

A COMPARATIVE CLINICAL STUDY OF EFFECT OF *SAMEER GAJ KESARI RAS*, *JVARHAR KWATH* AND *BALUKA SWEDA* ON *AMAVATA*

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ABSTRACT

Ayurveda, emphasizes on the prohibition of incompatible food intake i.e. *Viruddha – Aahara* for the protection of health, but now a days as man is climbing the step of success he is moving away from health, Indulgence in incompatible foods and habits, abnormal style of living, greed, anger have become a part of his life. Many diseases spread over in society with the symptoms of *Angamarda*, *Aruchi*, *Balabhramsha*, *Trishna*, *Alasya*, *Gaurava*, *Jvara*, *Apaka*, *Shunatanganam...etc.* *Amavata* is one of the challenging diseases for the physicians due to its chronicity, incurability, complications and morbidity. Here an attempt has been made clinically to evaluate the effect of *Sameer Gaj Kesari Ras* and *Jvarhar Kwath* with *Baluka Sweda* and without *Baluka Sweda* in the management of *Amavata*. Clinically diagnosed 30 patients of *Amavata* were selected from O.P.D. & I.P.D. of NIA Hospital, Jaipur. Total duration of treatment was 30 days. The improvement in symptoms of *Ama*, like *Gaurava*, *Alasya*, *Aruchi*, *Apaka* were statistically very significant in both the groups. As per clinical observation and statistics the improvement was statistically highly significant in both the groups in pain in joint, stiffness, *angmarda*, *jvara* but comparatively better results were observed in pain, stiffness, swelling, restriction of movement and tenderness in group B. The overall effect of *Sameer Gaj Kesari Ras* and *Jvarhar kwath* along with *Baluka Sweda* was found to be better in management of *Amavata*. The therapy has well tolerated and not shows any adverse reactions and serious complications of trial drug during entire period of clinical trial.

Keyword: *Amavata* , *Sameer Gaj Kesari Ras*, *Jvarhar Kwath*, *Baluka Sweda*

INTRODUCTION

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Gramya Many diseases spread over in society with the symptoms of *Angamarda*, *Aruchi*, *Balabhramsha*, *Trishna*, *Alasya*, *Gaurava*, *Jvara*, *Apaka*, *Shunatanganam.....etc.* *Amavata* is one of the challenging diseases for the physicians due to its chronicity, incurability, complications and mor-

Shoolahara, Vibandhahara, Vishaghna and Rasayana properties. Modern medical science has concluded that even after administration of their best drugs. The disease has a tendency to persist progress and cripples the patient. The clinical presentation of *Amavata* closely mimics with the special variety of Rheumatological disorders called Rheumatoid Arthritis, in accordance with their similarities on clinical features¹ like Pain, joint swelling, stiffness, fever, fatigue, anorexia, general debility are almost identical to that of *Amavata*, Modern Medicine provides the symptomatic relief but the underlined pathology goes on unchecked due to absence of effective therapy.

RA affects approximately 0.5 – 1% of the adult population world – wide. Like many other autoimmune diseases, RA occurs more commonly in females than in males, with a 3:1 ratio. The incidence of RA increases between 25 and 55 years of age, after which it plateaus until the age of 75 and then decreases². The WHO-ILAR COPCORD study covered over 55,000 individuals at 12 sites in India, and recorded a prevalence of 0.34 per cent, when projected over a population of 1.25 billion, still produces the theoretical figure of 4.25 million RA patients across the country³.

Amavata the term derives from the words as “Ama” and “Vata”. *Ama* is a type of Metabolic Toxin; it is an essential factor in the development of pathology⁴. *Mandagni* (Low digestive fire) produce *Ama* in the body⁵, when *Ama* gets associated with vitiated *vata* and starts circulating in the body and occupies in *sleshma sthana* (*Asthi Sandhi*) results in painful disease ‘ ‘ *Amavata* ’ ’⁶.

According to the nature of disease it is essential to work on such therapy which detoxified the *Amavisa* and *Vatahara* properties. In *Shaman* drug *Sameer Gaj Kesari Ras* contains *Ahiphena*, *Kupilu* and *Parada Visha* in form of *Hingula*, these drugs combination are very effective *Vedanasthapaka*, *Vata-shamaka* and *Amapachana* properties will help to disrupt the *Samprapti Vighatana* of *Amavata*.

Second *Shaman yoga* is *Jvarhar Kwath* is a combination of drugs having *Jvarghna*, *Amapachana*, *Vatashamaka*, *Vedanasthapaka*, *Srotoshodhaka*,

Shoolahara, *Vibandhahara*, *Vishaghna* and *Rasayana* properties.

In *Swedana* therapy, *Baluka Sweda* has been chosen for this study because it is easy to prepare and easily available. *Baluka Sweda* is a type of *Ruksha Sweda*, it removes *Ama* from the local site and it is an effective procedure to reduce the *Sandhishoola*, *Sandhistabdhatata* and *Sandhishotha*.

Aims and Objectives –

Present Research work has been undertaken with the following objectives

- To evaluate clinically the effect of *Shula Prashaman*, *Shotha Prashaman* and *Ama Pachan Prabhav*.
- To compare the effect of *Sameer Gaj Kesari Ras* and *Jvarhar Kwath* with *Baluka Sweda* and without *Baluka Sweda*.

Materials and Methods: -

These are embodied materials for the present study-

1. Research Proforma – To note all information.
2. Test Drugs - *Sameer Gaj Kesari Ras*, *Jvarhar Kwath* and *Baluka Sweda*.
3. Chemicals and Reagents – Required for various hematological investigation.
4. Honorable Patients, various equipments etc. required for study.

Plan of Study:-

1. 30 Patients will be selected randomly for the comparative clinical study of *Amavata*.
2. Patients will be selected from OPD/IPD from NIA, Jaipur.
3. They will be classified in to two groups 15 patients each group randomly.

A. Criteria for Selection of Patients.

Inclusion Criteria

1. The patients between the age group of 16 to 70 years of either sex.
2. Presenting clinical features of *Amavata*.
3. Patient willing to sign the consent forms.

Exclusion Criteria

1. Patients of age below 16 years and above 70 years of either sex.
2. Chronicity of *Amavata* more than 10 years.
3. Patients having severe crippling deformities.

4. Patients suffering from paralysis.
5. Patients having neoplasm of spine, Gout, Ankylosing, spondylitis, traumatic arthritis Osteoarthritis and pyogenic Osteomyelitis etc.
6. Patients having associated Cardiac disease, Pulmonary Tuberculosis, Diabetes Mellitus, Malignant Hypertension, Renal Function Impairment, etc.
7. Patients with extremely reduced joint space.
8. 8. Patients with bone deformity .
9. Pregnant women and lactating mother.

Test Drugs:-

Sameer Gaj Kesari Ras is selected as *shaman yoga* mentioned in *Ras Tantra Sara and Siddha Prayoga Sangraha (First Part) in Kharliya Rasayan Prakran,*

Ingredients of - Jvarhar Kwath :

SN	SANSKRIT NAME	BOTANICAL NAME	PART USED	QUANTITY
1.	<i>Musta</i>	<i>Cyperus rotundus</i>	Rhizome	1 part
2.	<i>Raktachandana</i>	<i>Pterocarpus santalinus</i>	Heartwood	1 part
3.	<i>Haritaki</i>	<i>Terminalia chebula.</i>	Fruit	1 part
4.	<i>Vibhitaka</i>	<i>Terminalia bellirica</i>	Fruit	1 part
5.	<i>Amalaki</i>	<i>Emblica officinalis</i>	Fruit	1 part
6.	<i>Kutaja</i>	<i>Holarrhena antidysentrica</i>	Bark	1 part
7.	<i>Guduchi</i>	<i>Tinospora cordifolia</i>	Stem	1 part
8.	<i>Katuki</i>	<i>Picrorhiza kurroa</i>	Root	1 part
9.	<i>Madhuyasti</i>	<i>Glycyrrhiza glabra</i>	Root	1 part
10.	<i>Kiratatikta</i>	<i>Swertia chirata</i>	Whole plant	1 part
11.	<i>Haridra</i>	<i>Curcuma longa</i>	Tuberous root	1 part
12.	<i>Nimba</i>	<i>Azadirachta indica</i>	Bark	1 part
13.	<i>Tulasi</i>	<i>Ocimum sanctum</i>	Leaf	1 part

Method of Preparation –

Above drugs were taken in equal proportion and converted into the *yavakuta churna* form. This drug was prepared in pharmacy of NIA Jaipur.

Dose - Jvarhar Kwath 50 ml 3 times in a day for 30 days.

Baluka Sweda : Application of the heat and there by inducing perspiration by using heated pack of sand is known as *Baluka Sweda*. It is a type of *Ruksha Sweda* and *Tapa Sweda*. In *Baluka Sweda* Body part is subjected to sudation procedure without prior application of oil, and is the unique feature of this treatment. For the same reason in diseased conditions where *snehana* is contraindicated, *Svedana* is best done by this procedure. *Ruksha Sweda* (Dry

It is an approved book of *Ayurvedic* systems of Medicine, The First Schedule and included in The Drugs and Cosmetics Act, 1940. Other *shaman yoga* is *Jvarhar Kwath*, It is an *Anubhuta Yoga* prepared in N.I.A. Pharmacy and use in N.I.A. Hospital to treat *Jvara*.

Ingredients of - Sameer Gaj Kesari Ras :

Shudh Hingula— 1 part (25%)

Shudh Ahiphena— 1 part (25%)

Shudh Kupilu— 1 part (25%)

Maricha— 1 part (25%)

Bhavana dravya— *Ardraka swarasa* (q.s.)

Dose: Sameer Gaj Kesari Ras (Each tab 125 mg) BD after meal for 30 days.

fomentation) of sand bag was prepared by heating the sand & making a cloth bag (*pottali*) for application.

Duration: 10 to 20 minutes.

B. Administration of Drug

30 clinically diagnosed & registered patients of *AmaVata* will be divided randomly into two groups each group will have 15 patients.

Group A—15 clinically diagnosed & registered patients of *AmaVata* will be treated by *Sameer Gaj Kesari Ras*. (Each table 125 mg) 1 tab with Luke warm water, after meal two times in a day and *Jvarhar Kwath* 50 ml 3 times in a day.

Group B—15 clinically diagnosed & registered patients of *AmaVata* will be treated by *Sameer Gaj*

Kesari Ras. (Each table 125 mg) 1 tab with Luke warm water, after meal two times in a day, Jvarhar Kwath 50 ml 3 times in a day and Baluka Sweda (Swelled and painful Joints).

Duration: —30 days.

C. Criteria for withdrawal

1. During the course of trial if any serious condition or any serious adverse effect occur which require urgent treatment?
2. Patients himself wants to with draw from the clinical trial will be permitted to quit.

Criteria for Assessment:-

All registered patients will be examined as per plan of study and finding observation will be noted on the research proforma specially prepared for this purpose. The following sign and symptoms of *Amavata* will be assessed for any improvement after the course of therapy. (Ref- *Madhava Nidana Amavatanidana 25/6*).

a) Subjective Parameter:-

1. *Sandhishoola* (pain in joint)
2. *Sandhishotha* (swelling of joint)
3. *Angmarda* (Bodyache)
4. *Aruchi* (Anorexia)
5. *Trishna* (Polydipsia)
6. *Alasya* (Lassitude)
7. *Gaurava* (Heaviness of body)
8. *Jwara* (Fever)
9. *Apaka* (Indigestion of food)
10. *Kostha Baddhata* (Constipation)
11. *Bahumutrata* (Polyuria)

The following sign and symptoms of Rheumatoid Arthritis were assessed for any improvement before and after the course of therapy.

1. Pain in joint
2. Stiffness of joint
3. Swelling of joints
4. Restriction of movement
5. Fever
6. Tenderness at joint.

• **Assessment of Subjective parameters-**

Clinical assessment of the disease, its severity, extent and grades of inflammation were objectively done in terms of Pain in joint by Visual Analogue Scale. The relative extent of all these criteria- Stiffness of joints, Swelling of joint, Restriction of movement, Tenderness of joints.& *Angmarda, Aruchi, Trishna, Alasya, Gaurava, Jwara, Apaka, KosthaBaddhata Bahumutrata* were recorded according to the rating scales in each patient at the initial stage . These are measured by simple count of clinically active joints.

1. Pain in joint:-

Assessment of pain will be done by Visual Analogue Scale-

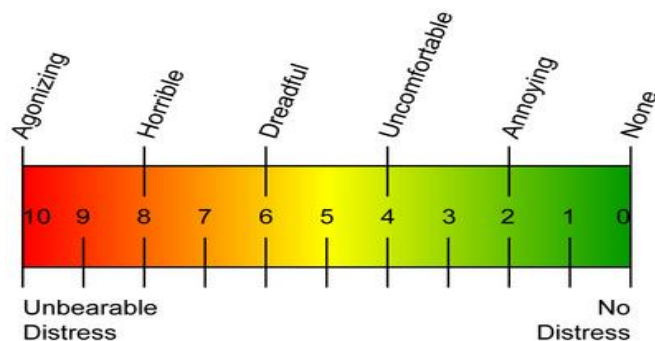


Table no. 1: Assessment of pain will be done by Visual Analogue Scale-

Sr. No.	Symptoms	Grading
1	No pain	00
2	Distress	01
3	Annoying (Pain is present but does not limit daily activity)	02 - 03
4	Uncomfortable (Can do most activity with Pain)	04
5	Dreadful (Unable to do some activity because of pain)	05 - 06
6	Horrible (Unable to do most activity because of pain)	08
7	Unbearable distress	09
8	Agonizing	10

Table 2. Stiffness in joint.

Sr. No.	Symptoms	Grading
1	No stiffness	00
2	< 15 min.	01
3	< 30 min.	02
4	< 1 hrs.	03
5	> 1 hrs	04

Table 3. Swelling of joint-

Sr.No.	Symptoms	Grading
1	No swelling	00
2	Felling of swelling	01
3	Felling of swelling + Heaviness	02
4	Apparent swelling	03
5	Huge (Synovial effusion) swelling.	04

Table 4. Restriction of movement-

Sr.No.	Symptoms	Grading
1	No symptoms / Free movement of joint.	00
2	Mild restriction of movement	01
3	Moderate restriction of movement	02
4	Severe restriction of movement	03
5	Unable to do movement of joint	04

Table 5. Tenderness at joint:-

Sr.No.	Symptoms	Grading
1	No tenderness	00
2	Says tender	01
3	Patient winces	02
4	Winces and withdraws	03
5	Not allowed to be touched	04

Table 6. Angmarda (Bodyache) :

Sr.No.	Symptoms	Grading
1	Nobody ache	00
2	Generalized body ache of and on during the day	01
3	Generalized body ache during most part of the day not affecting any work	02
4	Generalized body ache throughout the day but person is able to do normal routine	03
5	Generalized (<i>sarvanga</i>) bodyache/pain enough to affect routine work for all the day	04

Table 7. Aruchi (Anorexia):

Sr.No.	Symptoms	Grading
1	Willing toward all <i>Bhojya Padarth</i>	00
2	Unwilling toward some specific <i>Ahara</i> but less than normal	01
3	Unwilling toward some specific <i>rasa</i> i.e <i>Katu/Amala/Madhura</i> food	02
4	Unwilling for food but could take the meal	03
5	Totally unwilling for meal	04

Table 8 Trishna (Excessive thirst):

Sr.No	Symptoms	Grading
1	Feeling of thirst (7– 9 times/24 hours) & relieved by drinking water	00
2	Feeling of moderate thirst (>9 -11 times/24 hours) & relieved by drinking water.	01
3	Feeling of excess thirst (>11 – 13 times/24 hours) not relieved by drinking water.	02
4	Feeling of sever thirst (>13 times) not relieved by drinking water	03

Table 9. Alasya (Lazyness / Absence of enthusiasm):

Sr.No.	Symptoms	Grading
1	No <i>Alasya</i> (doing satisfactory work with proper vigor & in time)	00
2	Doing satisfactory work/late initiation, like to stand in comparison to walk.	01
3	Doing unsatisfactory work/late initiation, like to sit in comparisonto stand	02
4	Doing little work very slow,like to lie down in comparison to sit.	03
5	Don't want to do work/no initiation, like to sleep in comparison to lie down	04

10. Gaurava (Heaviness):

Sr.No.	Symptoms	Grading
1	No feeling of heaviness	00
2	Occasional feeling of heaviness	01
3	Continuous feeling of heaviness, but patient does usual work	02
4	Continuous feeling of heaviness which hampers usual work	03
5	Unable to do any work due to heaviness	04

Table 11. Jwara (Fever) :

Sr.No.	Symptoms	Grading
1	No fever	00
2	Occasional fever subsides by itself	01
3	Daily once subsides by itself	02
4	Daily once subsides by drug	03
5	Continuous fever	04

Table 12. Apaka (Indigestion of food)-

Sr. No.	Symptoms	Grading
1	No <i>Apaka</i> /Indigestion	00
2	Indigestion / prolongation of food digestion period occasionally related to heavy meal	01
3	<i>Avipaka</i> occurs daily after each meal takes four to six hour for <i>Udagara shuddhi</i> etc	02

	Lakshana	
4	Eat only once in a day and does not have hungry by evening	03
5	Never gets hungry always feeling heaviness in abdomen	04

Table 13. Koshtha Baddhata:-

Sr.No.	Symptoms	Grading
1	Absent	00
2	Occasional or intermittent symptoms relived by laxative	01
3	Persistent symptoms relived by regular use of laxative	02
4	Constipation relived by manual evacuation	03

Table 14. Bahumootrata (frequency of micturition per 24 hours):-

Sr. No.	Symptoms	Grading
1	Less than 4 times/24 hrs	00
2	4 - 6 times/24 hrs.	01
3	6-10times/24hrs	02
4	> 10 times/24 hrs	03

Objective parameters (laboratory profile):

For the purpose of diagnosis of disease its assessment, severity, clinical improvement and to assess the possible side effects, certain routine and specific investigations were performed in every patients.

1. Hematological Investigations:

1. Hemoglobin (Hb%)
2. Total Leucocytes Count (TLC)
3. Differential Leucocytes Count (DLC)
4. Erythrocyte Sedimentation Rate (ESR)
5. Blood Sugar Level (Fasting) [BSL (F)]
6. Serum Uric Acid.
7. C-Reactive Protein (CRP)
8. Rheumatoid Arthritis Factor (RA factor)

A detail proforma will be created to carry out this study in a scientific way. All data related to patient along with sign and symptom of disease will be noted. The result will be presented in the form of table, graph and diagram. Data obtained during the study will be analyzed statistically by using appropriate test of significance suitable for the study.

Statistical Analysis:

The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard

Deviation(SD) and Standard error (SE). In Stat Graph Pad 3 software was used & For Nonparametric Data Wilcoxon **on matched-pairs signed ranks test** is Used While for Parametric Data **Paired 't' Test** is used.

For intergroup comparisons, of **nonparametric variables** we used **Mann-Whitney Test** for statistical analysis & for the **parametric data**, we used **Unpaired 't' test**. The results were calculated.

- Insignificant : $P > 0.05$
- Significant : $P < 0.05$
- Highly significant: $P < 0.01$, $P < 0.001$, $P < 0.0001$.

Observations & Results:-

Study had shown that overall 60% patients belong to 3rd to 5th decade of life. Incidence of disease is found notably higher in females (86.67%) than in males (13.33%) i.e. (6.5:1). Majority of the patients (60%), belonged Hindu religion; 93.33% patients were married. Out of which, maximum 76.67% patients were housewives, about 70% patients belong to Middle class. Max. 50% Patients of *Vata-Kaphaj Prakriti* which highly associated with the development of *Amavata*, 53.33% patients showed *Madhyama Ahara Shakti*, 46.67% patients showed *Avara Ahara shakti*, 73.33% patients showed

Madhyama nature of *Koshtha* whereas 26.67% patients with *Kroora Koshth*, maximum 76.67% patients were of *Mandagni*. In this type of *Kostha & Agni* there is predominance of *Vata & Kapha Dosha*, which may play important role in developing the pathogenesis of *Amavata*, maximum addicted 90% patients found were Tea addiction, maximum 53.33% patients found duration of illness < 2 yrs, 83.33% patients have positive drug history of Allopathic & *Ayurvedic* medicine, maximum patients were found taking *Ati Guru Ahara* 80% then *Singdha Ahara* 76.66%, *Ati Madhura* 53.33%, *Atidrava Ahara* 50%, *Adhyashana* 76.66%, *Vishamashana* 70%, *Divasvapna* and *Nishchalata* 76.66%, *Bhojanottara Shrama & Ratri Jagarana* 63.33%, *Chinta* 43.33%, *Bhaya* 16.66%, *Shoka* 10%, 16.67% patients have positive family history of the disease, maximum 56.67% patients have CRP & 23.33% patients have RA factor positive before the treatment, 100% patients have pain in joint, stiffness of joint, swelling of joint, *Angamarda* and *Jwara*; 96.66% patients have complaint of *Aruchi*, 93.33% patients have complaint of Tenderness at joint, 80% patients have complaint of Restriction of movement, *Alasya*, *Gaurava*, *Apaka*,

Koshtha Baddhata, 40% patients have Complaint of *Trishna*, 36.67% patients have complaint of *Bahumutrata* before the treatment, maximum 93.33% patients were have proximal interphalangeal (hand) joint involvement, 73.33% Metacarpophalangeal, 26.67% distal interphalangeal (hand) joint, 80% wrist joint, 63.33% elbow joint, 26.67% shoulder joint, 60% ankle joint, 53.33% knee joint involvement, 66.67% Metatarsophalangeal and 3.33% had temporomandibular joint involvement.

Results:-

All the Results are calculated by using Software: In Stat Graph Pad 3.

- For Nonparametric Data **Wilcox on matched-pairs signed ranks test** is used while for Parametric Data **Paired ' t ' Test** is used and results calculated in each group.
- For calculating the Inter group comparison, **Mann-Whitney Test & Unpaired ' t ' Test** was used.

Table: A- Showing Effect of Therapy in Subjective Parameters. (Wilcox on matched pairs signed ranks test)

Subjective Parameter	Gr.	Mean		Mean Diff.	% Relief	SD±	SE±	P	Remark
		BT	AT						
Pain in joint	Gr. A	4.53	3.47	1.07	23.62	0.7037	0.1817	0.0005	HS
	Gr. B	4.60	2.46	2.13	46.36	0.5164	0.1333	<0.0001	HS
Stiffness of joint	Gr. A	2.00	1.33	0.67	33.33	0.4880	0.1260	0.002	HS
	Gr. B	2.53	1.07	1.46	57.91	0.5164	0.1333	<0.0001	HS
Swelling of joint	Gr. A	1.27	0.80	0.47	36.83	0.5164	0.1333	0.0156	S
	Gr. B	1.87	0.87	1.00	53.56	0.5345	0.1380	0.0002	HS
Restriction of move....	Gr. A	1.00	0.53	0.47	46.67	0.5164	0.1333	0.0156	S
	Gr. B	1.33	0.60	0.73	55.01	0.4577	0.1182	0.001	HS
Tenderness at joint	Gr. A	1.13	0.67	0.47	41.19	0.5164	0.1333	0.0156	S
	Gr. B	1.80	0.53	1.27	70.38	0.5936	0.1533	0.0001	HS
<i>Angmarda</i>	Gr. A	2.07	1.13	0.93	45.15	0.7037	0.1817	0.001	HS
	Gr. B	2.33	1.40	0.93	39.91	0.7037	0.1817	0.001	HS
<i>Aruchi</i>	Gr. A	1.33	0.60	0.73	55.01	0.7037	0.1817	0.0039	VS
	Gr. B	1.73	0.93	0.80	46.16	0.7746	0.2000	0.0039	VS
<i>Trishna</i>	Gr. A	0.47	0.33	0.13	28.56	0.5164	0.1333	0.3750	NS
	Gr. B	0.93	0.67	0.27	28.57	0.4577	0.1182	0.1250	NS
	Gr. A	1.33	0.80	0.53	39.84	0.5164	0.1333	0.0078	VS

<i>Alasya</i>	Gr. B	1.53	0.87	0.67	43.48	0.6172	0.1594	0.0039	VS
<i>Gaurava</i>	Gr. A	1.27	0.60	0.67	52.62	0.6172	0.1594	0.0039	VS
	Gr. B	1.47	0.67	0.80	54.53	0.6761	0.1746	0.0020	VS
<i>Jwara</i>	Gr. A	1.53	0.33	1.20	78.27	0.4140	0.1069	0.0001	HS
	Gr. B	1.73	0.47	1.26	73.11	0.5936	0.1533	0.0001	HS
<i>Apaka</i>	Gr. A	1.53	0.80	0.73	47.83	0.7037	0.1817	0.0068	VS
	Gr. B	1.60	0.80	0.80	50	0.7746	0.2000	0.0049	VS
<i>Koshtha Baddhata</i>	Gr. A	0.80	0.73	0.07	8.33	0.5936	0.1533	0.8125	NS
	Gr. B	1.13	1.07	0.07	5.88	0.7037	0.1817	0.8125	NS
<i>Bahumutrata</i>	Gr. A	1.27	1.07	0.20	15.78	0.4140	0.1069	0.2500	NS
	Gr. B	1.07	0.80	0.27	24.99	0.4577	0.1182	0.1250	NS

(HS: Highly Significant VS: Very Significant S: Significant NS: Non Significant)

Table:B - Intergroup Comparison of Group A & Group B for Subjective Parameters: (Mann-Whitney Test)

Subjective Parameter	Groups	(AT) Mean	SD±	SE±	P	Remark
Pain in joint	A	1.07	0.7037	0.1817	0.0002	HS
	B	2.13	0.5164	0.1333		
Stiffness of joint	A	0.67	0.4880	0.1260	0.0007	HS
	B	1.47	0.5164	0.1333		
Swelling of joint	A	0.47	0.5164	0.1333	0.0135	S
	B	1.00	0.5345	0.1380		
Restriction of movement	A	0.47	0.5164	0.1333	0.1496	NS
	B	0.73	0.4577	0.1182		
Tenderness at joint	A	0.53	0.5164	0.1333	0.0027	VS
	B	1.27	0.5936	0.1533		
<i>Angmarda</i>	A	0.93	0.7037	0.1817	0.9818	NS
	B	0.93	0.7037	0.1817		
<i>Aruchi</i>	A	0.73	0.7037	0.1817	0.8573	NS
	B	0.80	0.7746	0.2000		
<i>Trishna</i>	A	0.13	0.5164	0.1333	0.5010	NS
	B	0.27	0.4577	0.1182		
<i>Alasya</i>	A	0.53	0.5164	0.1333	0.6026	NS
	B	0.67	0.6172	0.1594		
<i>Gayrava</i>	A	0.67	0.6172	0.1594	0.6097	NS
	B	0.80	0.6761	0.1746		
<i>Jwara</i>	A	1.20	0.4140	0.1069	0.6591	NS
	B	1.27	0.5936	0.1533		
<i>Apaka</i>	A	0.73	0.7037	0.1817	0.8092	NS
	B	0.80	0.7746	0.2000		
<i>Koshtha Baddhata</i>	A	0.07	0.5936	0.1533	>0.9999	NS
	B	0.07	0.7037	0.1817		
<i>Bahumutrata</i>	A	0.20	0.4140	0.1069	0.6920	NS
	B	0.27	0.4577	0.1182		

(HS: Highly Significant VS: Very Significant S: Significant NS: Non Significant)

Table: Showing effect of Therapy on Lab Investigations (Objectives parameters) (Paired ‘t’ Test)

Objective Parameter	Group	Mean		MeanDiff.	% Relief	SD±	SE±	T	P	Remark
		BT	AT							
Hb% (gm %)	Gr. A	12.48	12.64	0.15	1.20	0.3270	0.0844	1.816	0.09	NS
	Gr. B	11.62	11.78	0.16	1.38	0.4579	0.1182	1.353	0.19	NS
TLC	Gr. A	7100	7026	73.33	1.03	291.47	75.25	0.9744	0.34	NS
	Gr. B	8793	8653	140	1.59	954.54	246.46	0.5680	0.57	NS
ESR	Gr. A	27.87	24.40	3.47	12.45	4.67	1.20	2.873	0.01	S
	Gr. B	41.13	34.20	6.93	16.85	8.34	2.15	3.221	0.006	VS

(Hb-Haemoglobin; TLC-Total Leucocytes Count; ESR-Erythrocyte Sedimentation Rate)

Table C: Intergroup Comparison of Group A & Group B for Lab investigation (Unpaired t Test)

Objective Parameter	Groups	(AT) Mean	SD±	SE±	t value	P	Remark
Hb%	A	0.1533	0.3270	0.0844	0.04588	0.96	NS
	B	0.1600	0.4579	0.1182			
TLC	A	-73.33	291.47	75.26	0.2587	0.79	NS
	B	-140	954.54	246.46			
ESR	A	-3.47	4.673	1.207	1.405	0.17	NS
	B	-6.93	8.336	2.152			

Table D: Showing the % Relief in Both the Groups in Subjective parameters:

Subjective parameters	% Relief in Group A	% Relief in Group B
Pain in joint	23.62	46.36
Stiffness of joint	33.33	57.91
Swelling of joint	36.83	53.56
Restriction of movement	46.67	55.01
Tenderness at joint	41.19	70.38
Angamarda	45.15	39.91
Aruchi	55.01	46.16
Trishna	28.56	28.57
Alasya	39.84	43.48
Gaurava	52.62	54.53
Jwara	78.27	73.11
Apaka	47.83	50
Koshtha Baddhata	8.33	5.88
Bahumutrata	15.78	24.99

Table E: Showing the % Relief in Both the Groups in Lab. investigation (Objective parameters)

Subjective parameters	% Relief in Group A	% Relief in Group B
Hb%	1.20	1.38
TLC	1.03	1.59
ESR	12.45	16.85

Overall Effects of Therapy -**Table F: For assessment of improvement in Clinical Manifestations following grading will be used:-**

Sr. No.	Observation	Percentage
1.	No relief	0%
2.	Mild relief	1-25%
3.	Moderate relief	26-50%
4.	Significant relief	51-75%
5.	Excellent relief	76-100%

Effects	Group A		Group B	
	No. of Patients	Percentage	No. of Patients	Percentage
No relief (Unchanged)	00	00	00	00
Mild relief	02	13.33	00	00
Moderate relief	08	53.33	05	33.33
Significant relief	05	33.33	06	40
Excellent relief	00	00	04	26.67

In group A - significant relief in 33.33%, moderate relief in 53.33% whereas 13.33% were found mild relief, while in group B- Excellent relief was found in 26.67% of patients, while significant relief in 40%, whereas 33.33% were found moderate relief.

Thus, in group B maximum number of patients i.e. 40% showed Significant relief & 26.67% showed Excellent relief, while in group A maximum number of patients i.e. 53.33% showed Moderate relief & 33.33% showed Significant relief.

DISCUSSION

The improvement was statistically highly significant in both the groups in pain in joint, stiffness, *angmarda*, *jvara* but comparatively better results were observed in pain, stiffness, swelling of joint, restriction of movement and tenderness in group B, may be because of the properties of *Swedana* therapy, *Baluka Sweda* is a type of *Ruksha Sweda*, it removes *Ama* from the local site and it is an effective procedure to reduce the *Sandhishoola*, *Sandhistabdhatata* and *Sandhishotha*.

Probable Mode of Action of the Therapy:-**1. Probable mode of action of Sameer Gaj Kesari Ras:-**

Sameer Gaj Kesari Ras is selected as *shaman yoga* mentioned in *Ras Tantra Sara and Siddha Prayoga Sangraha (First Part)* in *Kharliya Rasayan Prakran*, Contents of *Sameer Gaj Kesari Ras*, *Hingula*, *Ahiphena*, *Kupilu*, *Maricha*, in the proportion of 1:1:1:1 i.e. all drugs having equal proportion and *Bhavana Dravya* is *Ardra swarasa*. According to the nature of disease it is essential to work on such therapy which detoxified the *Amavisa* and *Vatahara* properties. In *Shaman drug Sameer Gaj Kesari Ras*, *Katu*, *Tikta* are dominant *Rasa*, *Ushna*, *Laghu*, *Teekshna* are dominant *Guna* and all *Dravya* having *Ushna Veerya*. These Pharmacodynamic Properties help in *Ama Pachana* and amelioration of vitiated *vata* and finally in breakage of pathogenesis of disease. These Drugs combination are very effective *Vedanasthapaka*, *Vatashamaka*, *Sothahara* properties. So these combinations were effective to relieve the pain and swelling, which were the chief complaints of the patients.

2. Probable mode of action of Jvarhar Kwath:-

The contents of *Jvarhar Kwath* are *Musta*, *Raktachandana*, *Haritaki*, *Vibhitaka*, *Amalaki*, *Kutaja*, *Guduchi*, *Katuki*, *Madhuyasti*, *Kiratatika*, *Haridra*, *Nimba* and *Tulasi*, all these contents are in

equal proportion. Properties of individual contents of this formulation are as following:-

1. *Triphala* having *Tridoshashamaka*, *Deepana*, *Pachana*, *Jvaraghna*, *Shothahara*, *Vedanasthapaka*, *Virechana* and *Rasayana* properties help in *Amapachana*. It also helps in reducing *Vibandha*, *Aruchi*, *Agnimandya*, *Shotha* and *Jwara*.
2. *Musta* having *Tikta*, *Katu Rasa*, *Laghu*, *Ruksha Guna*, *Katu Vipaka* help in *Deepan*, *Pachana* and use in *Jwara*, *Aruchi*.
3. *Raktachandan* with its *Tikta*, *Madhura Rasa* use in *Trishna*, *Jwara*.
4. *Kutaja* with its *Tikta*, *Katu Rasa* and *Katu Vipaka* help in *Deepana*, *Pachana* and use in *Amadosa*, *Jwara*.
5. *Guduchi* is a well known *Rasayana* and *Tridoshaghana* drug. Considering chronicity nature of the disease, it is very useful for treating the disease and also maintaining the health of the patients. *Guduchi* is also proved to have anti-rheumatic, anti-inflammatory and immune-stimulant properties. Due to chronic nature of the disease, the patients remain in the state of general debility (*Dourbalya*). Being *Rasayana* this drug improved the quality of *Dhatu* production and also brought the *Dushti* of *Dhatu* (*Dusya*) to a normal state.
6. *Katuki* with its *Tikta Rasa*, *Laghu*, *Ruksha Guna* and *Katu Vipaka* helps in *Deepana*, *Bhedana Karma*, use in *Arochaka*, *Agnimandya*, *Vibandha*, *Jwara*.
7. *Madhuyasti* having *Madhura Rasa*, *Madhura Vipaka*, *Sheeta Virya*, *Tridoshahara*, *Rasayana* properties use in *chardi*, *Trishna*, *Visha*, *Vata Vikara*, *Jwara*.
8. *Kiratatikta* with its *Tikta Rasa*, *Laghu*, *Ruksha Guna*, *Ushna Virya*, *Katu Vipaka* properties helps in *Deepana*, *Pachana*, *Amapachana*, *Anulomana*, *Sothahara*, *Jvaraghna Karma*, use in *Agnimandya*, *Ajirna*, *Vibandha*, *Jwara*.
9. *Haridra* having *Katu*, *Tikta Rasa*, *Ruksha Guna*, *Ushna Veerya*, *Katu Vipaka* Properties, use in *Visha*, *Aruchi*, *Shotha*.
10. *Nimba* having *Tikta Rasa*, *Laghu Guna*, *Sheeta Virya*, *Katu Vipaka* properties helps in *Vedanasthapana*, *Rochana*, *Amapachana*, *Sothahara*, *Jva-*

raghna, *Vishaghna Karma*, use in *Aruchi*, *Chardi*, *Vibandha*, *Amlapitta*, *jwara*.

11. *Tulasi* having *Katu*, *Tikta Rasa*, *Laghu*, *Ruksha Guna*, *Ushna Veerya*, *Katu Vipaka* helps in *Deepana*, *Pachana*, *Anulomana*, *Vatahara*, *Sothahara*, *Jvaraghna Karma* use in *Agnimandya*, *Ajirna*, *Chardi*, *Jwara*.

Jvarhar Kwath is a combination of drugs having *Jvarghna*, *Amapachana*, *Vatashamaka*, *Vedanasthapaka*, *Srotoshodhaka*, *Shoolahara*, *Vibandhahara*, *Vishaghna* and *Rasayana* properties. So, this combination is very effective to relieve the symptoms of *Amavata*.

3. Probable mode of action of *Baluka Sweda*:-

Svedana Therapy increased metabolic activity; increases blood flow circulation in the affected area making available an increased supply of oxygen, nutrients and antibodies, there by reduces inflammation. Pain may be subsided, removal of waste products from the tissue by the vasodilatation provided by heat of *Svedana*. *Baluka Sweda* is a *Ruksha* type of *Sweda*. It is the Procedure which relieves the pain, stiffness, heaviness and coldness of the body, produce sweating. *Swedana* increases the *Dhatwagni* at level of joint, thereby improving joint function and its mobility. *Baluka Sweda* is mostly used in *Kaphaja* disorders and disease originated out of *Ama*, especially in *Amavata*. Being dry in nature it does digestion of *Ama* and clean the micro channels. It removes stiffness of the joint and alleviates the pain. So it helps in relieving pain, stiffness and swelling in treatment of *Amavata*.

CONCLUSION

On evaluation of the knowledge of the literature and result obtained from present work, it may be concluded that:-

- Most of the patients Registered in this clinical trial were taking *Ati Guru*, *Snigdha Ahara* followed by *Atidrava Ahara*, which causes *Kapha Prakopa* and finally leads to *Mandagni* which is responsible for production of *Ama*. In view of *Vihara* most of the patients were taking *Viruddha* – *Cheshta* like *Divasvapna*, *Nishchalata*, *Bhojanottara Shrama* which again provoke the

production *Ama*. Production of *Ama* plays an important role in the *Samprapti* of *Amavata*.

- The Clinical presentation of *Amavata* closely mimics with the special variety of Rheumatological disorders called Rheumatoid Arthritis.
- From this study, it is concluded that *Viruddha-Ahara* and *Viruddha-Vihara* plays a major role in pathogenesis of disease. Hence, we can say that healthy food habits and lifestyle must be followed to achieve early and better results of the disease.
- The improvement in symptoms of *Ama*, like *Gaurava*, *Alasya*, *Aruchi*, *Apaka* were statistically very significant in both the groups.
- As per clinical observation and statistics the improvement was statistically highly significant in both the groups in pain in joint, stiffness, *angmarda*, *jwara* but comparatively better results were observed in pain, stiffness, swelling of joint, restriction of movement and tenderness in group B, may be because of the additive effect of *Swedana* therapy.
- The overall effect of *Sameer Gaj Kesari Ras* and *Jvarhara Kwath along with Baluka Sweda* was found to be better in management of *Amavata*.
- The therapy has well tolerated and not shows any adverse reactions and serious complications of trial drugs during entire period of clinical trial.
- The only unwanted effect of the drug is mild weight loss in some patients
- Although this study was conducted on small sample size with limited duration, hence any concrete conclusion may be premature but it is expected that the present study will disclose some definite clues to the future researchers.

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