

SAFETY AND EFFICACY OF GUGGULU FORMULATIONS IN THE MANAGEMENT OF RHEUMATOID ARTHRITIS - A SYSTEMIC REVIEW

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ABSTRACT

Background: Rheumatoid arthritis (RA) is widely prevalent throughout the world. The lifetime risk of developing RA is 3.6% for women and 1.7% for men. **Material and Method:** Subjected related published research article from journals were searched through online search engines google Scholar, Pubmed, AYUSH Research Portal Online, Ayu Journals. The data of Articles were analyzed to confirm their Safety and efficacy in management of RA. Total 138 review articles are found in the management of RA. Among these articles *Shamana Yoga* 62, *Shamana* and *Shodhana chikitsa yoga* 35 and *Shodhana yoga* 34 and *Yogika chikitsa*, *Satvavajaya chikitsa* were also given. **Results and Discussion:** Total 5 Clinical Studies on management of RA with *Guggulu* Formulation are selected for the study. 4 studies were Randomized Controlled Trials (RCTs), 1 open Random trial. Among 4 RCTs, 2 RCTs studies were suggested *Shodhana* and *Shanama Chikitsa* both were given, and the obtained results was showing more effectiveness than only *Shamana Chikitsa*. Maximum *Guggulu* preparations were given in management of RA. **Conclusion:** It is revealed that all therapies were found to be significantly effective. This systemic review investigates the evidence regarding safety and efficacy of *Guggulu* formulation in RA. No ADR was noticed.

Keywords: *Amavata*, Rheumatoid Arthritis (RA), *Guggulu* formulations

INTRODUCTION

Rheumatoid Arthritis (RA) is a joint disorder that involves inflammation and possible weakening of the lining of different body joints. The affected joints may lose their shape that leads to loss of normal mobility and the body attacks its own tissue including joints. In severe cases, it attacks internal organs. RA is widely prevalent throughout the world. RA is generally starting between the ages of 30 and 60 in women and

somewhat later in life in men. The lifetime risk of developing RA is 3.6% for women and 1.7% for men. However, RA can strike at any age even small children can get it. Out of every 1,00,000 people 41 are diagnosed with RA every year. About 1.3 million Americans have RA. Women are about two to three times more likely to get RA than men.¹

Amavata is made up of a combination of two words, *Ama* and *Vata*. The disease is mainly due to derangement of *Agni*, resulting in the production of *Ama* which circulates in the body and gets located in the *Sandhisa* causing pain, stiffness, and swelling over the joints. According to modern medicine, it can be correlated with RA, which is a chronic Auto immune disease that causes inflammation of the joint.

Ayurved, an Indian system of medicine, is well known for its unique therapeutic techniques. *Guggulu* is an established anti-inflammatory and anti-arthritis drug and used in the treatment of *Amavata*. *Guggulu* formulations are drug of choice them for the treatment of RA. These formulations are more popular in therapeutics because of its smaller dose, palatability, shelf life and efficacy. *Guggulu* formulations are prepared from processed herbal drugs, *Guggulu* etc. Herbal drugs are used in pharmaceutical process which act as a chelating agent and provide large number of trace elements. Ayurvedic classics have described some basic rules for all formulations regarding their preparation and prescription such as dose, duration, adjuvant and diet restriction.

In Rheumatoid Arthritis disease some *Guggulu* formulations have also found in routine practice such as *Simhanada Guggulu*, *Vatari Guggulu*. These formulations are widely prescribed by Ayurvedic physicians since ancient age and they are safe and effective in RA. Present work is a humble effort to collect and highlight some evidences regarding safety and efficacy of the *Guggulu* formulations in RA.

Materials and Methods: Subject related published research articles from reputed journals were searched through four online search engines - Google scholar, Pubmed, Ayush research portal and Ayu journals. Articles published in English language were included in the review. Full text of these studies is available in pdf format through the related publishing websites.

Objective - To evaluate the safety and efficacy of *Guggulu* formulations in the management of RA.

Search strategy: Published literatures on recent advancements in assessing the safety and efficacy of *Guggulu* formulations on Rheumatoid Arthritis which includes original articles and research papers in data-

bases such as Google scholar, Pubmed, AYUSH research portal, Ayu journals were taken into the study for review.

A literature search to collect relevant data was performed using the Mesh terms

- clinical trials on *Amavata* by Ayurvedic drugs
- *Amavata* disease
- Management of RA in Ayurved

- *Guggulu* formulations in the management of RA
- Ayurvedic management in RA

A total of 138 abstracts appeared with this combination. Total of 5 articles were retrieved for review.

Search engine

- Google Scholar
- PubMed
- AYUSH Research portal
- Ayu journals

Types of studies: Only clinical trials described in proper scientific manner were included in this review. Randomized trial, open label, single and double blind trials and the trials evaluated safety and efficacy of Ayurvedic *Guggulu* formulations in management of RA is included in the review. Case reports, case series, pharmacological studies, and observation studies were excluded from the review. *Vamana*, *Virechana Karma* in management of RA were also excluded.

Types of interventions: Studies designed to treat RA by Ayurvedic *Guggulu* formulations were included in the review. In all studies *Guggulu* formulations as interventions were given by oral route and some of them *Basti* was given. *Guggulu* formulations were prescribed in proper dose along with proper adjuvant.

Types of outcome measurement: For the outcome's measurement, assessment of before and after intervention and a follow up period were essential for the review. Hematological and Biochemical investigations have been taken as a safety measure.

Quality of evidence: Studies that were nonrandomized, limited, indirect or imprecise or exhibited publication bias were considered as a low-quality evidence. studies that were randomized trial were consider for medium to high quality evidence and based of randomization, blinding, reliability, and external validity were applied on them.

Data extraction: Standard proforma was prepared for data analyzing that comprised the following items; author, study design, participants, disease, age, intervention, safety measures and results. (Efficacy)

Study selection and exclusion: In Google scholar 69, Pubmed 9, AYUSH research portal 47, Ayu journals

11 articles clinical trials on RA were found. Total 138 clinical trials through Ayurvedic treatment in RA were found, respectively.

Results

Figure 1: Flow diagram showing the number of studies identified, screened, assessed for eligibility, excluded and included in the systemic review.

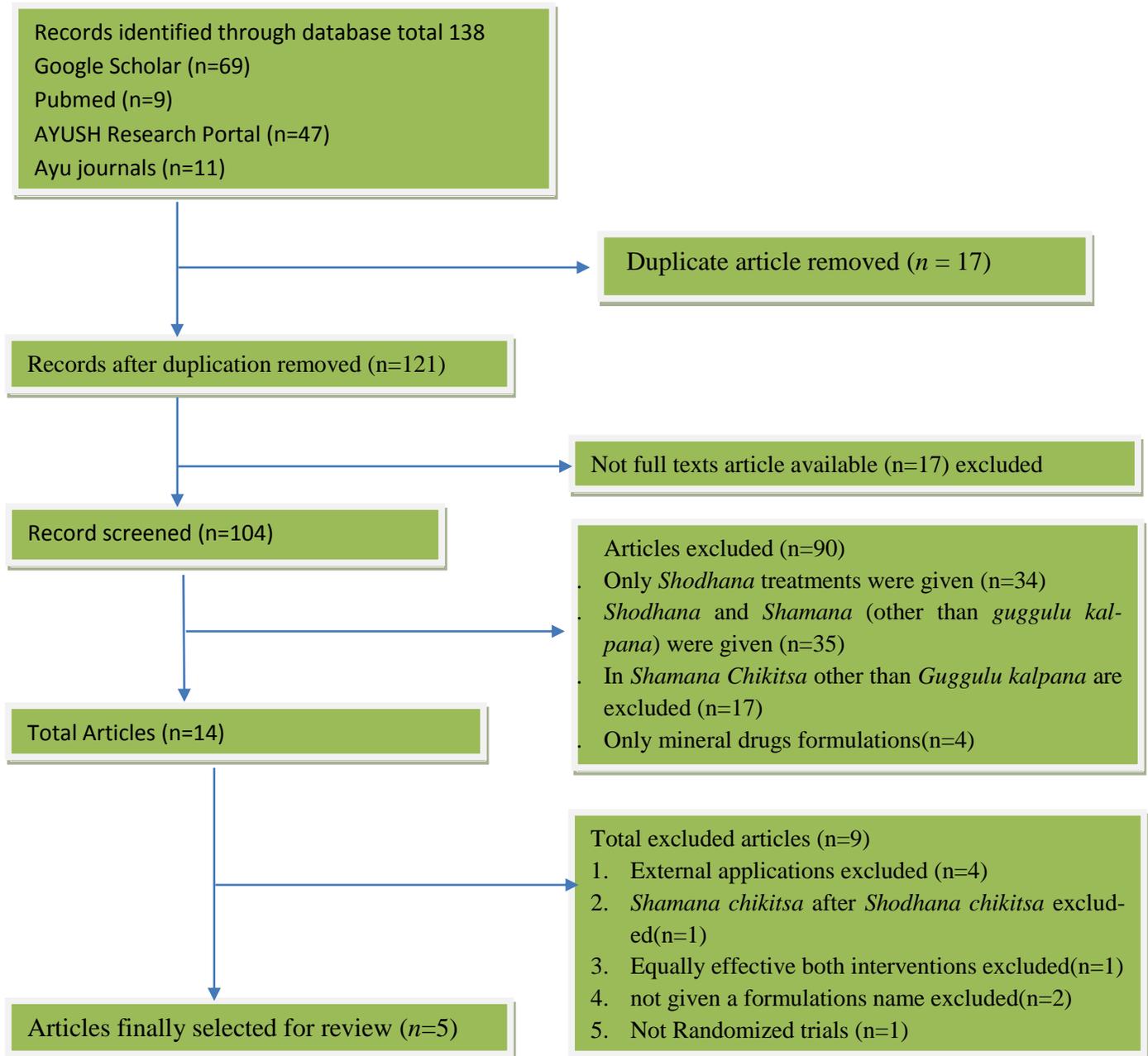


Table 1: Shows the characteristics of the interventions in the included studies.

| 1. Rita Khagram et al -2010 ² | |
|---|---|
| Method | Design:- Randomized Control Trials Duration:- 45 days follow up 1 month after completion of treatment |
| Participants | Number randomized:- 113 patients Group A (50 pt) Group B (53pt) Age of Participants:- 16-60 years Inclusion criteria of the study Morning stiffness Arthritis of three or more joints and hand joints Symmetrical arthritis Presence of RA factor - Diagnostic criteria is made with four or more criteria. RA factor Hematological investigation Urine analysis Exclusion criteria of the study Chronicity for more than 10 years Having severe crippling deformity Patients suffering with cardiac disease, pulmonary TB, DM etc. |
| Interventions | Group -A <i>Matra Basti</i> and <i>Vatari guggulu</i> Vatari guggulu -2vati(500mg) thrice a day with lukewarm water <i>Matra Basti</i> -60 ml -of <i>Brihat saindhavadi taila</i> Group -B <i>Vatari guggulu</i> 2vati(500mg) thrice a day with lukewarm water |
| Outcomes | Group A patients had better relief in most of the cardinal signs and symptoms of the disease |

| 2. Shweta et al - 2012 ³ | |
|--|---|
| Method | Design:- Randomized Control Trials Duration:- 8 weeks and follow up for 8 weeks after completion of treatment |
| Participants | Number randomized:- 24 patients (12 pt in Both Group) Age of Participants:- Age 18-60 yrs Inclusion criteria of the study Morning stiffness Arthritis of three or more joints and hand joints Symmetrical arthritis Presence of RA factor - Diagnostic criteria is made with four or more criteria. RA factor Hematological investigation Urine analysis Exclusion criteria of the study Chronicity for more than 10 years Having severe crippling deformity Patients suffering with cardiac disease, pulmonary TB, DM etc. |
| Interventions | Group -A <i>Shiva Guggulu</i> 6gm/day with lukewarm water |

| | |
|-----------------|--|
| | Group -B <i>Simhanada Guggulu</i> 6gm/day with lukewarm water |
| Outcomes | <i>Simhanada Guggulu</i> provided better results as compared to <i>Shiva Guggulu</i> . |

3. Shashikant s. Nikam et al- 2015 ⁴

| | |
|----------------------|---|
| Method | Design:- open Randomized Trials Duration:- 45 days |
| Participants | Number randomized: - 30 Patients Age of Participants: - 20-70 years Inclusion criteria of the study Patients of RA fulfilling the criteria of clinical symptoms of RA. - Diagnostic criteria based on clinical features of the diseases. RA factor Exclusion criteria of the study All complicated cases having any adverse deformity of RA. Cardiac disease, pulmonary and pregnant woman. |
| Interventions | Single Intervention <i>Rasanadyo Guggula</i> 1 g BD with Lukewarm water |
| Outcomes | The statistical analysis reveals that there was significant relief of symptoms ($p < 0.05$) at 5% level of significant |

4. Shiv shankar shukla et al - 2017⁵

| | |
|----------------------|--|
| Method | Design:- Double blind Randomized interventional Trials Duration:- 3 months follow up at every 15 days |
| Participants | Number randomized: - 60 patients (30 pt in Both Group) Age of Participants: - 20-60 years Inclusion criteria of the study Patients of RA fulfilling the criteria of clinical symptoms of RA. - Diagnostic criteria based on clinical features of the diseases. RA factor CRP less than 1 Exclusion criteria of the study All complicated cases having any adverse deformity of RA. Cardiac disease, pulmonary and pregnant woman. |
| Interventions | Group -A <i>Bhallathaka Churna</i> with guda 2.5 gm twicw a day Group -B <i>Bhallataka Guggulu</i> 500mg TDS |
| Outcomes | Group B showed faster and better improvement. Highly significant result found. |

5. Valiparambil c Deep et al - 2017 ⁶

| | |
|---------------------|---|
| Method | Design: - open label Duration: - 12 weeks |
| Participants | Number randomized: - 111 pt Age of Participants: - 20-60 yrs Inclusion criteria of the study Morning stiffness Arthritis of three or more joints and hand joints |

| | |
|----------------------|---|
| | <p>Symmetrical arthritis Presence of RA factor - Diagnostic criteria based on clinical features of the diseases. RA factor Reduction in DAS-28 Exclusion criteria of the study All complicated cases having any adverse deformity of RA. Cardiac disease, pulmonary and pregnant woman.</p> |
| Interventions | <p>Internal -<i>Simhanada Guggulu</i>-1.5 gm (3 tabs of 500mg each) Lukewarm water External- <i>Saindhavadi taila</i> local application</p> |
| Outcomes | <p>The statistical analysis reveals that there was significant relief of symptoms ($p < 0.05$) at 5% level of significant</p> |

DISCUSSION

Rheumatoid Arthritis is a joint disorder that involves inflammation and possible weakening of the lining of different body joints. Arthritis means inflammation of one or more joints. Inflammation of joints brings lot of pain, stiffness and even swelling. It can be correlated with *Amavata* in view of its clinical features.

Guggulu formulation are used in treatment of RA. *Guggulu* is *Katu Vipaka*, *Ushna Veerya*, *Vedahara Guna*. so that used in RA. *Basti* therapy is considered as prime among all the therapeutic, especially for management of *Vatavyadhies*. *Basti dravyas* can act as *Vatahara*, *Shulahara*, *Shothahara*, *Strotoshodhaka*, *Yogavahi*, *Agnideepaka* and *Rasayana*.

1) Rita Khagram et al

Group A- *Matra basti* with *Brihat saindhavadi taila* along with *Vatari guggulu*

Group B- *Vatari guggulu*

All the patients responded favorably to the treatment in both the groups: however, patients treated with *Matra basti* had better relief in most of the cardinal signs and symptoms of the disease. Effect of therapies in the *Matra basti* group that most of the patients (52%) showed marked improvement, while in the *Vatari guggulu* group most of the patients (54.72%) showed mild improvement. Thus, both therapies provided significant relief of the cardinal symptoms as well as general symptoms of RA. However, there was better relief in *Matra Basti* group than in the *Vatari guggulu* group.

2) Shweta Pandey et al

Group A- *Shiva guggulu*

Group B- *Simhanada guggulu*

on analysis of the results, it was found that *simhanada guggulu* provided better results as compared to *Shiva guggulu* in management of RA. In Group A, marked improvement in 30% and moderate improvement in 70% of patients was observed, whereas in group B, 40% of patients showed marked improvement and moderate improvement was seen in 60%.

3) Shashikanta nikam et al

Rasanadyo guggulu:- The mean symptoms significantly reduced after the treatment. The statistical analysis reveals that was significant relief of symptoms ($p < 0.05$) at 5% level of significance. *Rasnadyo guggulu* was significantly effective in symptoms of RA.

4) Shiv Shankar Shukla et al

Group - A *Bhallathaka churna* with *guda* 2.5 gm twice a day.

Group -B *Bhallataka guggulu* 500mg TDS

Present study reflects that both regimes have given very good relief in sign and symptoms of *Amavata* but in Group B who received *Bhallataka guggulu* showed faster and better improvement. *Bhallataka Guggulu* is safe, beneficial and very effective in management of *Amavata* and in RA.

5) Valiparambil C Deep: Internal -*Simhanada Guggulu*-1.5 gm (3 tabs of 500mg each) Lukewarm water
 External- *Saindhavadi taila* local application. *Simhanada Guggulu* and *Brihata Saindhavadi taila* administered together in the above-mentioned dose were found effective, safe and tolerable in patients with RA.

CONCLUSION

There is strong conclusion evidence that *Guggulu* formulations can be used in management of RA.

There was a systemic review investigating the evidence regarding safety and efficacy of Ayurvedic *Guggulu* formulations RA. In this review Ayurvedic *Guggulu* formulations are found quite safe to the use in RA with proper dose and adjuvant. *Basti* treatment followed by *Shamana Aushadha* with *Pathya Aahara* was found as a suitable treatment plan to manage RA. Among the *Shamana Aushadhas* usage of *Guggulu* formulations proved to have a significant effect on the recovery of RA. It also revealed the fact that all the therapies were found to be significantly effective and clinically safe as no adverse drug reaction were reported during treatment period among any of the screened studies.

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