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Efficacy of Simhanada Guggulu in Managing Gulpha Sandhi involvement in Amavata: A Prospective Clinical Evaluation

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Abstract:
This study thoroughly investigates the effectiveness of Ayurvedic treatment for rheumatoid arthritis, specifically concentrating on the ankle joint. Known in Ayurveda as Amavata, rheumatoid arthritis leads to considerable joint pain, stiffness, and swelling. By examining the ankle joint (Gulpha Sandhi) through an Ayurveda. We recognize its sensitivity and its heightened vulnerability to significant pain. Our research closely observes patients with rheumatoid arthritis, meticulously documenting the disease's impact on their ankle joints. We also explore the application of Simhanada Guggulu, a potent Ayurvedic herbal medicine, to alleviate these troubling symptoms. This treatment is grounded in Ayurvedic principles, which view rheumatoid arthritis as resulting from toxin buildup and imbalances within the body. We seek to determine whether Simhanada Guggulu can effectively reduce pain, enhance joint mobility, and significantly improve the overall quality of life for patients. The findings of this study are expected to provide valuable insights into the integration of traditional Ayurvedic treatments alongside modern medicine for managing rheumatoid arthritis. This research represents a significant advancement in combining ancient Ayurvedic wisdom with contemporary scientific methodologies. By focusing on a common autoimmune disorder and a specific joint, we aim to offer innovative solutions for treating this chronic condition.

Keywords: Gulpha Sandhi, Simhanada Guggulu , Amavata

1. Introduction

Rheumatoid arthritis, known in the realm of Ayurvedic medicine as Amavata, is a debilitating chronic autoimmune disorder that significantly diminishes the quality of life for millions of individuals across the globe.[1] This condition not only manifests physically but also impairs emotional well-being, often leading to feelings of frustration and helplessness. While modern medicine offers a range of treatment options, including medications and therapies, there is increasing interest in exploring holistic approaches rooted in ancient healing traditions. This study endeavors to connect the profound insights of traditional Ayurvedic wisdom with contemporary medical research by focusing on a particular manifestation of rheumatoid arthritis: its effects on the ankle joint, referred to as Gulpha Sandhi in Ayurvedic

terminology. The ankle joint is a pivotal structure in the human body, facilitating essential movements such as walking, running, and jumping. When rheumatoid arthritis affects this joint, individuals experience significant challenges, including persistent pain, debilitating stiffness, and a marked reduction in functional capacity. Ayurvedic medicine interprets this complex condition through the lens of bodily imbalances and the build-up of toxins, thereby providing a unique perspective on its origins and implications. The purpose of this research is to delve deeper into these traditional Ayurvedic concepts, integrating them with modern medical understanding to develop comprehensive treatment strategies. At the heart of this study lies Simhanada Guggulu,[2] a revered traditional Ayurvedic formulation known for its potency in alleviating the symptoms associated with Amavata. By meticulously observing and analyzing the anatomy and functional capabilities of the ankle joint in patients suffering from rheumatoid arthritis, alongside the application of this time-honored remedy, this research seeks to rigorously evaluate its efficacy as a potential treatment option. This observational study not only contributes valuable evidence to the expanding field of Ayurvedic treatments for rheumatoid arthritis but also signifies a substantial advancement in the synthesis of traditional knowledge with modern research methodologies. The findings emerging from this investigation may provide novel insights into the management of this challenging condition, ultimately leading to enhanced quality of life and well-being for those affected by rheumatoid arthritis.

The rigidity and stability of the human body rely on Asthi (bones) and Sandhi (joints). These structures are vital for locomotion and weight balance. Injury to the Sandhi can disrupt daily activities and lead to pain and disability. Acharya Sushruta identified the Gulpha Sandhi (ankle joint) as crucial for locomotion and balance, making its anatomical understanding essential for addressing pathological conditions and improving management strategies.[3] Approximately 10% of RA patients progress to severe disability within a decade, often requiring surgical intervention. Long-term use of allopathic medications results in numerous side effects, toxicity, and systemic complications. Ayurveda provides hope for addressing these challenges through safer and more effective treatments. While significant research has been conducted on Amavata and RA, there is a lack of studies exploring the anatomical effects of Simhanada Guggulu on Amavata. This study aims to evaluate the efficacy of Simhanada Guggulu in managing Amavata from both symptomatic and anatomical perspectives, potentially offering a comprehensive and sustainable treatment approach.[4]

2. Aim & Objective:

1. To Observe the effect of Simhanada Guggulu on Gulpha Sandhi in patient after getting effected with Amavata.
2. To study structural changes in Gulpha Sandhi sharir in patient after getting effected with Amavata.

3. Materials and Methods

Selection of the Patient: The patients are selected from the OPD/IPD of GAC OSMANABAD A sample of 30 patients in single group was assessed in the clinical study.

Study Design: Clinical study: prospective, randomized, open clinical trial using single group of patient.

Number of patients – 30

Duration of trial – 6 months

Follow up visit – After every 1 month till the completion of trial

Diagnostic Criteria: The patients were diagnosed based on clinical features of *Amavata* as well as Rhe-

umatoid Arthritis. For diagnosis of Rheumatoid Arthritis criteria given By American College of Rheumatology (ACR)

Inclusion Criteria

1. Patient suffering from Amavata, fulfilling the revised criteria for Rheumatoid arthritis fixed by the American college of Rheumatology in 1987.
2. Patient between 18 to 60 years of age group.
3. Patient irrespective of gender, religion, socio-economic status, marital status.
4. Patient of RA positive

Exclusion Criteria

1. Patient below 18 yr. and above 60 yrs. of age.
2. Patient having permanent bone deformity.
3. Patient of Amavata with HTN, DM, TB, cardiac problem, renal disorder, liver disorder, HIV, malignancy, thyroid disorder
4. Patient having Osteo arthritis, septic arthritis, Gout, Psoriatic arthritis.
5. Pregnant women are also excluded.

Investigations

Routine investigations such as Hb%, CBC, BSL, Urine routine and microscopic examination, RA test, ESR, CRP.

Dose of drug –
Simhanada Guggulu - 500 mg Thrice a day
Route of drug administration – Oral
Anupan – Lukewarm water
Duration of Administration of drug - 6 month
Time of taking drug – After meal

Table No. 1 : Drug composition:

S.No.	Name of the Drug	Latin name	Family	Part used	Proportions
1	Haritaki	Terminila chebula (Retz.)	Combretaceae	Pericarp	1 Part
2	Vibhitaki	Terminila bellirica (Roxb.)	Combretaceae	Pericarp	1 Part
3	Amalaki	Emblica officinalis (Gaertn.)	Euphorbiaceae	Pericarp	1 Part
4	Shudh guggulu	Commiphora wightii (Hook ex. Stocks)	Burseraceae	Oleo - Gum Resin	1 Part
5	Erand Tail	Ricinus communis (Linn.)	Euphorbiaceae	Seed oil	1 Part
6	Shudh gandhaka		Sulphur		4Part

Assessment Criteria:

Subjective criteria – Table no. 2

Parameter / Score	0	1	2	3
Sandhishoola	No pain	Mild	Modrate	severe
Sandhishotha	No swelling	Mild	Modrate	severe
Sandhistabdhta(morning stiffness)	No stiffness / lasting for 5 mins	Stiffness lasting from 5 min to 2 hrs.	Stiffness lasting from 2 to 8 hrs	Stiffness more than 8 hrs.
Ushna sparsha	Normal Temp.	Mild	Modrate	severe

Objective Criteria – All the routine laboratory investigations were done along with diagnostic parameters.

Hematological Investigations: Complete Blood Cytogram (CBC): Hemoglobin,BSL, Urine,C - reactive protein (CRP titer) , Rheumatoid factor (RA titer)

Table No. 3 : Objective Profile

Parameter / Score	0	1	2	3
Synovitis	No Synovitis	Mild	Modrate	severe
Bone edema	No edema	1-33 % bone edematous	34-66 %	67- 100 %
Bone Erosion	-	No erosion- **0**, 1-10 % bone eroded – ***1,*** 11-20 % - ***2***, 21-30 %-***3,*** 31-40 %-***4,*** 41-50%-***5,*** 51-60 % -**6,** 61-70 %- **7** , 71-80%- **8**, 81-90 % -**9**, 1-100 % -**10**		

4.Observations and Results-

Table no. 4 – No. of Patients Suffered

Score /grade	**Sandhishoola**		**Sandhishotha**		**San-dhistabdhata**		**Ushna Sparsha**	
	No of Patients							
BT- Before Treatment AT- after Treatment	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**
3	23	0	10	0	0	0	5	0
2	7	2	20	2	16	0	17	1
1	0	16	0	13	14	14	8	13
0	0	12	0	15	0	16	0	16
Total	30	30	30	30	30	30	30	30
Observation	It was observed that Shula has decreased after treatment.		It was observed that Shotha has decreased after treatment.		It was observed that Stabdhata has decreased after treatment.		It was observed that Ushna Sparsha has decreased after treatment.	

Table No. 5 Shows changes in Anatomical deformities BT and AT

Sr. No.	Deformity	BT/AT	No of patients	
			Present	Absent
1	Synovitis	BT	24	6
		AT	14	16
2	Bone Edema	BT	19	11
		AT	12	18
3	Bone Erosion	BT	13	17
		AT	13	17

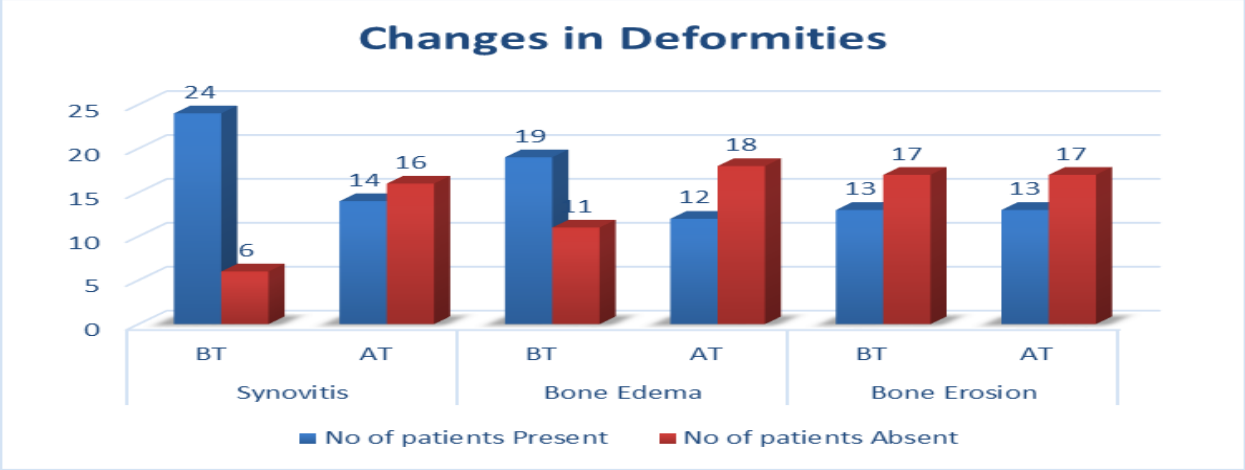

Table No. 6 - Statistical analysis

Parameter	BT/AT	N	Mean	Median	W	P
Sandhishoola	BT	30	2.767	3	465	<0.0001
	AT	30	0.666	1		
SandhiShotha	BT	30	2.333	2	465	<0.0001
	AT	30	0.566	0.5		
Sandhistabdhta(morning stiffness)	BT	30	1.533	2	406	<0.0001
	AT	30	0.466	0		
Ushna sparsha	BT	30	1.900	2	465	<0.0001
	AT	30	0.500	0		
Anatomical Deformities						
Synovitis	BT	30	1.067	1	120	<0.0001
	AT	30	0.566	0		
Bone Edema	BT	30	0.666	2	36	0.0078
	AT	30	0.400	1		
Bone Erosion	There was no change in score of Bone erosion after treatment. As BT and AT symptom score values are same, statistical test is not applicable.					

Table no. 7 Effect of Simhanada Guggulu according to relief in Patients

Relieved score and % relief in Patients

Pt. No.	Group A				Pt. No.	Group A			
	B.T.	A.T.	Relieved	Relief %		B.T.	A.T.	Relieved	Relief %
1	11	3	8	72.73	**16**	12	5	7	58.33
2	12	3	9	75	**17**	9	3	6	66.67
3	11	5	6	54.55	**18**	11	3	8	72.73
4	13	4	9	69.23	**19**	10	2	8	80
5	13	4	9	69.23	**20**	14	7	7	50
6	11	3	8	72.73	**21**	9	1	8	88.89
7	9	1	8	88.89	**22**	8	3	5	62.5
8	11	2	9	81.82	**23**	11	4	7	63.64
9	14	10	4	28.57	**24**	14	7	7	50
10	10	2	8	80	**25**	9	1	8	88.89
11	13	6	7	53.85	**26**	9	2	7	77.78
12	8	2	6	75	**27**	11	4	7	63.64
13	13	6	7	53.85	**28**	12	4	8	66.67
14	9	4	5	55.56	**29**	7	1	6	85.71
15	8	4	4	50	**30**	10	3	7	70

Table no. 8 Effect of Simhanada Guggulu according to relief in Symptoms

Sr. No.	Symptoms	B.T.	A.T.	Relieved	% Relief
1	Shula	83	20	63	75.9
2	Shotha	70	17	53	75.71
3	Stabdhata	46	14	32	69.57
4	Ushna Sparsha	57	15	42	73.68
5	Synovitis	32	17	15	46.88
6	Bone Edema	20	12	8	40
7	Bone Erosion	14	14	0	0

Sr. No.	Head	Average % Relief
1	Symptoms of Amavata	73.71
2	Synovitis & Bone Edema	43.43
3	Bone Erosion	00.00

Table no. 9 - Average % Relief in Symptoms & Deformities

5. Result:

Shula (Pain): A statistically significant difference ($p < 0.05$) was observed between baseline (BT) and after-treatment (AT) scores in the Shula (pain) symptom. This indicates that Simhanada Guggulu is significantly effective in reducing pain associated with Gulpha Sandhi in Amavata.

Shotha (Swelling): BT vs. AT had a statistically significant difference ($p < 0.05$) on the Shotha (swelling) symptom. This showed that Simhanada Guggulu significantly diminishes swelling in Gulpha Sandhi in Amavata.

Stabdhata (Stiffness): BT vs. AT had a statistically signific and difference ($p < 0.05$) in the Stabdhata symptom. This reflects that Simhanada Guggulu significantly decreases stiffness related with Gulpha Sandhi in Amavata.

Ushna Sparsha (Heat): A statistically significant difference ($p < 0.05$) was observed between BT and AT scores in the Ushna Sparsha (heat) symptom. This implies that Simhanada Guggulu has significant effects on the reduction of the feeling of heat in the involved joint.

Synovitis: There was a significant difference between BT and AT scores in Synovitis with $P < 0.05$. This shows that Simhanada Guggulu is highly effective in reducing synovitis conditions related to Gulpha Sandhi of Amavata.

Bone Edema: There was also a significant difference between BT and AT scores in Bone Edema with $P < 0.05$, which showed that Simhanada Guggulu significantly reduced bone edema in the conditions of Amavata, Gulpha Sandhi.

Bone Erosion: There was no significant alteration in the score of Bone Erosion after treatment.

Statistical Analysis for Bone Erosion: Since the BT and AT symptom scores for Bone Erosion were the same, a statistical test could not be applied [table no. 6]

6. Discussion:

The above study was undertaken to evaluate the efficacy of the drug Simhanada Guggulu on ankle joint after it is effected by Amavata. It was a prospective, randomized, open clinical trial with a minimum 30 patients suffering from Amavata were selected irrespective of their caste, gender, religion, fulfilling the inclusive and exclusive criteria. All the patients were selected from the OPD and IPD of Panchakarma department of our institute. The parameters regarding the signs and symptoms of the disease was scored with the help of standard methods and analyzed statistically. The signs and symptoms of the disease that were assessed included Shoola (pain), Shotha (swelling), Stabdhata (stiffness), Ushna Sparsha (warmth) of the joint and also structural changes at the ankle joint included synovitis, bone edema, bone erosions are assessed by radiological examination before and after treatment. The present study was conducted to evaluate the effect of drug Simhanada Guggulu on Ankle joint after getting effected with Amavata. The study was conducted for 6 months during this time period patient was put on Simhanada Guggulu.

Effect on Pain (Shoola): The severity of Pain is markedly decreased after treatment. The mean score of the pain is decreased from 2.767 (BT) to 0.666 (AT) and it shows the result was statistically significant with 75.9% of improvement with p value <0.001. The Shoola Lakshana in Amavata is mainly due to the margavrodhjanya Samprapti of Amavata, the Ama formed due to Mandagni get accumulated in the Kaphasthahana and it obstruct the prakrut gati of Vata and leads to Vata Prakopa and the Shoola is the Lakshana of Vata Prakopa. The Simhanada Guggulu has Strotoshodhaka, Ampachana and Vatakaphashamaka property which digest the Ama and removes the obstruction and it also pacify the vitiated Vata and ultimately it subsides the pain.

Effeect On Swelling (Shotha): It was observed that the severity of Swelling is decreased after treatment. The mean score of the Shotha was decreased from 2.333 (BT) to 0.566 (AT) and it shows the result was statistically significant with 75.71% improvement with p value <0.001. The Shotha in Amavata is mainly due to the obstruction of the channels of circulation due to Ama which is mainly responsible for

the vitiation of Vata, this vitiated Vata causes the accumulation of Kapha, Pitta and Rakta and forms Utsedha which termed as Shotha. The drug Simhanada Guggulu contains Eranda Taila which mainly having the properties of Vatakaphahara, Deepana, Bhedana, Amashodhana, Shothahara. The Eranda Taila due to its Ushna Virya and Deepana property it digest the Ama and by its Bhedana property it removes the channels of obstruction and by its Shothahara Guna it ameliorate Shotha. It was observed that the severity of Stabdhata decreased after treatment. The mean score of Stabdhata was decreased from 1.533 (BT) to 0.466 (AT) and it shows the result was statistically significant with 69.57% improvement with p value <0.001.

Stabdhata: stabdhata is the cardinal symptom of Ama. The Simhanada Guggulu has Laghu, Ushna, Tikshna Guna, Katu, Tikta Rasa and the Ushna Virya these properties are against the Snigdha, Guru, Sheeta, Picchila properties of the Ama. The Deepana property of drug stops further formation of Ama so it relives the symptom Stabdhata which is mainly due to the Ama.

Effect on Ushna Sparsha (Warmth): It was observed that severity of Ushna Sparsha decreased after treatment. The mean score of Ushna Sparsha was decreased from 1.900 (BT) TO 0.500 (AT) and it shows the result statistically significant with 73.68% improvement with p value <0.001.

Effect on Synovitis: It was observed that the Synovitis decreased after treatment. The mean score of Synovitis was decreased from 1.067 (BT) to 0.566 (AT) and it shows statistically significant with 46.88% improvement with p value <0.001.It shows that the Simhanada Guggulu is significantly effective to reduce Synovitis of Gulpha Sandhi in Amavata. The synovium is site of inflammatory process, the anti-inflammatory, analgesic and anti-arthritic property of drug helps to reduce the synovitis in RA.

Effect on Bone marrow edema: It was observed that the bone edema decreased after treatment. The mean score of Bone edema was decreased from 0.666 (BT) to 0.400 (AT) and shows statistically significant with 40% improvement with p value <0.001. It shows that the Simhanada Guggulu is significantly effective to reduce Bone marrow edema of Gulpha Sandhi. Bone marrow is a site of inflammatory reaction and autoreactive response, inflammatory chances within the bone marrow leads to bone marrow edema. The anti-inflammatory, analgesic and anti-arthritic property of drug combat with the inflammatory reaction and helps to reduce the Bone marrow edema.

Effect on Erosion: It was observed that there was no change in the score of Bone erosion after treatment. As before treatment and after treatment score values are same, so it shows that Simhanada Guggulu is not effective to reduce Bone erosion at Gulpha Sandhi in Amavata.[table no. 7]

7. Conclusion:

The study underscores the significant therapeutic potential of **Simhanada Guggulu** in managing *Amavata* (rheumatoid arthritis) with a specific focus on its impact on the *Gulpha Sandhi* (ankle joint). Results revealed substantial improvement in key symptoms such as pain (*Shula*), swelling (*Shotha*), stiffness (*Stabdhata*), and warmth (*Ushna Sparsha*). Additionally, a notable reduction in synovitis and bone marrow edema was observed. However, the treatment showed no effect on bone erosion, indicating the need for additional interventions to address advanced joint damage.The findings validate the anti-inflammatory, analgesic, and *Ama-pachana* (detoxifying) properties of **Simhanada Guggulu**, aligning with its described actions in Ayurvedic texts. By addressing the root cause of *Amavata* through toxin elimination and dosha balance, this formulation offers a holistic and side-effect-free alternative to conventional therapies. Given the chronic and debilitating nature of rheumatoid arthritis, integrating Ayur-

vedic modalities like **Simhanada Guggulu** into treatment protocols can improve the quality of life for patients while minimizing dependency on allopathic medications with adverse effects. Future research should explore the combination of Ayurvedic and modern medical approaches to achieve comprehensive and sustainable management of *Amavata*.

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