

## COMPARATIVE STUDY ON THE EFFICACY OF *GUDUCHI-SUNTHI* YOG IN AMAVATA (RHEUMATOID ARTHRITIS)

Dr. Kalpesh Gulve<sup>\*1</sup>, Dr. Vaishali Kuchewar<sup>2</sup> and Dr. Shubham Shinde<sup>3</sup>

<sup>1,3</sup>PG Scholar, Dept. of Kayachikitsa, Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod(H), Datta Meghe Institute of Medical Sciences (DU), Sawangi, Wardha.

<sup>2</sup>Professor, Dept. of Kayachikitsa, Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod(H), Datta Meghe Institute of Medical Sciences (DU), Sawangi, Wardha.

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**\*Corresponding Author**

**Dr. Kalpesh Gulve**

PG Scholar, Dept. of  
Kayachikitsa, Mahatma  
Gandhi Ayurveda College,  
Hospital and Research  
Centre, Salod(H), Datta  
Meghe Institute of Medical  
Sciences (DU), Sawangi,  
Wardha.

### ABSTRACT

The two primary causes of *Amavata* production are *Ama* and *Vata*. The primary factor for this illness, which generates *Ama*, is *Agni* derangement. This *Ama* is circulated throughout the body by the vitiated *vata dosha* and becomes localised in the *Sandhis* (joints), resulting in *shool*, *sandhigraha*, and *shoth* over the joints. The rheumatological disorder known as Rheumatoid Arthritis, which is a chronic, progressive, auto-immune, inflammatory disease, is strikingly similar to the clinical signs of *Amavata*. Modern medicine uses NSAIDs, glucocorticoids, DMARDs, and immune suppressants to address the symptoms. All of these drugs could have detrimental physiological adverse effects. This emphasises the importance of utilising an Ayurvedic treatment strategy to mitigate RA's impacts. **Aim:** Comparative study on the efficacy of *Guduchi-Sunthi yog* in *Amavata* (Rheumatoid Arthritis). **Material and methods:** 60 *Amavata* patients (30 in each group) who met the inclusion criteria were chosen for the current study. Group B (trial) received treatment with *Guduchi-Sunthi Yog* (4 gm thrice a day), whereas Group A (control) received

treatment with *Sunthi Churna* (2 gm thrice day). Both groups received *Valuka Pottali Swedana* twice daily for 30 days and *Eranda Taila* 10–30ml (as per the patient's *Koshtha*) twice a week on an empty stomach with lukewarm water. **Results:** Both groups' subjective

and objective parameters significantly improved throughout the course of treatment. However, the trial group showed superior improvement. **Conclusion:** The study offered solid support for the effectiveness and security of *Guduchi-Sunthi Yog* along with *Eranda Taila* and *Valuka pottali swedana*.

**KEYWORDS:** *Amavata*, *Ama*, Rheumatoid arthritis, *Guduchi*, *Sunthi*, *Valuka pottali swedana*.

## INTRODUCTION

*Amavata* as an illness was initially elaborated thoroughly by *Madhvakara* in his *Madhav Nidan* along with its *Nidanpanchaka*.<sup>[1]</sup> According to Ayurveda, *Amavata* as a disease the word is composed of two words “*Ama*” and “*Vata*”.<sup>[2]</sup> In Ayurveda, *Ama* means indigestible *ahararasa* and unripe due to *Mandagni*. This *Ama* carried by vitiated *Vata* and circulates throughout the body which gets located in the *Sandhis* and *Amavata* occurs.<sup>[3]</sup> *Ama* and *Vata* plays important role in the *Samprapti*. *Amavata* is the chronic disorder affecting the population with pain of the joints, swelling over synovial joints along with stiffness of joints. It has similarities to many arthritis disease condition but mainly compared with Rheumatoid Arthritis. It is an auto-immune inflammatory disorder is one of the challenging conditions for the physician. Rheumatoid Arthritis is a chronic, immune-inflammatory systemic illness that causes swelling over synovial joints and extraarticular symptoms in about 1% of the world's population.<sup>[4]</sup> The genetic predisposition is responsible for 60% of whole disease. The incidence rate of Rheumatoid Arthritis in India, it has been observed that 0.5 to 3.8% in females and from 0.15 to 1.37% in males, with highest incidence in the fourth decades of life span.<sup>[5]</sup> The “Bone and Joints Decade (BJD) 2000-2010” program which is organized by WHO, the slogan ‘Keep People Moving’ in order to improve quality of life and reduction in mortality rate.<sup>[6]</sup> In *Amavata*, formation of *Ama* & vitiation of *Vata dosha* are the initiating factors in the pathogenesis. Considering *Ama* as a key causative factor, *ayurveda* can provide lead in the management of this condition. In *Chakradatta samhita*, it is said that *Guduchi-Sunthi Yog*<sup>[7]</sup> & *Eranda Taila*<sup>[8]</sup> both have *Amvatahara* properties. *Eranda Taila* is known for its *Amapachak* & *Mruduvirechak* property.

Hence, the two important medicines i.e *Sunthi churna* and *Guduchi-Sunthi Yog* along with *Eranda taila* had been selected for clinical evaluation on the management of *Amavata* (Rheumatoid arthritis).

## AIMS AND OBJECTIVES

1. To assess the effect of *Guduchi-Sunthi Yog* on the *Ama Lakshan*, *Sandhishool*, hand grip power, foot pressure, ESR and CRP
2. To assess the effect of *Sunthi churna* on the *Ama Lakshan*, *Sandhishool*, hand grip power, foot pressure, ESR and CRP
3. To compare the efficacy of treatment in both groups

## MATERIALS AND METHODS

According to the *Amavata* (rheumatoid arthritis) diagnostic criteria, a total of 65 patients were enrolled in the current clinical study, and 5 patients withdrew from the study before it was complete. (CTRI registration no. CTRI/2020/11/029365). The patients had been selected from the O.P.D. & I.P.D. of Department of Kayachikitsa (General Medicine), Mahatma Gandhi Ayurved College, Hospital and Research Centre (DMIMSDU), Wardha, Maharashtra as per the criteria given below.

### Inclusion Criteria

1. Age between 20-50 years of either sex
2. Patient showing classical symptoms of *Amavata* such as *Sandhishool*, *Sandhishoth*, and *Sparshasahatva*.
3. Presence of any four features from the criteria of an American school of Rheumatology.<sup>[9]</sup>
  - Morning stiffness for at least one hour which must be present for at least six weeks.
  - Swelling of three or more joints for at least six weeks.
  - Swelling of the wrist, Metacarpophalangeal, and Proximal interphalangeal joints for six or more weeks.
  - Symmetrical joint arthritis.
  - Rheumatoid nodules.
  - Positive Serum Rheumatoid factor.
4. Diagnosed cases of RA having chronicity less than 3 years.
5. Patients who are willing to participate in the study.

### Exclusion criteria

- Patient who develops secondary complications of RA like Rheumatic heart disease.
- Pregnant & lactating women.

RA factor, ESR and C-Reactive-Protein investigations had been done in all the patients for diagnosis and severity of the disease.

**Plan of study:** Out of the 65 patients that were registered, 60 patients completed the treatment, and 5 patients left the treatment before it was completed. For group A, the treatment schedule was, *Sunthi Churna* 6 gm (2 gm thrice a day after meal) with *Koshna Jala* as the standard drug was given and in group B the *Guduchi-Sunthi Yog* 12 gm (4 gm thrice a day after meal) with *Koshna Jala* was given as a trial drug. *Valuka Pottali Sweda* twice a day for 30 days and *Eranda Taila* 10-30 ml (as per *Koshtha* of the patient) in the morning empty stomach weekly twice was given for both the groups. Dietary modifications in the form of *Laghu Ahar* i.e *Laja*, *Jawar Roti* were advised to eat.

**Ethical clearance:** The Institutional Ethical Committee (IEC) of DMIMSDU granted approval for this study via letter number MGACHRC/IEC/August-2020/95 dated on 13.08.2020 prior to beginning the clinical trial on *Amavata* patients who have received a clinical diagnosis.

### Parameters for assessment

Following parameters had been taken for the assessment of the clinical study.

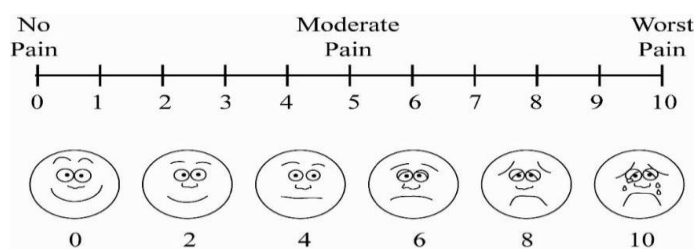
**A. Subjective:** (On 0 day, 7<sup>th</sup> day, 15<sup>th</sup> day, 21<sup>st</sup> day, 30<sup>th</sup> day of the treatment)

1. *Lakshanas of Ama* were assessed as per the following table.

**Table no.1: Assessment of *Ama Lakshana* (present or absent).**

Sr. No	Lakshana
1	<i>Balabhransha</i> (Loss of strength)
2	<i>Gauravaata</i> (feeling of heaviness in the body)
3	<i>Alasya</i> (Lassitude)
4	<i>Apakti</i> (Indigestion)
5	<i>Nishthiv</i> (Excessive salivation)
6	<i>Malasanga</i> (Constipation)
7	<i>Aruchi</i> (Loss of appetite)
8	<i>Klama</i> (Exhaustion)

2. *Sandhishool* (Pain in joints) was assessed based on the Visual Analogue Scale.<sup>[10]</sup>



3. *Sparshasahatva* (local tenderness) was assessed as per the following grading.<sup>[11]</sup>

**Table no. 2: Gradation of *Sparshasahatva*.**

No tenderness	0
Subjective experience of tenderness	1
Wincing of face on pressure	2
Wincing of face & withdrawal of affected part on pressure	3
Resist to touch	4

**4. Hand grip power** (in the involvement of upper limb) was assessed as per follows<sup>[12]</sup>-

The Cuff of the sphygmomanometer is inflated up to 50 mmHg. Then the patient is asked to squeeze it & the grip power is recorded in mmHg of mercury depending upon the rise of the mercury column.

**5. Foot pressure** (in the involvement of lower limb) was assessed as per follows<sup>[13]</sup>-

The patient is asked to put pressure on the weighing scale with his leg. The foot pressure is recorded in kg depending upon the weight displayed on weighing scale.

**B. Objective:** (On 0<sup>th</sup> day & 30<sup>th</sup> day of treatment)

1. Erythrocyte sedimentation rate
2. C-reactive protein

## OBSERVATIONS

**Age:** In this clinical trial, it was observed that out of 60 patients a maximum number of patients 56 (93.33%) were within the age group of 30-50 years.

**Gender:** The gender-wise distribution in this study revealed that the maximum of patients (58.33%) were female.

**Prakruti:** Among the 60 patients, the majority of the patients (50%) belonged to *Vata-Pittaj Prakruti*, 33.33% patients belonged to *pitta-vataj prakruti* and 23.33% patients had *vata-kaphaj prakruti*.

**Diet and Agni:** The distribution of patients as per dietary habits, the status of *Agni* & condition of *Jivha* showed that the majority (71.66%) of the patients consumed a mixed diet (vegetarian and nonvegetarian) and most (70%) of patients had *Mand Agni*. Also, the majority (73.33%) of patients had *Saam Jivha*.

## Subjective and objective parameters

Table no. 3: Comparison of *Sandhishool* between group A and group B.

	Day 0	Day 7	Day 15	Day 21	Day 30
Group A	7.66±0.66	7.16±0.64	6.66±0.71	6.03±0.66	5.23±0.72
<b>Comparison with Day 0 i.e. baseline (Wilcoxon Signed Rank Test)</b>					
z-value	-	5.38	20.85	18.25	23.45
p-value	-	0.0001, S	0.0001, S	0.0001, S	0.0001, S
Group B	7.80±0.61	7.33±0.54	6.60±0.56	5.80±0.48	4.70±0.65
<b>Comparison with Day 0 i.e. baseline (Wilcoxon Signed Rank Test)</b>					
z-value	-	4.06	16.15	18.65	27.95
p-value	-	0.0001, S	0.0001, S	0.0001, S	0.0001, S
<b>Comparison in two groups (Mann-Whitney U Test)</b>					
z-value	0.89	0.97	0.18	1.46	2.79
p-value	0.37, NS	0.33, NS	0.85, NS	0.14, NS	0.005, S

Table no. 4: Comparison of Hand grip power between group A and group B.

	Day 0	Day 7	Day 15	Day 21	Day 30
Group A	84±16.93	89±13.22	96.66±10.93	109.66±8.89	121±7.58
<b>Comparison with Day 0 i.e. baseline (Student's Paired t-test)</b>					
z-value	-	5.38	6.07	12.06	16.39
p-value	-	0.0001,S	0.0001,S	0.0001,S	0.0001,S
Group B	83±16.43	90±13.13	99.33±9.44	111.33±7.76	122±6.10
<b>Comparison with Day 0 i.e. baseline (Student's Paired t-test)</b>					
z-value	-	5.88	7.71	12.57	13.87
p-value	-	0.0001,S	0.0001,S	0.0001,S	0.0001,S
<b>Comparison in two groups (Student's unpaired t-test)</b>					
z-value	0.23	0.29	1.01	0.77	0.56
p-value	0.81,NS	0.77,NS	0.31,NS	0.44,NS	0.57,NS

Table no. 5: Comparison of foot pressure between group A and group B.

	Day 0	Day 7	Day 15	Day 21	Day 30
Group A	10.30±1.34	12.30±1.08	13.73±0.98	14.90±0.75	16.06±0.63
<b>Comparison with Day 0 i.e. baseline (Student's Paired t-test)</b>					
z-value	-	15.76	25.83	28.16	32.51
p-value	-	0.0001,S	0.0001,S	0.0001,S	0.0001,S
Group B	9.83±1.26	11.86±1.10	13.53±0.68	14.90±0.71	16.03±0.61
<b>Comparison with Day 0 i.e. baseline (Student's Paired t-test)</b>					
z-value	-	22.72	28.86	31.95	32.95
p-value	-	0.0001,S	0.0001,S	0.0001,S	0.0001,S
<b>Comparison in two groups (Student's unpaired t-test)</b>					
z-value	1.38	1.53	0.91	0.00	0.20
p-value	0.17,NS	0.13,NS	0.36,NS	1.00,NS	0.83,NS

Table no. 6: Comparison of *Sprshasahatva* between group A and group B.

	Day 0	Day 7	Day 15	Day 21	Day 30
Group A	2.46±0.50	2.06±0.25	1.80±0.40	1.26±0.44	0.93±0.36
<b>Comparison with Day 0 i.e. baseline(Wilcoxon Signed Rank Test)</b>					
z-value	-	4.39	6.67	16.15	16.55
p-value	-	0.0001,S	0.0001,S	0.0001,S	0.0001,S
Group B	2.73±0.44	2.03±0.18	1.83±0.37	1.23±0.43	0.90±0.30
<b>Comparison with Day 0 i.e. baseline(Wilcoxon Signed Rank Test)</b>					
z-value	-	8.22	10.25	16.15	26.49
p-value	-	0.0001,S	0.0001,S	0.0001,S	0.0001,S
<b>Comparison in two groups(Mann-Whitney U Test)</b>					
z-value	2.09	0.58	0.33	0.29	0.35
p-value	0.037,S	0.55,NS	0.74,NS	0.76,NS	0.72,NS

Table no. 7: Distribution of patients according to the gradation of *Sparshasahatva*.

	Day 0	Day 7	Day 15	Day 21	Day 30
<b>Group A</b>					
Grade 0	0(0%)	0(0%)	0(0%)	0(0%)	3(10%)
Grade 1	0(0%)	0(0%)	6(20%)	22(73.33%)	26(86.67%)
Grade 2	16(53.33%)	28(93.33%)	24(80%)	8(26.67%)	1(3.33%)
Grade 3	14(46.67%)	2(6.67%)	0(0%)	0(0%)	0(0%)
Grade 4	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
<b>Group B</b>					
Grade 0	0(0%)	0(0%)	0(0%)	0(0%)	3(10%)
Grade 1	0(0%)	0(0%)	5(16.67%)	23(76.67%)	27(90%)
Grade 2	8(26.67%)	29(96.67%)	25(83.33%)	7(23.33%)	0(0%)
Grade 3	22(73.33%)	1(3.33%)	0(0%)	0(0%)	0(0%)
Grade 4	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)



Table no. 8: Distribution of patients according to *Lakshanas* of *Ama* in two groups at day 0, day 15, and day 30.

Parameters	Group A (Comparison between day 0 and day 30)				Group B (Comparison between day 0 and day 30)				p-value Overall
	Day 0	Day 15	Day 30	p-value	Day 0	Day 15	Day 30	p-value	
<i>Balabhransha</i>	29 (96.67%)	26 (86.67%)	19 (63.33%)	10.42 P=0.001, S	28 (93.33%)	11 (36.67%)	6 (20%)	36.27 P=0.0001,S	6.15 0.046,S
<i>Gauravata</i>	29 (96.67%)	27(90%)	18 (60%)	11.88 P=0.006, S	26 (86.67%)	12 (40%)	4 (13.33%)	32.27 P=0.0001,S	6.51 0.038, S
<i>Alasya</i>	29 (96.67%)	26 (86.67%)	17 (56.67%)	13.42 P=0.0002,S	27 (90%)	10 (33.33%)	5 (16.67%)	32.41 P=0.0001,S	6.26 0.043,S
<i>Apakti</i>	28 (93.33%)	3 (10%)	0 (0%)	52.50 P=0.0001,S	29 (96.67%)	7 (23.33%)	0 (0%)	56.13 P=0.0001,S	0.31,NS
<i>Nishthiv</i>	9(30%)	4(13.33%)	3(10%)	3.75 P=0.05,NS	7 (23.33%)	5(16.67%)	1(3.33%)	5.19 P=0.022,S	1.06 0.58,NS
<i>Malasanga</i>	21(70%)	10(33.33%)	0(0%)	32.31 P=0.0001,S	26 (86.67%)	12(40%)	0(0%)	45.88 P=0.0001,S	P=1.00,NS
<i>Aruchi</i>	30(100%)	22(73.33%)	0(0%)	60 P=0.0001,S	30 (100%)	20(66.67%)	0(0%)	60 P=0.0001,S	0.84,NS
<i>Klama</i>	17(56.67%)	12(40%)	9(30%)	4.34 P=0.037,S	22(73.33%)	6(20%)	2(6.67%)	27.78 P=0.0001,S	6.24 P=0.044,S



**Table no. 9: Comparison of ESR (in mm/hr) between group A and group B.**

Group	Day 0	Day 30	Mean Difference	Student's Paired t-test (t-value)
Group A	51.33±18.62	32.16±16.43	19.16±7.88	13.31 P=0.0001, S
Group B	53.30±11.02	28.66±8.24	24.63±5.02	26.83 P=0.0001, S
Comparison of mean difference in two groups (Student's unpaired t-test) →			t-value	p-value
			3.20	0.002, S

**Table no. 10: Comparison of CRP (in mg/dl) between group A and group B.**

Group	Day 0	Day 30	Mean Difference	Student's Paired t-test (t-value)
Group A	63.60±34.10	40.93±21.18	22.66±16.38	7.57 P=0.0001, S
Group B	68.80±34.07	42.80±21.29	26±16.40	8.68 P=0.0001, S
Comparison of mean difference in two groups (Student's unpaired t-test) →			t-value	p-value
			0.78	0.43, NS

## RESULTS

Significant improvement was found in the cases between the pre and post-treatment in various symptomatic domains of both group individuals.

**Effect on Sandhishool:** Patients in Group-A reported relief in *Sandhishoola* at a rate of 31.72 percent, but those in Group-B reported improvement at a rate of 39.74 percent. Both findings had statistical significance.

**Effect on hand grip power:** Patients in Group-A showed a 44.05 percent improvement in hand grip power, whereas those in Group-B showed a 46.99 percent improvement. In both groups, the relief was statistically very significant.

**Effect on foot pressure:** Results in foot pressure were highly significant in both groups. However, compared to Group-A, the percentage was found to be higher in Group-B (63.07 percent) (55.92 percent). Both were highly significant statistically.

**Effect on Sparshasahatva:** *Sparshasahatva* showed a significantly substantial improvement in both Groups (Tenderness at joints). Group A exhibited a respite of 62.20 percent, while Group B indicated a relief of 67.03 percent.

**Effect on *ama lakshana*:** Both groups' responses to therapy on the majority of the *lakshanas* of *ama* were determined to be statistically significant, however group B performed better.

**Effect on Erythrocyte Sedimentation Rate:** ESR decreased in group A by 37.35 percent while it decreased in group B by 46.22 percent. However, both groups experienced a marked improvement.

**Effect on C-reactive protein:** In group A, CRP reduced by 35.64% in group A, while in group B it was reduced by 37.79%. However, the improvement was significant in both groups.

## DISCUSSION

*Amavata* is described as a disease of *Madhyamroga Marga* and it affects *Sandhis* and *Hridaya Marma*.<sup>[14]</sup> *Agnimandya* is the main causative factor behind *Amavata*. Various factors like dietary, environmental, or psychological cause *Agnimandya* which is responsible for the production of *Ama*. This *Ama* causes *Vataprakopa* due to *Strotoavrodh* and gets lodged in the *Sleshmasthanas* of the body, especially *Sandhi* giving rise to the production of various symptoms of *Amavata*.<sup>[15]</sup> It can be compared to rheumatoid arthritis because of the similarity in their clinical traits. In *Ayurveda*, multimodal treatment including dietary modifications is described in the management of *Amavata*. The present study aimed to compare the efficacy of *Guduchi-Sunthi Yog* along with *Eranda taila* in *Amavata* (Rheumatoid arthritis).

In this study it was found that females are more prevalent to develop the disease than males. It was also observed that the disease is prevalent in the young and middle age groups. In this age group, people are exposed to unwholesome food habits which may lead to *agnimandya* and *Ama* formation ultimately resulting in *Amavata*. Also, majority of the patients have *Vata-Pittaj Prakruti*.

Treatment given to all patients was found to be effective in subjective as well as objective parameters. *Shoola* is a *Lakshana* of *Vataprakopa* and in the present context, *Vataprakopa* is due to *Margavrodha* due to *Ama*. The trial drugs act directly on *ama* and hence remove the *Avrodha* for *Vata*. Once *Avrodha* due to *Ama* is removed, *Vata Dosha* starts moving in its normal *Gati* and *Marga*. Thus, the *Sandhishool* significantly gets alleviated. The severity of *Sparshasahatva* depends on *Sandhisool* and *Sandhishoth*. Hence along with the reduction in

*Sandhishool*, a significant reduction in *Sparshasatva* was also observed after 30 days in both the groups. Hand grip power and foot pressure are a combined effect of joint movement and muscular strength. Therefore, improvement in other symptoms, particularly *Sandhishool* and *Sparshasatva*, results in improvement of hand grip power and foot pressure. The chief properties of the trial drugs given in treatment are *Deepana*, *Pachana*, *Vatakaphahara*, *Balya*, and *Rasayana* which might have helped in the alleviation of all the above symptoms of *Ama*. ESR and CRP are the inflammatory markers in the body. RA being an auto-immune inflammatory disorder, the levels of ESR and CRP were raised in patients of both groups. The anti-inflammatory action of the drugs helped in the significant reduction of ESR and CRP.

### Probable mode of action of therapy

*Guduchi-Sunthi Yog* contains *Guduchi Churna* and *Sunthi Churna* in equal quantity. *Guduchi* has *Guru* and *Snigdha Guna*, *Tikta Kashaya Rasa*, *Ushna Veerya* and *Madhur Vipaka*<sup>[16]</sup> and properties as *Tridoshashamak*, *Sangrahi*, *Balya*, *Dipana*, *Rasayan*, *Raktasodhak*, *Jwaraghna*, *vedanasthapana* and *shothahara*. Rheumatoid arthritis is being autoimmune and inflammatory arthritic disorder, the immunomodulatory<sup>[17]</sup> and anti-inflammatory<sup>[18]</sup> activity of *Guduchi* may also help in alleviating the symptoms of the disease. *Sunthi* has *Agneya*, *Laghu Guna*, *Katu Tikta Rasa*, *Ushna Veerya*, and *Madhura Vipaka* and *Deepana Pachana*<sup>[19]</sup> properties. These properties aided in *Amapachana* and *Agnivardhana*, and thus all the symptoms of *Ama* may get alleviated. *Shoolprashamana* and *Shothahara*<sup>[20]</sup> properties may help in alleviating *Sandhishool*, *Sandhishoth*, and *Sparshasatva* along with ESR and CRP levels which work in tandem in improving grip power and foot pressure. *Vata* and *Kapha* are the two main doshas involved with *Amavata*. *Eranda Taila* possesses *Vatakaphahara* characteristics as well as *Ushna Virya*, allowing it to work on *Amavata*. *Valuka Pottali Sweda* is a dry *Ruksha Sweda* that aids in the treatment of *Kaphaj* illnesses as well as diseases involving *Ama*. Because it is dry in nature, it promotes local *Amapachan* and diminishes *Strotoavarodha*.<sup>[21]</sup>

In *Amavata*, the predominant *Doshas* are *Vata* and *Kapha*. All the drugs used in this study are having *Vata Kaphahara* as well as *Agnivardhak* and *Amapachak* properties. So, it is very helpful in breaking the *Samprapti* of *Amavata*.

## CONCLUSION

From this study, it can be concluded that *Guduchi-Sunthi Yoga* as well as *Sunthi* with *Eranda Taila* and *Valuka Potali* is effective in alleviating *Sandhishool*, *Sparshasahatva*, and *Lakshans* of *Ama*. The therapy was beneficial in improving hand grip power, foot pressure, ESR, and CRP also. Both groups showed significant improvement, but the improvement was better in trial group. Therefore, it can be inferred that *Guduchi-Sunthi Yog* is more effective than *Sunthi Churna* in relieving certain *Lakshanas* of *Ama*, namely *Balabhransha*, *Gauravata*, *Alasya*, and *Klama* linked to *Amavata* along with ESR. Also, during the study, no adverse effects were found in any of the groups.

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