



Research Article

## A RANDOMISED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SADHYOVIRECHANA WITH GANDHARVAHASTADI ERANDA TAILA FOLLOWED BY AGNILEPA AND DHANYAMLA DHARA IN THE MANAGEMENT OF AMAVATA

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### ABSTRACT

*Amavata* is a *Kruchrasadya vyadhi* caused due to formation of *Ama*, vitiation of *Vata* and *Agni vaishmya*. *Madhavakara* mentions it as a '*Sa kashtah sarva roganam*'. *Amavata* is an *Ama pradhana vyadhi*, it requires *Ama pachana* as primary management. Hence in the present study, *Sadhyovirechana* as *Abhyantara Shodhana Chikitsa* followed by *Bahya chikitsa* in the form of *Agnilepa* and *Dhanyamla Dhara* in two different groups were used to evaluate their efficacy in the management of *Amavata*. **Aims and Objectives:** **1.** To evaluate the efficacy of *Sadhyovirechana* with *Gandharvahastadi Eranda Taila* followed by *Agnilepa* in *Amavata*. **2.** To evaluate the efficacy of *Sadhyovirechana* with *Gandharvahastadi Eranda Taila* followed by *Dhanyamla dhara* in *Amavata*. **3.** To compare the efficacy of both the groups in *Amavata*. **Methods:** This is a comparative clinical study with pre-test & post-test design where in 40 patients diagnosed with *Amavata* of either sex were randomly assigned into two groups viz., Group A & Group B. **Intervention: Group A:** *Sadhyovirechana* on 1<sup>st</sup> day followed by *Agnilepa* for next 7 days. **Group B:** *Sadhyovirechana* on 1<sup>st</sup> day followed by *Dhanyamla Dhara* for next 7 days. **Results:** The effect of the treatment in both the groups were assessed by applying Wilcoxon's rank sum test within the groups and Mann-Whitney U test between the groups, it showed that Group A showed better results than Group B. **Conclusion:** It can be concluded from the study that in the management of *Amavata*, *Sadhyovirechana* followed by *Agnilepa* and *Dhanyamala Dhara Chikitsa* drugs and procedures of both the groups are highly effective in treating *Amavata*.

### INTRODUCTION

The concept of *Ama* is unique to Ayurveda. The reduced understanding of *Ama* in general public leads to repeated indulgence in *Nidana* causing *Ama*. This *Ama* in the body carried by *Dooshitha Vaata* leads to *Stabdhattha* and *Gurutha* of *Gaathra*. *Amavata* management involves *Langhana*, *Swedana*, and the utilization of *Tikta* and *Katu Rasa* drugs with *Deepana* qualities. This approach aids in addressing associated *Ama* concerns.

The *Agni Mandya* and *Sama* stages are unsuitable for treatments. Thus, the crucial focus lies on eliminating *Ama* from *Koshta* and *Shakha*, while also improving or normalizing *Jataragni* function. This is of utmost importance in *Amavata* management. Since *Ama*, circulated throughout the body, including deeper *Dhatu*, results from aggravated *Vata Dosha*, managing *Vata Dosha* becomes an important aspect. Consequently, a combined treatment approach that influences *Agni*, eliminates *Ama Dosha*, and manages *Vata* and *Kapha Dosha* plays a key role in promoting the formation of a healthy *Rasa Dhatu*. *Madhavakara* was first *acharya* who elaborated this disease in detail. *Lakshanas* like *Angamarda*, *Aruchi*, *Trushna*, *Aalasya*, *Gourava*, *Jwara*, *Apaka* and *Shunathaanganam*.<sup>[1]</sup>

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*Amavata* is the disease of *Rasavaha Srotas* and having several features similar to Rheumatoid Arthritis, *Amavata* can be correlated with Rheumatoid Arthritis (RA). The disease prevalence worldwide is approximately 0.3% to 1% global of the population, In India the prevalence of R.A. is 0.3% to 0.75%.<sup>[2]</sup> In the conventional medicine R.A. is managed with NSAIDs, glucocorticoid therapy, DMARDs, meanwhile long-standing use of these medications may give raise to many adverse effect and re-occurrence of signs and symptoms.

In the classical text the line of treatment for *Amavata* is mentioned as *Langana*, *Swedana*, use of *Tikta* and *Katu rasa dravyas*, *Deepana dravyas*, *virechana* and *Basti karma*. *Rooksha swedana* is a preferred *Bahirparimarjana chikithsa* mentioned in *Ashtanga Hrudaya* and *Madhava nidhana*.

### Methodology

*Agnilepa* being a result-oriented treatment used in folklore medicine for *Amavata*. The noteworthy focus of *Dhanyamla Dhara*, proven *Ruksha sweda* lies in its application within *Amavata*, given the significance of *Ama* in the body.

### Source of Data

- Literary source:** Available Ayurvedic literatures, contemporary text books, journals, E-books and Imprint resources in library about Disease, procedure and drugs were reviewed and documented for the present clinical study.
- Sample source:** 40 Patients with *Lakshanas* of *Amavata* coming under inclusion criteria approaching Out-patient department and In-patient department of Panchakarma of Shri Shivayogeeshwar Rural Ayurvedic Medical College & Hospital, Inchal, will be selected for the study.
- Drug source:** The identified dry and wet drugs required for the preparation of *Agnilepa* and *Dhanyamla* were purchased from approved vendors and post purchase medicines were prepared in Rasa Shala-Pharmacy of our college-Shri Shivayogeeshwar Rural Ayurvedic Medical College & Hospital, Inchal.

### Study Design

- Study Type: Interventional
- Allocation: Randomized
- Endpoint Classification: Efficacy study
- Intervention Model: Double group assignment
- Primary Purpose: Treatment

- Masking: Open label
- Treatment duration: 8 days
- Total duration of study: 15 days

### Diagnostic Criteria

- The patients presenting with *Lakshanas* of *Amavata*.
- The patients with Rheumatoid Arthritis Factor positive.
- The patients with increased C-Reactive Protein and Erythrocyte Sedimentation Rate levels.

### Inclusion Criteria

- Subjects of either gender presenting with the *Lakshanas* of *Amavata*.
- Subjects fit for *Sadhyovirechana karma*, *Lepa* and *Dhara*.
- Age group of 20-60 years.

### Exclusion Criteria

- Subjects with any other systemic disorders that interfere with the course of treatment.
- Subjects who are unfit for *Sadhyovirechana Karma*, *Lepa* and *Dhara*.

### Interventions

40 patients who fulfilled the inclusion criteria were selected and randomly assigned into 2 groups as Group-A and Group-B comprising of 20 patients each.

### *Sadhyovirechana karma*: For both Group A and Group B

#### a. *Poorva Karma*

- *Sarvanga Abhyanga* – *Mahavishagarbha taila* <sup>[3]</sup>
- *Sarvanga mrudu Bashpa Swedana* – *Ushna jala*
- *Ushna jala Snana*

#### b. *Pradhana karma*

- Administration of *Gandharvahastadi Eranda taila* <sup>[4]</sup> with *Ksheera*.
- *Kala* – *Shleshmagata Kala* (8:30am to 10am)
- Dose: 30ml *Gandharvahastadi Eranda taila*.
- Half glass of hot water was made to drink after each *Vega*.

#### c. *Pashchat karma*

- Observation of *Vegas*.
- Once the *Vegas* stopped *Pathya Ahara* was given.

**Agnilepa and Dhanyamala Dhara****Table 1: Agnilepa and Dhanyamala Dhara Poorva, Pradhana and Paschat Karma**

Procedure	Group A	Group B
<i>Poorva karma</i>	Collection of all necessary equipment and collection of raw and wet drugs. All the dry drugs ( <i>Lashuna, Lavanga, Maricha, Sarshapa, Haridra</i> ) are made into powder in the mixer. Wet drugs (fresh leaves of <i>Agnimantha, Tulasi, Nirgundi</i> ) are washed, leaves veins are removed and chopped into small pieces. All the drugs should be pounded with little quantity of water and made into paste.	Collection of all necessary equipment and collection of raw and wet drugs. [ <i>Tandula, Prathuka, Kulatha, Laja, Kangu Beeja, Kodrava, Nagara, Nimbuka, Deepyaka and Jala</i> ]
<i>Pradhana karma</i>	Freshly prepared <i>Agnilepa</i> paste is applied in <i>Pratiloma gati</i> (opposite direction to the hair follicle) to the whole body below the neck (avoiding the face). The application is done in the morning hours in between 8am to 10am. After the <i>Lepa</i> [5] application patient is allowed to sit in <i>Nivatagruha</i> until the paste gets dried.	For every single procedure 5 liters of <i>Dhanyamala</i> [6] is taken with 3 liters of hot water. <i>Dhanyamla</i> is indirectly made warm and used as per patients' tolerance. Luke warm <i>Dhanyamla</i> is poured at a height of 12 <i>Angulas</i> [7] in a circular manner bilaterally with the help of <i>Dhara patra/ Khindi</i> . <i>Dhara</i> is carried out till the appearance of <i>Samyak Swinna Lakshana</i> .
<i>Pashchat karma</i>	Once the paste gets dried, it is removed and patient is advised to take lukewarm water bath. Patient is advised to take <i>Laghu, Ushna, Anabhishtyandi bhojana</i> .	After <i>Dhara</i> the body is cleaned using a soft towel. Rest is advised for one hour and then asked to take bath with <i>Ushna Jala</i> . Patient is Advised to take <i>Drava, Laghu, Ushna, Anabhishtyandi</i> and <i>Asankirna Bhojana</i> .

**Duration of the Study****Table 2: Duration of the study for both Group A and Group B**

Group	No. of Pt.	Procedure	Day	Trial Duration	Follow up	Study Duration
Group A	20	<i>Sadhyo-virechana</i>	1 <sup>st</sup> day	1 day+	After 7 days-on 15 <sup>th</sup> day	15 days
		<i>Agnilepa</i>	2 <sup>nd</sup> day -8 <sup>th</sup> day	7 days		
Group B	20	<i>Sadhyo-virechana</i>	1 <sup>st</sup> day	1 day+	After 7 days-on 15 <sup>th</sup> day	15 days
		<i>Dhanyamala dhara</i>	2 <sup>nd</sup> day- 8 <sup>th</sup> day	7 days		

No. = Number, Pt. = Patients

**Chart for Grading of Subjective Criteria****Table 3: Grading of Subjective Criteria for Group A and Group B**

S. No.	Criteria	Assessment grading
1.	<b>Sandhi Shoola (Pain in Joints)</b>	0 = Occasional 1 = Mild pain of bearable nature 2 = Frequent moderate pain, but no difficulty in joint movement 3 = Slight difficulty in joint movement due to severe pain, requires medication and

		may remain throughout the day 4 = Severe pain with more difficulty in moving the joints, disturbing sleep and requires strong analgesics
2.	<b>Sandhi Shotha (Swelling in Joints)</b>	0 = No swelling 1 = <10% increased circumference of the affected joint 2 = >10% increased circumference of the affected joint 3 = >20% increased circumference of the affected joint
3.	<b>Stabdhatrata (Morning Stiffness)</b>	0 = No stiffness 1 = 0 - 10 minutes 2 = 10 - 120 minutes 3 = 2 - 8 hours 4 = >8 hours
4.	<b>Angamarda (Malaise)</b>	0 = No <i>Angamarda</i> 1 = Occasional <i>Angamarda</i> but patient is able to do usual work 2 = Continuous <i>Angamarda</i> but patient is able to do usual work 3 = Continues <i>Angamarda</i> which hampers routine work 4 = Patient is unable to do any work
5.	<b>Aruchi (Anorexia)</b>	0 = Normal desire for food 1 = Eating timely without much desire 2 = Desire for food little late, then normal time 3 = Desire for food only after long intervals 4 = No desire at all
6.	<b>Trushna (Thirst)</b>	0 = Normal feeling of thirst 1 = Eating timely without much desire 2 = Satisfactory quench after increased intake of fluids but no awakening during nights 3 = Satisfactory quench after increased intake of fluids with regular awakening during nights 4 = No quench after heavy intake of fluids
7.	<b>Alasya (Tiredness)</b>	0 = No tiredness 1 = Starts work in time with efforts. 2 = Unable to start work in time but complete the work 3 = Delay in start of work and unable to complete 4 = Never able to start the work and always likes rest
8.	<b>Gourava (Heaviness)</b>	0 = No Feeling of heaviness 1 = Occasional heaviness in body but does usual work 2 = Continuous heaviness in body but does usual work 3 = Continuous heaviness which hampers usual work 4 = Unable to do any work due to heaviness
9.	<b>Jwara (Fever)</b>	0 = No Fever 36°C - 37.2°C 1 = Low grade fever 37.3°C - 38.2°C 2 = Moderate fever 38.3°C - 40.2°C 3 = High grade fever 40.3°C - 42.2°C 4 = Hyper pyrexia - >42.3°C
10.	<b>Apaka (Indigestion)</b>	0 = No <i>Apaka</i> at all 1 = Occasional indigestion once or twice a week in one meal

	2 = Occasional indigestion 3 – 5 times a week in one meal 3 = Indigestion 3 – 5 times a week in both meal 4 = Indigestion after every meal
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S. No. = Serial Number, °C = Degree Celsius

**Chart for Grading of Objective Criteria**

**Table 4: Grading of Objective Criteria for Group A and Group B**

Sl. No.	Criteria	Assessment grading
1.	<b>E.S.R. – After 1<sup>st</sup> Hour</b>	0 = 0-20 1 = 21-35 2 = 36-50 3 = >50
2.	<b>R.A. Factor</b>	0 = Inactive 1 = Minimally active 2 = Moderately active 3 = Severely active
3.	<b>C- Reactive Protein</b>	0 = <10 mg/L 1 = 11-13 mg/L 2 = 14-17 mg/L 3 = >18 mg/L

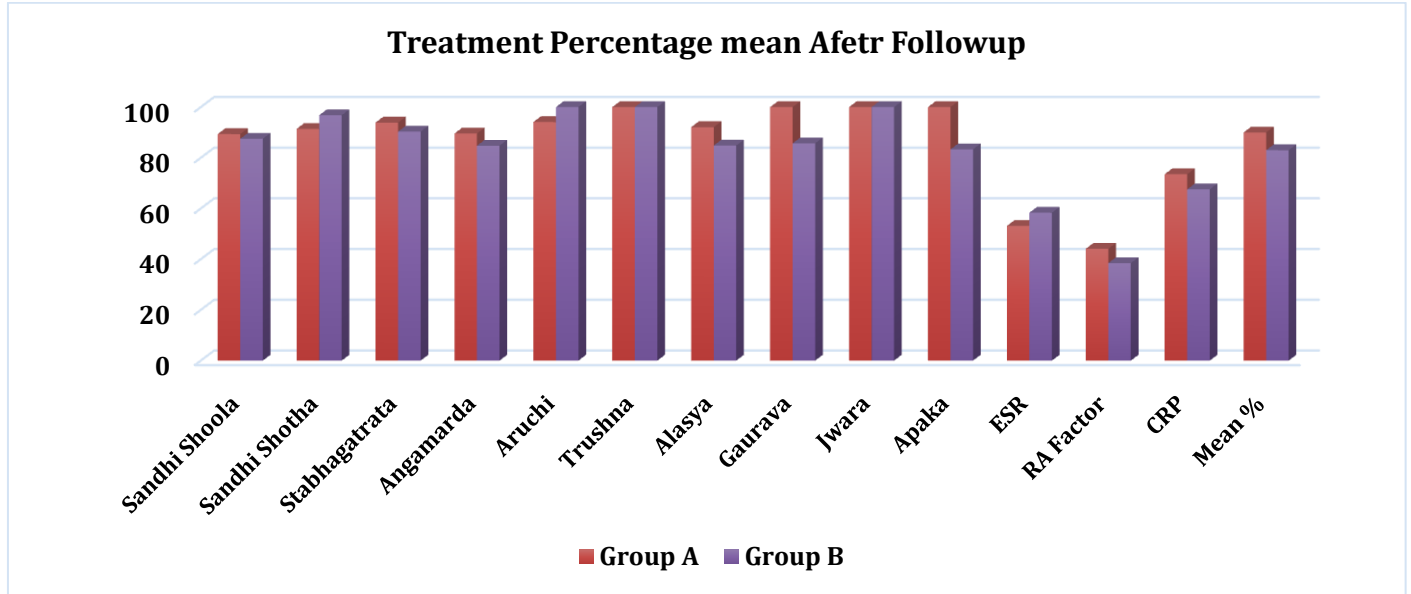
E.S.R. = Erythrocyte Sedimentation Rate, R.A. Factor = Rheumatoid Factor, mg/L = Milligrams/Litre

**Overall Assessment**

**Table 5: Overall Assessment of Treatment Percentage Mean of all Criteria**

S.No.	Parameters	Mean Change Treatment %			
		Group A		Group B	
		AT	AF	AT	AF
<b>Objective Parameters</b>					
1.	<i>Sandhi Shoola</i>	57.44%	89.36%	56.25%	87.50%
2.	<i>Sandhi Shotha</i>	74.28%	91.42%	71.87%	96.8%
3.	<i>Stabdhatrata</i>	72.72%	93.90%	74.19%	90.32%
4.	<i>Angamarda</i>	56.25%	89.58%	78.26%	84.78%
5.	<i>Aruchi</i>	67.64%	94.11%	61.53%	100%
6.	<i>Trushna</i>	74.07%	100%	85.7%	100%
7.	<i>Alasya</i>	60.52%	92.10%	81.81%	84.84%
8.	<i>Gaurava</i>	66.66%	100%	77.14%	85.71%
9.	<i>Jwara</i>	92.80%	100%	63.66%	100%
10.	<i>Apaka</i>	76.47%	100%	83.30%	83.33%
<b>Subjective Parameters</b>					
11.	ESR	28.12%	53.12%	41.66%	58.33%
12.	RA Factor	29.41%	44.11%	20.51%	38.46%
13.	CRP	52.94%	73.52%	51.35%	67.56%
<b>Total Mean %</b>		<b>62.24%</b>	<b>86.24%</b>	<b>65.17%</b>	<b>82.89%</b>

AT = After Treatment, AF = After Follow-up



Graph 1: Overall Assessment of Treatment Percentage Mean of all Criteria

## DISCUSSION

*Agnilepa* and *Dhanyamla dhara* are one among the *Bahya upakramas* used in this study to achieve *Ama pachana*, *Deepna* etc. To prepare any formulation for external use it is important to choose an appropriate *Dravya* and the *Gunas* of each *dravya* in order to facilitate its penetration in to the skin.

### *Agnilepa*

It is a folklore practice which consists of combination of *Ushna veerya dravyas* and said to bring about its effect in reduction of signs and symptoms in *Sandhi shoola*, *Shotha*, *Stabdagatrata*, *Angamarda*, *Gourava*, *Trushna*, *Aruchi*, *Alasya*, *Jwara* and *Apaka* by delivering their respective *Guna* when applied over skin, it does *Kapha vatahara*. *Ushna veerya* of *Lepa* is absorbed by skin through *Bhrajaka pitta* into all *Siras*. *Ushnateekshna*, *Pachana deepana guna* does *Amapachana*, *Srotoshodhana vata shamana* and *Shoshana* of *Abhishyanna* and *Picchila srotas*.

### *Dhanyamla*

It is a *Sandhana* preparation i.e., it is having *Agneya*, *Teekshna*, *Ushna guna* and most of the ingredients in them are *Ushna veerya* which have a combined effect of *Gunas* of *Sandhana Varga*, there by showing its effect at the level of skin.

### *Karmukata of Lepa and Dhanyamla Dhara*

*Agnilepa* and *Dhanyaamla Dhara* both when applied and poured on the skin are acted upon by the *Bhrajaka pitta*. *Acharya Vagbhata* explains the functions of it as:<sup>[8]</sup> *Abhyanga*, *Pariseka*, *Lepa pachana* i.e., it is the *Bhrajaka pitta* which is situated in *Avabhasini* (the outermost layer of the skin) that is

responsible for the drugs to be absorbed when in contact with the skin. The active ingredients in the formulation are acted upon by the *Bhrajaka pitta* which results in releasing of particles which help in reduction of signs and symptoms in *Amavata* as the *Veerya* ensures *Pachana* of *Ama* and does *Sroto vishodhana*.

*Amavata*, the *Sama dosha* are spread throughout the body and hence *Ushna veerya* of *Agnilepa* was transported throughout the body via *Tiryak Vaha Sira*. As the *Lepa* was freshly prepared every day and applied in *Pratiloma gati* and it was in contact with the skin until its dries up, the *Veerya* acted upon *Bhrajaka pitta* by this *Veerya* of drug enters the *Romakupa*. *Veerya* of *Dravya* further enters the *Siramuka* through the *Sweda vaha siras* and exhibits its action. *Tiryak gata siras* as mentioned in *Sushruta Shareera sthana*, take up the action of supplying nourishment to all bodyparts via *Sthoola* and *Sukshma srotas* just like a garden is supplied with water with various channels<sup>[9]</sup>. *Siras* in the *Romakupa*, through which *Sweda abhivahana* and *Rasa abhitarpana* occurs these *Siras* take the *Veerya* of the drug used for *Lepa* after undergoing *Paka* by *Bhrajaka pitta* in *Twak*. *Twak* is formed when all *Dhatus* are formed and hence it has a close relation to all the *Dhatus* from *Rasa* to *Shukra*<sup>[10]</sup>. Hence, *Sroto shodhana* was achieved by *Ama Pachana*.

The *Teekshana* and *Ushna veerya* of *Dhanyamla Dhara* acted in the same manner and also provided added effects of *Swedana*. In *Charaka Samhita Teeka*, *Acharya shivadese sena* explained *Dhanyamla* does the *Bahir pitta haratvam* and *Antah*

*pitta karatvam*, and *Shakhagata vataharatvam*, *Kukshigata vatakaratvam*.<sup>[11]</sup>

In *Dhara kalpa*, the reason behind starting *Dhara chikitsa* from *Urdhwa shakha* to *Nabhi* and from *Adho shakha* to *Nabhi* throws light at the importance of *Nabhi*. As it is the point of conjunction of all *Sira* in body and becomes the reservoir for transportation of *Veerya* to *Sthula* and *Sukshma srotas* thereby resulting in *Ama Pachana* and *Sroto shodhana* just like fire becomes extinguished by pouring water on it, similarly the heat of the *Doshas* get subsided by *Dhara*.

### **Sadyovirechana Karma**

*Sadyo Virecana* implies rapid purgation. This process is administered in conditions like *Pitta vyadhi* before applying *Shodhana* or *Shamana Aushadha* to cleanse the *Koshtha*, which is why it is also referred to as *Koshtha Suddhi*.

### **Gandharvahastadi Eranda Taila**

*Eranda* having *Tikta*, *Kashaya*, *Madhura rasa*, *Madhura vipaka* and *Ushna veerya* by virtue of *Madhura rasa* and *Madhura vipaka* it counteracts *Vata*. Because of *Tikta rasa ushna veerya* and *Agni deepana guna*, it counteracts *Ama*. In this *Taila* most of the drugs possess *Ushna veerya*, *Vata-Kaphahara guna*, and acts as *Deepana*, *Pachana*, *Rochana*, *Vatanulomana*, *Shothahara* and *Vedanastapana*.

### **Mahavishagarbha Taila**

Acharya mentioned this *Taila* in *Vatavyadhi Roga*, it is mainly used for external application. The drugs are having *Ushna veerya*, *Vata-Kaphahara*, *Laghu-Rooksha-Teekshna guna* by these properties it acts as *Shothahara*, *Vedana sthapana*, *Angamarda Prashamana* etc.

### **Comparison of Study**

The effect of treatment has showed statistically highly significant results in both the groups with *p* value <0.001 in almost all the parameters. On comparison between the groups, Group A has an edge over Group B based on the mean rank value, which can be concluded that, *Sadyovirechana* with *Gandharvahastadi Eranda Taila* followed by *Agnilepa* has shown better effect in reducing the symptoms of *Amavata*.

The effect of treatment was statistically non-significant between the Groups- Group A and Group B with respect to all 13 assessment parameters.

However, statistically when mean rank and mean were compared between groups.

Group A was comparatively better than Group B in 8 parameters like *Sandhi Shoola*, *Stabdhatrata*, *Angamarda*, *Alasya*, *Gourava*, *Apaka*, RA factor and CRP.

Group B was comparatively better than Group A in 3 parameters like *Sandhi Shotha*, *Aruchi* and ESR.

Group A and Group B had same effects in 2 parameters like *Trushna* and *Jwara*.

### **Overall Treatment Assessment after Treatment (BT-AT)**

- BT-AT within Group A is 62.24%
- BT-AT within Group B is 65.17%
- BT-AT between Group A is 49% & Group B is 51%

### **Overall Treatment Assessment after Follow up (BT-AF)**

- BT-AF within Group A is 86.24%
- BT-AF within Group B is 82.89%
- BT-AF between Group A is 51% and Group B is 49%.

### **CONCLUSION**

'*Ama*' is one of the chief pathogenic factors of the disease. *Ama* is generated at various levels in the body which are at *Jatharagni* level, *Bhutagni* level and *Dhatwagni* level. *Amavata* is a *Madhyama Rogamarga Vyadhi* presenting with *Sandhishoola*, *Sandhishotha*, *Sandhistabdata*, along with *Samanya* and *Pravruddha Amavata lakshana*. *Samprapthi vighatana* in *Amavata* is achieved by administering drugs having *Gunas* like *Ushna*, *Teekshna*, *Rooksha*, *Laghu* and with *Pachana*, *Deepana dravyas* *Sadyovirechana* with *Gandharvahastadi Eranda Taila* mentioned in *Astanga Sangraha*. *Agnilepa* is taken from folklore medicine. *Dhanyamla Dhara* is mentioned in *Sahasrayoga*.

The present study is a comparative clinical study wherein, 40 patients who fulfilled the inclusion criteria were selected and randomly assigned into 2 groups as Group-A and Group-B comprising of 20 patients each. The patients of Group A were subjected to *Sadyovirechana* with *Gandharvahastadi Eranda Taila* followed by *Agnilepa*.

The patients of Group B were subjected to *Sadyovirechana* with *Gandharvahastadi Eranda Taila* followed by *Dhanyamla dhara* until attainment of *Samyak swinna lakshanas* respectively. No adverse effects were observed in both the groups during the course of study.

In the present study, maximum patients were married and females (57.5%) belong to middle class (65%), belonging to hindu religion (95%). Maximum of them is *Vatakapha Prakruti* (67.5%) and *Krura koshta* (62.5%) and having *Mandagni* (72.5%).

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