD B: *Simhanaada Guggulu* 250 mg BD	Subjective: Objective: RA Factor. ESR. walking time, foot pressure, grip strength	Group B showed better outcomes than Group A ESR- no significant difference between groups	Intra-Group-Analysis not done. Methods for mean value determination- not reported. No SE observed.
17	Singh J (2022) [29]	Randomised	30 (10/10/10)	20- to 60	Both ACR-EULAR, 2010	A: *Panchasama Churna*, 3g, with warm water BD, after food for 60 days B : *Erand Paka* - 5-10 g with warm water/milk BD, after food for 60 days C: Both for 60 days	Subjective: *Sandhishoola*, *Sandhishotha*, *Sandhistabdhata*, *Sparsasahatvam* Objective: CRP, ESR, RA factor and Antinuclear Antibody (ANA), Anti-cyclic citrullinated (anti-CCP) Antibody Functional: walking time, grip strength, foot pressure, general functional capacity.	Significant improvement in both subjective and functional parameters in all groups. Significant result in ESR for three groups, RA factor –significant change Group-C, but not in A and B Group A - mild improvement in 100% Group B - marked relief in 10%, moderate response in 30% and mild improvement in 60%. Group-C- marked relief in 10%, moderate response in 70% and mild improvement in 20%.	

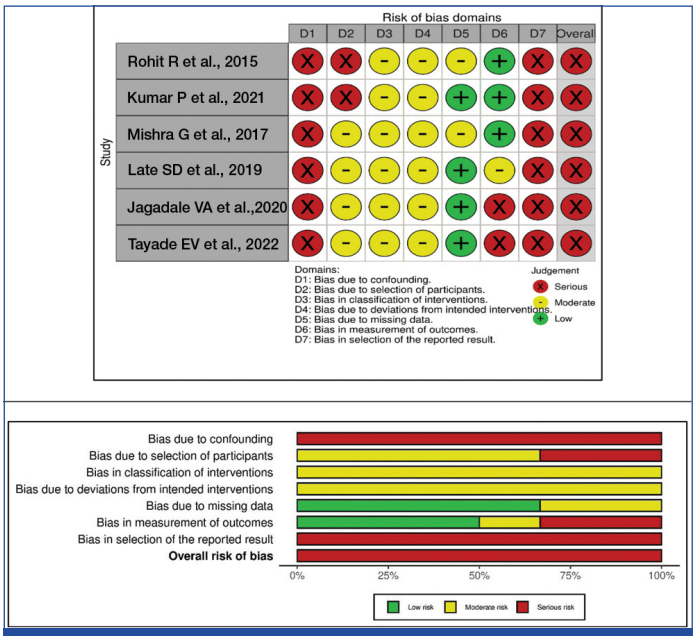
18	Sharma A et al., (2023) [30]	Open-Randomised Controlled	30 (15/15)	16 to 60	Diagnosed cases of *Amavata* Separate diagnostic criteria are not mentioned	A: *Shatyadi Kwatha* 20 mL, BD with lukewarm water after meal, for 45 days B: *Maharasnadi Kwatha* 20 mL, BD with lukewarm water after meals for 45 days	Subjective: *Sandhi Shoola*, *Sandhishotha*, *Sandhistabdhata*, *Sparsasahatvam etc.,* Objective: handgrip strength, foot press strength, DAS 28	Significant improvement in both subjective and objective parameters in both groups, with no significant difference between groups. Improvement in: *Sandhishoola*- 57.73% (Group A), 59.03% (Group B). *Sandhistabdhata*- 60.45% (Group A), 66.5% (Group B). Swelling- 57.73% (Group A), 59.03% (Group B). DAS 28 response Criteria- 36.53% (Group A), 37.58% (Group B). moderate improvement- 26.67% (Group A), 40% (Group B).Mild improvement- 73.33% (Group A), 60% (Group B) Percentage relief in Group B is better than A.	
19	Tayade EV, Jaydeo BL (2022) [31]	Non-randomised	60 (30/30)	18 to 60	Ayurveda& ARA	A: *Devdarvyadi Churna* (dose not mentioned) for 28 days B: *Pathyadi Churna* (dose not mentioned) for 28 days	Subjective: *Sandhi Shoola*, *Sandhishotha*, *Sandhistabdhata*, *Sparsasahatvam etc* Objective: ESR, RA Factor	*Improvement in -Sandhishoola*: 72.22% (Group A) and 64.81% (Group B), *Sandhishotha*: 65.00% (Group A) and 70.55% (Group B), *Sandhistabdhata*: 62.96% (Group A) and 64.19% (Group B), *Sandhi Sparshasahatva*: 67.28% (Group A) and 61.72% (Group B). In Group A, 43% showed moderate and 57% mild improvement; in Group B, 47% moderate and 53% mild. ESR improved by 51.35% (A) and 51.53% (B); RA Titre by 38.69% (A) and 36.51% (B).	Methodology and results- inadequate. Outcome measures lack proper analysis, no clear definition of control and intervention groups.
20	Singh N et al., (2023) [32]	Randomised single blind	34 (17/17)	30 to 70	Both ACR criteria.	A: *Pathyadi Churna* 5gm BD with lukewarm water for 6 weeks B: *Shunthyadi Kwatha* 25 mL BD. It was prepared by boiling 25 g of raw drug in 400 mL of water and reducing it to 50 mL, which was then given in two equally divided doses for 6 weeks.	Subjective: *Sandhishotha*, *Sandhishoola*, *sparshasahtva*, *Jadya* (Stiffness) etc., Haematological: TLC, DLC, ESR, SGOT/SGPT, blood urea, and serum creatinine were assessed pre- and post-treatment for safety. CRP, RA titer Functional: Walking time, Grip power and pressing power.	Both groups showed significant result on subjective and functional parameters. Significant reduction in ESR, CRP in both groups. RA factor – insignificant in both groups	Two patients dropped out from each group; reasons unspecified. No adverse events reported. Safety parameters remained normal pre- and post-treatment.
21	Sharana-gouda and Kadlimatti SM (2022) [33]	Randomised controlled	40 (20/20	20 to 60	Ayurveda	A: *Lavangadi Churna*, 3 gm BD, with Lukewarm water, post prandial for 30 days B: *Ajamodadya Churna*, 3 gm BD, with lukewarm water, postprandial for 30 days	Subjective: Pain, Stiffness etc., Objective: Swelling, Loss of function, Grip Strength, Foot Pressure, Range of movement, functional ability	Overall improvement was 99% in Group A and 60% in Group B. Group A showed significant improvement in both subjective and objective parameters. Group B showed significant improvement in all parameters except grip strength, foot pressure, and range of movement	Two patients dropped out from both Group A and B due to symptom aggravation.

[Table/Fig-3]: Characteristics of the studies selected for the systematic review [13-33].
OD: Once daily; BD- Twice daily; TLC: Total leukocyte count (total WBC count); DLC: Differential leukocyte count

Among four RCTs using Ayurveda controls, one (study no. 18) found no difference; one (study no. 21) favoured the trial drug; and two (study no. 1,19) did not include inter-group statistical comparisons.



[Table/Fig-4]: Graphs depicting the Risk of Bias (RoB) in reviewed randomised trials (Study no. 2-7,9-12,14,17,18,20,21 as per [Table/Fig-3]).



[Table/Fig-5]: Graphs depicting the Risk of Bias (RoB) in reviewed non-randomised trials (Study no-1,8,13,15,16,19 as per [Table/Fig-3]).

Safety Assessment and Adverse Events

Out of 21 studies, safety evaluations using CBC, Liver Function Test (LFT), and Kidney Function Test (KFT) were reported in only two studies (study no. 5,20). ADR/AEs were addressed in just two studies (study no. 15,20), and Side-Effects (SE) were assessed in only three studies (study no. 4,5,16), indicating that most studies did not report on the presence or absence of these safety outcomes.

DISCUSSION

The critical appraisal of the included studies indicates that the majority did not employ standardised diagnostic criteria for RA. Instead, diagnosis was often based on clinical presentation or investigator-defined parameters. This raises concerns about the accuracy of case identification, increases the risk of misclassification bias, and limits the comparability and validity of the reported findings. Randomisation methods, allocation concealment, and blinding are critical components of a clinical trial design, yet most studies either inadequately described or entirely omitted these elements. Such deficiencies undermine the validity of findings by increasing the risk of selection, performance, and detection biases. If the double-blind study designs are not feasible due to practical challenges, employing assessor blinding can effectively reduce bias and strengthen the internal validity of the study. The inadequate documentation of sample size calculations or statistical parameters such as alpha (Type I error) and beta (Type II error), raises concerns about the statistical power and precision of the results.

Although a few studies have employed standardised tools for outcome assessment, there was a lack of consistency in the scoring systems adopted to evaluate subjective outcomes. Moreover, considerable variation existed in both subjective and objective parameters reported across the studies. Many studies failed to provide reasons for attrition. In addition, they did not clarify the analysis methods whether it was intention-to-treat or per-protocol, compromising the interpretability and generalisability of the findings.

Another major concern observed in this review was selective reporting. Most studies lacked a comprehensive assessment of clinically relevant endpoints. Inadequate monitoring of laboratory safety parameters was common, and the evaluation of treatment effects on quality-of-life parameters was largely overlooked. AEs, SAEs, and ADRs were often underreported or omitted entirely. Such omissions stand in the way of a proper assessment of safety and the overall effectiveness of treatments on the well-being of the patients. Further, a follow-up to assess the long-term sustainability of treatment effects was largely absent. None of the studies reported any quality control measures for the Ayurvedic formulations used, which raises concern about the consistency and reproducibility of the findings.

Most studies were published in non-indexed journals with limited peer-review standards. Furthermore, the studies were not reported according to Consolidated Standards of Reporting Trials (CONSORT) guidelines, which compromises the credibility, transparency, and reproducibility of the evidence. While Ayurvedic practices are rooted in traditional knowledge and empirical experience, their evidence base is currently limited by significant methodological flaws. There is a compelling need for high-quality clinical research in Ayurveda that aligns with contemporary methodological standards. Further trials should consider standardised diagnostic criteria, rigorous randomisation and blinding protocols, robust statistical planning, and comprehensive outcome reporting-including safety and quality-of-life measures to ensure the reliability of findings. Such improvements are essential to strengthen the scientific foundation and global credibility of Ayurvedic interventions for RA.

Limitation(s)

The present systematic review has certain limitations also. The included randomised controlled trials exhibited considerable heterogeneity in outcome measures, assessment criteria, and statistical analysis methods. Due to these inconsistencies in reporting, a formal meta-analysis or quantitative data synthesis could not be conducted.

Recommendations for Future Research: Future studies should adopt rigorous, well-structured study designs with active controls using conventional drugs to strengthen internal validity and reduce bias. In case of any practical challenges in the blinding methods, assessor-blind study designs should be considered to minimise bias and strengthen the study findings. The clinical and patient-reported outcomes including quality of life should be assessed by validated and standardised assessment tools, to ensure consistency and reliability across studies. Laboratory markers and adverse event reporting should be included in study protocol for comprehensive safety evaluations. Adherence to standard reporting guidelines, such as the CONSORT statement, should be ensured to enhance transparency, reproducibility, and overall scientific quality. Good quality peer-reviewed, indexed journals should be prioritised for publication to ensure wider dissemination and accessibility of findings. Adhering to standard research protocols will enhance methodological consistency and comparability. Considering the individual variations in clinical presentations in RA patients, black

box or pragmatic trial designs may be more appropriate than traditional RCTs or parallel group comparisons.

CONCLUSION(S)

Ayurvedic treatments demonstrate therapeutic potential for RA; however, the evidence is marred by the high RoB in most studies. There is a critical need for rigorously designed, multicentre RCTs, blinded assessments, and use of standardised outcome measures including safety parameters.

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