



Research Article

## AN OPEN RANDOMIZED COMPARATIVE CLINICAL STUDY ON THE EFFECT OF SHIVA GUGGULU AND VATARI GUGGULU ALONG WITH KOTTAMCHUKKADI LEPA IN AMAVATA

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### Article info

#### Article History:

Received: 21-11-2024

Accepted: 19-12-2024

Published: 15-01-2025

#### KEYWORDS:

Shiva Guggulu,  
Vatari Guggulu,  
Kottamchukkadi  
Lepa, Amavata,  
Rheumatoid  
Arthritis.

### ABSTRACT

Rheumatoid Arthritis (*Amavata*) is an autoimmune seditious complaint that causes pain, swelling, stiffness, destruction and functional disability in the affected joints. It's defined as a habitual multisystem complaint characterized by patient seditious synovitis, generally involving supplemental joints in a symmetric distribution with eventuality to beget cartilage destruction and bone attritions. According to Ayurveda, the main cause of the complaint is conformation of *Ama* due to *Agnimandya*. Even though many researches has been done in *Amavata* management, there is still huge scope to explore new course of action. Here we tried the formulation to treat *Amavata* according to Ayurvedic classics. To evaluate the effect of *Shiva guggulu* along with *Kottamchukkadi lepa* and *Vatari guggulu* along with *Kottamchukkadi lepa* in the management of *Amavata*. 60 patients who were diagnosed with *Amavata* were allocated randomly in two groups. The trial drug *Shiva guggulu* 2gram TID after food with lukewarm water as *Anupana* along with application of *Kottamchukkadi lepa* was given to 30 patients of group A and *Vatari guggulu* in the dosage of 1gram TID after food with lukewarm water as *Anupana* along with application of *Kottamchukkadi lepa* was given to 30 patients of group B for duration of 30 days.

### INTRODUCTION

In the present era people are busy in their lifestyle. The food habits and seasonal regimen of human being has modified a lot. Indulgence of similar factors leads to impairment in *Agni*. *Amavata* is result of such disturbed lifestyle. The disease *Amavata* was first explained by Madhvakara in *Madhavanidana*<sup>[1]</sup>. It is n't only the complaint of locomotor system but is a systemic complaint. When *Ama* and *Vatadi doshas* are vitiated simultaneously and enter *Trikasandhi* and renders the body into stiffness<sup>[2]</sup>.

Ayurveda is an ancient Indian system of medicine, which emerges between 2000 to 5000 years. The term Ayurveda is derived from the Sanskrit words *Ayur* (life) and *Veda* (science or knowledge). This Ayurveda translates to knowledge of life and it is often called as mother of all healing.

The disease *Amavata* is formed due to vicious amalgamation of morbid *Vata* and *Ama*. The poor *agni* seldom digests the food, improperly digested food cannot be assimilated and becomes a mixture of weak digestive enzymes and un assimilated food in *Amashaya* is rendered into "*Dusta ahara rasa*" which cannot nourish and cannot be converted into *Rasa dhatu*. This resultant stasis of *Dusta ahara rasa* is referred to as *Ama*<sup>[3]</sup>.

The *Vata* gets vitiated and push the *Ama* into different parts of the body through circulation. Mainly *Vata* push the *Ama* into *Shleshma sthana*, mainly bony joints and muscles.

*Amavata* affects the individual who indulges the activities such as *Vyayama*, *Vyavaya* (sex), swimming soon after taking *Viruddhahara*. The causes of *Mandagni* are *Mithyaahara vihara*, *Akala bhojana*, *Atimaatra bhojana*, *Ahita bhojana* and *Vishama bhojana*. *Mithya vihara* refers a debilitated person overdoing work and a strong person sitting idle. *Snigdha bhojana* by a person suffering from *Mandagni* leads to accumulation of *Ama*. Further, the *Vyayama* (physical activities) would mobilize the *Ama* from the

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<https://doi.org/10.47070/ayushdhara.v11i6.1837>

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gut instead of being dissolved, it would enter the *Srotas* by *Dustavata*. The *Vata* gets more seriously aggravated, due to exercises in *Ama* conditions<sup>[4]</sup>.

Some of the symptoms of *Amavata* can be identified with rheumatoid arthritis. Rheumatoid arthritis is a common form of seditious arthritis, being throughout the world and in all ethnical groups. It basically attacks synovial joints with redundant articular instantiations in which pain remains a cardinal symptom. The frequency of RA is roughly 0.8%- 1.0% in Europe and south Asia, with a womanish to manly rate of 3:1. It's a habitual complaint characterized by a clinical course of exacerbations and remittals. RA is a complex complaint with both inheritable and environmental factors. Absolution may do during gestation and occasionally RA first presents post-partum. The typical donation is with pain, common lump and stiffness affecting the small joints of hands, feet and wrists in a symmetrical fashion. Large joint common involvement, systemic symptoms and redundant articular features may also occur. Occasionally RA has an acute onset, with severe early morning stiffness, polyarthritis and pitting oedema. This occurs more commonly in old age<sup>[5]</sup>.

#### OBJECTIVES OF THE STUDY

- To evaluate the therapeutic effect of *Shiva Guggulu* along with *Kottamchukkadi Lepa* in reducing the signs and symptoms of *Amavata*.
- To evaluate the therapeutic effect of *Vatari Guggulu* along with *Kottamchukkadi Lepa* in reducing the signs and symptoms of *Amavata*.
- To compare the therapeutic effect of *Shiva Guggulu* and *Vatari Guggulu* along with *Kottamchukkadi Lepa* in reducing the signs and symptoms of *Amavata*.

#### MATERIALS AND METHODS

##### a) Literary Source

Literary aspect of the study will be collected from Ayurvedic, classical, modern text books, medical publications and internet.

##### b) Sample source

Patient who fulfils the inclusion criteria will be randomly selected from OPD and IPD of Karnataka Ayurveda Medical College and Hospital and also from referral sources and special camps conducted for the purpose.

##### c) Pharmaceutical source

The *Shiva guggulu*, *Vatari guggulu* and *Kottamchukkadi lepa* was prepared in the department of Rasa Shastra and Bhaishajya Kalpana, Karnataka Ayurveda medical College, Mangalore.

#### METHOD OF COLLECTION OF DATA

The subjects suffering from *Amavata* is screened under strict diagnostic, inclusion and exclusion criteria and selected for the study. Eligible subjects then is invited to participate in the study after signing a detailed informed consent and then registered for this clinical trial. Thus registered participants are treated with the medication as per the plan of intervention. The outcome measures are assessed at baseline by comparing the efficacy of *Shiva guggulu* along with *Kottamchukkadi lepa* and *Vatari Guggulu* along with *Kottamchukkadi lepa* in *Amavata*.

#### Design of the study

Study Type: Interventional

Estimated enrollment: 60 participants

Allocation: Randomized

Endpoint Classification: Comparative study

Intervention model: Double group assignment

Masking: Open label study

Primary purpose: Treatment

#### Diagnostic criteria

- Clinical diagnosis of *Amavata*, based on typical history and clinical presentation of progressive involvement of joints with pain swelling and stiffness that is worst in morning and night.
- Presence of prominent feature of *Amavata* i.e., *Vrushchika damshtavat vedana*.
- The (2010) American College of Rheumatology - European League
- Against Rheumatism (ACR-EULAR) classification Criteria for RA.

#### Inclusion Criteria

- Patient with *Amavata* irrespective of sex
- < than 1 year of chronicity
- Erythrocyte sedimentation rate of  $\geq 28$ mm/hr.
- CRP  $\geq 0.8$ mg/dl
- Age between 16-70 years
- Patient who willing to give written informed consent.
- Both fresh and treated (discontinuing the exciting medicines).

#### Exclusion Criteria

- Patient with joint deformity and rheumatoid nodules formed.
- Patient who has developed secondary complications of RA.
- Patient with any other systemic disease which interfere with the treatment.
- Pregnant and lactating women
- Patient with history of Juvenile Idiopathic Arthritis (JIA).

**Intervention**

The selected patient will be randomly divided into 2 groups of 30 each by adapting the permuted block randomization method.

**Group A:** Recruited subjects will be treated with *Shiva guggulu* in the dosage of 2gram TID after food with lukewarm water as *Anupana* along with application of *Kottamchukkadi lepa* for 30 days.

**Group B:** Recruited subjects will be treated with *Vatari guggulu* in the dosage of 1gram TID after food with lukewarm water as *Anupana* along with application of *Kottamchukkadi lepa* for 30 days.

**Duration of the study**

**Group A:** The study includes 30 days of medication with *Shiva guggulu* and *Kottamchukkadi lepa* followed

by another 30 days of follow up period. Total duration of the study was 60 days.

**Group B:** The study includes 30 days of medication with *Vatari guggulu* and *Kottamchukkadi lepa* followed by another 30 days of follow period. Total duration of the study 60 was days.

**Follow up**

30 days after treatment.

**Investigation**

- CBC (complete blood count) – HB% TC, DC ESR
- CRP
- Reumatoid Factor Test
- RBS (Random Blood Sugar)
- Radiological– X ray of affected joints
- CCP anti body (cyclic citrullinated peptide anti body).
- Anti-nuclear anti body (ANA)

**Table 1: Criteria of Assessment (Grading)**

S.No	Grading
1.	<b>Pain in the joints</b> <ul style="list-style-type: none"> <li>• No pain- 0</li> <li>• Mild (on motion only)- 1</li> <li>• Moderate( at rest )- 2</li> <li>• Severe (wakes patient from sleep)- 3</li> </ul>
2.	<b>Morning stiffness</b> <ul style="list-style-type: none"> <li>• 0- 5 min- 0</li> <li>• 5 min- 2 hours- 1</li> <li>• 2hours -8 hours- 2</li> <li>• 8 hours or more- 3</li> </ul>
3.	<b>Swelling in the joints</b> <ul style="list-style-type: none"> <li>• Absent- 0</li> <li>• Mild- 1</li> <li>• Moderate- 2</li> <li>• Severe- 3</li> </ul>
4.	<b>Redness</b> <ul style="list-style-type: none"> <li>• Absent- 0</li> <li>• Mild- 1</li> <li>• Moderate- 2</li> <li>• Severe- 3</li> </ul>
5.	<b>Warmth</b> <ul style="list-style-type: none"> <li>• Absent- 0</li> <li>• Mild- 1</li> <li>• Moderate- 2</li> <li>• Severe- 3</li> </ul>
6.	<b>Tenderness in the joints</b> <ul style="list-style-type: none"> <li>• No tenderness- 0</li> <li>• Says tender- 1</li> <li>• Patient winces- 2</li> <li>• Winces and withdraws- 3</li> <li>• Not allowed to touch- 4</li> </ul>

7.	<b>Alasya</b> <ul style="list-style-type: none"> <li>Fully active- 0</li> <li>Mild laziness, slow initiative in work- 1</li> <li>Initiative in some works, absent in others- 2</li> <li>Absolute lack of initiative even though capacity for work exists- 3</li> </ul>
8.	<b>Angamarda</b> <ul style="list-style-type: none"> <li>No symptoms- 0</li> <li>Mild symptoms- 1</li> <li>Moderate symptoms- 2</li> <li>Severe symptoms- 3</li> </ul>
9.	<b>Sandhi shoola</b> <ul style="list-style-type: none"> <li>No symptoms- 0</li> <li>Mild symptoms- 1</li> <li>Moderate symptoms- 2</li> <li>Severe symptoms- 3</li> </ul>
10.	<b>Sandhi shota</b> <ul style="list-style-type: none"> <li>No symptoms- 0</li> <li>Mild symptoms -1</li> <li>Moderate symptoms- 2</li> <li>Severe symptoms- 3</li> </ul>
11.	<b>Stabdata</b> <ul style="list-style-type: none"> <li>No symptoms- 0</li> <li>Mild symptoms- 1</li> <li>Moderate symptoms- 2</li> <li>Severe symptoms- 3</li> </ul>
12.	<b>Aruchi</b> <ul style="list-style-type: none"> <li>No symptoms- 0</li> <li>Mild symptoms- 1</li> <li>Moderate symptoms- 2</li> <li>Severe symptoms- 3</li> </ul>
13.	<b>Jwara (in degree Fahrenheit): Symptom Grading</b> <ul style="list-style-type: none"> <li>No fever- 0</li> <li>Mild (99.0° F-101.0° F)- 1</li> <li>Moderate (101. 1° F-103.0° F)- 2</li> <li>Severe (&gt;103.1° F)- 3</li> </ul>

Table 2: Ingredients of Shiva Guggulu<sup>[6]</sup>

Drugs	Botanical name	Proportion
Haritaki	<i>Terminalia chebula</i>	1 part
Vibitaki	<i>Terminalia bellerica</i>	1 part
Amalaki	<i>Emblica officinalis</i>	1 part
Erandamoola choorna	<i>Ricinus communis</i>	4 parts
Shudda Gandhaka	Purified sulphur	2 parts
Shudda Guggulu	<i>Commiphora mukul</i>	1 part
Rasna	<i>Pluchea lanceolata</i>	1 part
Vayu vidanga	<i>Embelia ribes</i>	1 part
Maricha	<i>Piper nigrum</i>	1 part
Pippali	<i>Piper longum</i>	1 part
Dantimoola	<i>Baliospermum montanum</i>	1 part
Jatamamsi	<i>Nordostachys jatamansi</i>	1 part

Shunti	Zingiber officinale	1 part
Devadaru	Cedrus deodara	1 part

**Table 3: Ingredients of Vatari Guggulu<sup>[7]</sup>**

Drugs	Botanical name	Proportion
Eranda taila	Ricinus communis	100ml
Shuddha Gandhaka	Purified sulpher	100gm
Shuddha Guggulu	Commiphora mukul	100gm
Triphala choorna	Emblica officinalis (Amalaki), Vibhitaki (Terminalia belerica), Terminalia chebula (Haritaki)	300gm

**Table 4: Ingredients of Kottamchukkadi Lepa<sup>[8]</sup>**

Drugs	Botanical name	Proportion
Kushta	Saussurea Lappa	1 part
Nagara	Zingiber Officinalis	1 part
Vacha	Acorus Calamus	1 part
Shigru	Moringa Oliefera	1 part
Lashuna	Allivum Sativum	1 part
Kartoti	Hugonia mystax	1 part
Devadaru	Cedrus Deodar	1 part
Sarshapa	Brassica campestris	1 part
Rasna	Pluchea Lanceolata	1 part

**Statistical Analysis**

For assessing the improvement of symptomatic relief and to analyse statistically the observations were recorded before and after the treatment. The mean, percentage, S.D, S.E, and t-value were calculated from the observation recorded. The data obtained will be analysed statistically with unpaired t test.

The observations that were made in these patients will be explained in detail under the following headings:

- Observations in demographic data
- Observations in personal history
- Observations in Dashavidha Pariksha
- Observations in disease history

**OBSERVATIONS AND RESULTS**

**Table 5: Observations**

Observation	Group A	Group B	Total
<b>Age</b>			
16-40	14	8	22 (36.66%)
41-70	16	22	38 (63.33%)
<b>Sex</b>			
Male	12	9	21 (35%)
Female	18	21	39 (65%)
<b>Religion</b>			
Hindu	24	17	41 (68.33%)
Christian	3	1	4 (6.66%)
Muslim	3	12	15 (25%)
<b>Socio economic status</b>			
Lower	11	12	23 (38.33%)
Middle	19	13	32 (53.33%)
Upper	0	5	5 (8.33%)
<b>Nidra</b>			
Good	5	2	7 (11.66%)
Disturbed	25	28	53 (88.33%)
<b>Bowel</b>			
Regular	8	3	11 (18.33%)

Irregular	3	9	12 (20%)
Constipated	19	18	37 (61.66%)
<b>Occupation</b>			
House wife	14	14	28 (46.66%)
Working persons	16	16	32 (53.33%)
<b>Marital status</b>			
Married	29	30	59 (98.33%)
Unmarried	1	0	1 (1.66%)

**RESULTS****Table 6: Statistical analysis of Subjective and Objective parameters**

Symptom	Group A (mean score)	Group A (t value)	Group A (p value)	Group B (mean score)	Group B (t value)	Group B (p value)
Pain	BT-2.37 AT-1.37 AF-1.03	AT-7.902 AF-10.54	<0.05 <0.05	BT-2.50 AT-1.50 AF-1.10	AT-7.62 AF-11.82	<0.05 <0.05
Swelling	BT-2.03 AT-1.13 AF-0.80	AT-6.99 AF-8.63	<0.05 <0.05	BT-2.50 AT-1.50 AF-1.10	AT-8.59 AF-10.47	<0.05 <0.05
Joint tenderness	BT-2.30 AT-1.40 AF-1.07	AT-6.35 AF-9.67	<0.05 <0.05	BT-2.53 AT-1.53 AF-1.13	AT-7.63 AF-10.69	<0.05 <0.05
Jwara	BT-0.90 AT-0.47 AF-0.13	AT-2.19 AF-4.26	<0.05 <0.05	BT-1.33 AT-0.60 AF-0.13	AT-3.96 AF-7.20	<0.05 <0.05
Apaka	BT-0.57 AT-0.37 AF-0.03	AT-1.15 AF-3.49	<0.05 <0.05	BT-1.30 AT-0.70 AF-0.13	AT-2.44 AF-5.32	<0.05 <0.05
Gouravam	BT-1.07 AT-0.57 AF-0.20	AT-2.35 AF-4.47	<0.05 <0.05	BT-1.77 AT-1.07 AF-0.30	AT-3.48 AF-7.77	<0.05 <0.05
ESR (mm/hr)	BT-63.33 AT-48.37 AF-33.67	AT-2.38 AF-5.14	<0.05 <0.05	BT-73.67 AT-52.50 AF-35.57	AT-5.03 AF-9.50	<0.05 <0.05
CRP (mg/dl)	BT-2.65 AT-2.08 AF-1.52	AT-0.80 AF-1.75	<0.05 <0.05	BT-2.12 AT-1.62 AF-1.17	AT-3.60 AF-7.14	<0.05 <0.05
DAS28	BT-4.94 AT-4.39 AF-3.99	AT-3.55 AF-6.07	<0.05 <0.05	BT-5.09 AT-4.42 AF-3.78	AT-3.60 AF-7.14	<0.05 <0.05
RA FACT	BT-87.14 AT-75.20 AF-64.30	AT-1.23 AF-2.40	<0.05 <0.05	BT-66.73 AT-50.99 AF-35.05	AT-2.85 AF-5.86	<0.05 <0.05

**Assessment of Total Effect of Therapy**Overall effect of *Shiva Guggulu* along with *Kottamchukkadi Lepa* Group-A.**Table 7: Result on group A**

Effect of Treatment in Group - A		
Class	Grading	No of patients
0-25%	Minimal	0
26%-50%	Mild	1
51% - 75%	Moderate	27

76% - 99%	Marked	2
100%	Complete remission	0

Effects of *Vatari guggulu* along with *Kottamchukkadi Lepa* (Group-B)

**Table 8: Overall effect of Group-B**

Effect of Treatment in Group - B		
Class	Grading	No of patients
0-25%	Minimal	0
26%-50%	Mild	2
51% - 75%	Moderate	19
76% - 99%	Marked	9
100%	Complete remission	0

**Table 9: Comparative results of Group-A and Group-B**

Signs and Symptoms	Group A (Mean Score)	Group B (Mean Score)	SD	SE	T Value	P Value
Pain	1.60	1.69	0.597	0.111	1.01	>0.05
Swelling	1.36	1.32	0.600	0.111	0.10	>0.05
Joint tenderness	1.61	1.75	0.553	0.103	1.29	>0.05
<i>Jwara</i>	0.49	0.68	0.738	0.137	1.37	>0.05
<i>Apaka</i>	0.33	0.74	0.657	0.122	2.58	<0.05
<i>Gouravam</i>	0.63	1.01	0.881	0.164	2.67	<0.05
ESR (MM/HR)	48.46	53.91	19.647	3.648	1.20	>0.05
CRP (MG/DL)	2.08	1.64	2.238	0.416	1.05	>0.05
DAS28	4.44	4.43	0.734	0.136	0.05	>0.05
RA Factor (Iu/mL)	75.55	50.92	43.682	8.112	3.24	<0.05

**Table 10: Comparative results of Group A and Group B**

Group A	Group B	Mean Difference	SE (±)	T value	P value
65.37	71.72	6.35	2.53	2.54	<0.05

## DISCUSSION

*Amavata* is one of the destructive complaint-causing excruciating painful conditions. It is not only a complaint of locomotor system but is a systemic complaint. It's a complaint of *Rasavahasrotas*. The person who's taking inharmonious food, infelicitous body movements, *Mandagni*, greedy food input, vigorous exercising incontinently after consuming unctuous or adipose food, the consumed *Ahara* becomes *Ama* in the body. In which malign ingredients are majorly *Ama* and *Vata*. Aggravated *Vata* circulates the *ama* in the whole body through *Dhamanies* takes the sanctum in *Sleshma sthana* especially in joints manifest symptoms similar as stiffness, swelling and tenderness in the small joints and big joints, making a person lame. *Amavata* is distributed into 3 types grounded on the involvement of *Dosha* as *Vatanuga*, *Pittanuga* and *Kaphanuga*. It becomes incorrigible when it involves all the joints, severe pain suggesting that of scorpion sting. If this complaint remains undressed it'll run veritably long course leading to endless disfigurement and numerous other systemic complications. Due to common symptoms *Amavata*

should clinically discerned from *Sandhigatavata*, *Vatarakata* and *Koshtukasheersha*.

### Probable mode of action of *Vatari Guggulu*

The main constituents of *Vatari Guggulu* are *Eranda taila*, *Shudha gandhaka*, *Shudha Guggulu*, *Haritaki*, *Vibhitaki*, and *Amalaki* in equal proportions. Utmost medicines of *Vatari guggulu* have *Ushna veerya* and *Katu vipaka*. It has *Vatakapha Shamana* property. *Amalaki*, *Haritaki*, and *Gandhaka* have *Rasayana* goods, and the antioxidant goods of *Amalaki* has been proved.

In the progression of complaint *Amavata*, the main *Doshas* involved are *Vata* and *Kapha*. In the first stage of complaint *Mandagni* leads to conformation of *Ama* and *Vatari Guggulu* has *Amapachana* property because of its *Laghu*, *Ruksha*, *Tikshna Guna*, *Katu*, *Tikta Rasa*, *Ushna Virya*, and *Katu Vipaka*, all of which acts against the *Guru*, *Snigdha*, *Pichhila*, etc. parcels of *Ama*. Aggravation of *Vata* and *Kapha* normalized by *Vatari guggulu*. Further, conformation of *Ama* is stopped by *Deepaniya* action of medicine. It reduces the symptoms like *Sandhishoola* (pain in joints), *Sotha* (swelling),

*Aruchi* (dislike for food), etc., by its *Vednasthapana* (analgesic) and *Sothahara* (anti-inflammatory) action. Accordingly, due to its *Deepana- Paachana* and *Vata Kapha Shamaka* property, it's veritably well suited for breaking the pathogenesis of the complaint and fight against the main lawbreakers, i.e., *Vata, Kapha (Ama)*, and *Mandagni*, that are the root cause of *Amavata*.

## CONCLUSION

*Vatari guggulu* along with *Kottamchukkadi lepa* was found to be more effective in being able to tackle *Amavata* in comparison to *Shiva guggulu* along with *Kottamchukkadi lepa* in relieving the symptoms. In case of the patients with chronic disease, *Shiva guggulu* acts as *Vatakaphahara, Vedanasthapana, Deepana pachana* and *Rasayana*. *Vatari guggulu* acts as *Amapachaka, Shothahara, Shoolahara* and *Vatakaphashamaka*, along with *Kottamchukkadi lepa* external application acts as *Vatavyadhiprashamana, Shothahara, Shoolahara* in *Amavata*. The improvements observed by the medications are definite as proved by tests of statistical significance although the time factor of the study was limited. Further detailed study might land up in providing a better proof about the complete efficacy of *Vatari guggulu* along with *Kottamchukkadi lepa* and *Shiva guggulu* along with *Kottamchukkadi lepa*. *Amapachaka, Shothahara, Shoolahara* in the form of *Vatari guggulu* along with *Kottamchukkadi lepa* was found to be more effective in being able to tackle *Amavata* in comparison to *Shiva guggulu* along with *Kottamchukkadi lepa* in relieving the symptoms in case of the patients with chronic disease and the *Samprapthi* being in a stage where in the disease has undergone further aggravation. The improvements observed by the medications are definite as proved by tests of statistical significance although the time factor of the study was limited further detailed study might land up

in providing a better proof about the complete efficacy of *Shiva guggulu* along with *Kottamchukkadi lepa*.

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### Cite this article as:

Murshida Banu, Waheeda Banu. An Open Randomized Comparative Clinical Study on the Effect of Shiva Guggulu and Vatari Guggulu along with Kottamchukkadi Lepa in Amavata. AYUSHDHARA, 2024;11(6):112-119.

<https://doi.org/10.47070/ayushdhara.v11i6.1837>

Source of support: Nil, Conflict of interest: None Declared

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