

CLINICAL STUDY OF CHARAKOKTA “SHOOLPRASHAMAN MAHAKASHAYA” IN AMAVATA

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INTRODUCTION

Today pain is a serious public health issue. Now a days pain is probably the commonest and biggest problem seen in human beings. It may be due to inflammation or injuries. According to ayurvedic perspective *Vata* & *Kapha* is the main *dosha* involved in pain & inflammation. *Amavata* is the second most common joint disorder. *Amavata* is a disease caused due to aggravation of *Vayu* associated with *Ama*. The main causative factor, *Ama*, is caused due to malfunctioning of the digestive and metabolic mechanisms. Various drug trials were already carried out on *Amavata*, yet there is a lacuna in the management of *Amavata*. According to *Aacharya Charak shooplprashamana mahakashaya* can be used in any type pain in body (Ca.Su 4/17). It contains ten ingredients *Pipali*, *Pipali mula*, *Chavya*, *Chitark*, *Sunthi*, *Marich*, *Ajmoda*, *Ajgandha*, *Ajaji* and *Gandir* having *Agni Deepana*, *Pachana*, analgesic & anti-inflammatory properties which are useful to reduce pain. The purpose of my clinical study is to provide relief specially in pain & other associated symptoms in *amavata*.

AIMS AND OBJECTIVES

- To assess the clinical efficacy of “*Shooplprashaman Mahakashaya*” in the management of *Amavata* patients.
- Therapeutic uses of “*Shooplprashaman Mahakashaya*”.

MATERIALS AND METHODS

Source of data

- Hence, in the present clinical study, 60 patients were registered from the O.P.D. & I.P.D., Department of Samhita siddhant, Government (Auto.) Ayurved College Rewa, (M.P.), India, fulfilling the criteria selected for this study.

Inclusion criteria

- Patients fulfilling the diagnostic criteria, of either sex with age between 16 to 70 years.

- The patients who have come under the criteria in selected proforma based upon *Ayurvedic* literature and the “American Rheumatism Association” were selected and registered for detailed investigation and follow-up for the research work.
- For confirmation, all patients were investigated for CBC, ESR, RA Factor, Uric acid and Random Blood Sugar.

Exclusion criteria

- The patients who had deformities were excluded from the study, for example, ulnar deviation, swan neck deformities, Ankylosis of wrist and elbow, and so on.
- Patients having severe systemic illness diseases like hypertension, DM, MI, Chronic alcoholism, Pulmonary Tuberculosis, Hypertension, Epilepsy etc.

- Pregnant women.
- Chronicity more than 4 years.

Study design

- In the present study, selected patients were divided into two groups with 30-30 patients in each group.
- **Group A (Treatment Group):** In this group *Shoolprashaman Mahakashaya* was given the doses of 50 ml BD of Lukewarm *Kwatha* for 1 month with empty stomach. In group A, 26 patients were completed the treatment and 4 patient discontinued treatment in between.
- **Group B (Control Group):** In this group, 2 Capsules (Placebo drug) BD was given. In group B,

23 patients were completed the treatment and 7 patient discontinued treatment.

- **Duration of treatment:**– 30 days

Preparation of *Shoolprashaman Mahakashaya*

- *Shool Prashamana Mahakashaya* was prepared in Pharmacy of Govt. Ayurved College Rewa, (M.P.), India. Ingredients, part used and ratio of the drugs is given in Table. All ingredients were taken in equal quantity in the form of *Yavakuta* (coarse powder) and mixed thoroughly.

Content	Botanical name	Part used	Proportion
Pippali	<i>Piper longum</i>	Fruit	1-Part
Pippali mula	<i>Piper longum</i>	Root	1-Part
Chavya	<i>Piper Retrofractum Vahl.</i>	Stem	1-Part
Chitrak	<i>Plumbago zeylanica Linn.</i>	Root	1-Part
Sunthi	<i>Zingiber officinale Rosc.</i>	Rhizome	1-Part
Marica	<i>Piper nigrum</i>	Fruit	1-Part
Ajmoda	<i>Carum Roxburghianum</i>	Fruit	1-Part
Ajaji	<i>Cuminum cyminum Linn;</i>	Fruit	1-Part

Criteria for assessment

- After completion of therapy, scores were assessed and the symptoms of *Amavata* were graded on a four point scale scoring from 0 to 3.
- Laboratory investigations such as Hb%, TLC, DLC, ESR, RA Factor and RBS were also carried out before and after treatment.
- The obtained data, on the basis of the observation were subjected to statistical analysis in terms of Mean, Standard deviation and Standard error, and the 'Wilcoxon matched pairs signed ranks test, Mann-whitney U-statistic, Paired & Unpaired t- test conceded at a level of $P > 0.05$ (insignificant), $P < 0.05$ and $P < 0.01$ (significant), and $P < 0.001$ (highly significant) for the final results.

Criteria for assessment of the effect of therapy

Detailed clinical observations were done every week for the assessment of results and the final data has been divided into four groups.

- **Excellent(Complete remission):** complete or above 75% relief of signs and symptoms with normal ranges of laboratory investigations.
- **Good(Markedly improved):** 50 to 75% relief of the above-mentioned signs and symptoms and close to normal (above normal range) or with 50% reduction in their values in laboratory investigations.
- **Fair(Moderately improved):** 25 to 50% relief of signs and symptoms, and less than 50% reduction in their laboratory values.
- **Poor(Mild Improved):** less than 25% relief of signs and symptoms, and a laboratory test with no change.

OBSERVATIONS AND RESULTS

Most of the patients i.e. 28.33% belonged to 40 – 60 years of age group. 51.66% patients were Female, 71.67% patients were Hindu, 81.67% patients were Married, 48.33% patients were Housewives (as, maximum patients were middle aged female), 41.66% were Uneducated, 60% were vegetarian, 61.67% were coming from Middle class, 57.00% were in Rural habitat. Maximum patients i.e. 81.67% were having Negative Family history, 80.25% patients were having Gradual Onset, 92.35% patients were having Relapsing Course and 44.46% were having Chronicity of less than 2 years, 80.21% patients were of Poor Appetite, 43.66% were *Krura Kostha* (Constipated). All the patients suffered more in *Varsha ritu* (Rainy season) & *Shita ritu* (winter season). Cold and moist environment was Aggravating factor for all the patients. R.A. factor positive was found in 23.31% patients and it supports the criteria of Rheumatoid arthritis by the American Rheumatology Association in 1988 that R. A. Factor positive is not a compulsory criteria for Rheumatoid arthritis, Rheumatoid nodule and Deformity were observed in 19.13% and 4.06% patients respectively. In majority of patients (92.33%) wrist joint was involved along with Metacarpophalangeal (83.13%), Metatarsphalangeal (81.47%), Ankle (81.04%), Knee (72.36%), Elbow (24.37%), PIP (25.55%), Shoulder (10.21%), Hip (3.45%), Jaw (3.33%), DIP (6.33%), Lumbo-sacral (4.41%) and Cervical (2.32%) joints were involved. According to *Samanya Lakshana* (General clinical features) *Angamarda* (body ache), *Gaurava* (heaviness of the body) and *Agni-daurbalya* (impaired digestive capacity) were observed in 68.34%, 63.47% and 82.65% patients respectively. According to *Pratyatma Lakshana*

(Cardinal clinical features) all the patients were suffering from *Sandhishula* (Joint-pain), *Sandhi-shotha* (Joint-swelling), *Sandhi-stabdhata* (Joint-stiffness) and *Sandhisparshasahyata* (Joint-tenderness).

RESULTS

Symptoms	Group	Mean		Difference of Mean	% of Relief & Loss	SD	SE	Wilcoxon matched pairs signed- ranks test & P- value
		BT	AT					
<i>Angamarda</i> (Body ache)	A (N-26)	2.65	1.07	1.577	59.62	0.504	0.099	W=351, (n=26) P < 0.0001, H.S
	B (N-23)	2.17	2.35	-0.174	-8.29	0.717	0.150	W= -26, (n=12) P= 0.3394, N.S
	Mann – Whitney U-statistic = 22, U'= 576, P < 0.0001, H.S							
<i>Aaruci</i>	A (N-26)	1.73	0.38	1.346	78.03	0.797	0.156	W=231, (n=21) P < 0.0001, H.S
	B (N-23)	1.82	1.87	-0.043	-2.74	0.638	0.133	W= -5, (n=9) P=0.8203, N.S
	Mann – Whitney U-statistic = 69, U'= 529, P < 0.0001, H.S							
<i>Trishna</i>	A (N-26)	0.88	0.23	0.654	73.86	0.892	0.175	W=66, (n=11) P = 0.001, H.S
	B (N-23)	0.91	1.04	-0.130	-14.3	0.548	0.114	W= -12, (n=7) P=0.3750, N.S
	Mann – Whitney U-statistic = 156, U'= 442, P = 0.0009, H.S							
<i>Aalashya</i>	A (N-26)	2.23	0.76	1.462	65.91	0.760	0.149	W=300, (n=24) P < 0.0001, H.S
	B (N-23)	2	2.04	-0.043	-2	0.638	0.133	W= -5, (n=9) P=0.8203, N.S
	Mann – Whitney U-statistic = 46, U'= 552, P < 0.0001, H.S							
<i>Gaurava</i> (Heaviness of the Body)	A (N-26)	2.19	0.65	1.538	70.31	0.647	0.127	W=300, (n=24) P < 0.0001, H.S
	B (N-23)	2	2	00	00	0.603	0.126	W=00, (n=8) P > 0.9999, N.S
	Mann – Whitney U-statistic = 39, U'= 559, P < 0.0001, H.S							
<i>Jwara</i>	A (N-26)	1.03	0.11	0.923	89.32	0.796	0.156	W=238, (n=23) P < 0.0001, H.S
	B (N-23)	1	1.17	-0.174	-17	0.576	0.120	W= -18, (n=8) P=0.2500, N.S
	Mann – Whitney U-statistic = 84.5, U'= 513.5, P < 0.0001, H.S							
<i>Agni-dourblya</i> (Impaired digestive capacity)	A (N-26)	1.53	0.42	1.115	72.54	0.816	0.160	W=190, (n=19) P < 0.0001, H.S
	B (N-23)	1.65	1.69	-0.043	-2.42	0.562	0.117	W= -4, (n=7) P=0.8125, N.S
	Mann – Whitney U-statistic = 90.5, U'= 507.5, P < 0.0001, H.S							
<i>Sandhishotha</i> (Joint swelling)	A (N-26)	2.11	0.92	1.192	56.39	0.491	0.096	W=325, (n=25) P < 0.0001, H.S
	B (N-23)	1.91	2	-0.087	-4.71	0.668	0.139	W= -11, (n=10) P=0.6250, N.S
	Mann – Whitney U-statistic = 48.5, U'= 549.5, P < 0.0001, H.S							

Symptoms	Group	Mean		Difference of Mean	% of Relief & Loss	SD	SE	Wilcoxon matched pairs signed- ranks test & P-value
		BT	AT					
djkaxqY;kfLFkIfU/k	A (N-26)	1.57	0.77	0.807	51.22	0.491	0.096	W=210, (n=20) P < 0.0001, E.S
	B (N-23)	1.39	1.52	-0.130	-9.37	0.548	0.114	W= -12, (n=7) P = 0.3750, N.S
	Mann – Whitney U-statistic = 79, U'= 519, P < 0.0001, H.S							

Ekf.kcU/k IfU/k	A (N-26)	1.53	0.77	0.769	49.98	0.587	0.115	W=171, (n=18) P < 0.0001, E.S
	B (N-23)	1.39	1.52	-0.130	-9.37	0.458	0.095	W= -9, (n=5) P = 0.3125, N.S
	Mann – Whitney U-statistic = 88 , U'= 510 , P < 0.0001 , H.S							
dwiZj IfU/k	A (N-26)	1.50	0.77	0.730	48.72	0.604	0.118	W=153, (n=17) P < 0.0001, E.S
	B (N-23)	1.35	1.56	-0.217	-16.12	0.422	0.088	W= -15, (n=5) P = 0.0625, N.S
	Mann – Whitney U-statistic = 81 , U'= 517 , P < 0.0001 , H.S							
val IfU/k	A (N-26)	1.57	0.77	0.807	51.21	0.567	0.111	W=190, (n=19) P < 0.0001, E.S
	B (N-23)	1.26	1.17	0.087	6.89	0.417	0.087	W= 5, (n=4) P = 0.3750, N.S
	Mann – Whitney U-statistic = 113 , U'= 485 , P < 0.0001 , H.S							
iknkaxqY;kfLFk IfU/k	A (N-26)	1.65	0.73	0.923	55.81	0.560	0.109	W=231, (n=21) P < 0.0001, E.S
	B (N-23)	1.39	1.48	-0.087	-6.25	0.417	0.087	W= -5, (n=4) P = 0.3750, N.S
	Mann – Whitney U-statistic = 61.5 , U'= 536.5 , P < 0.0001 , H.S							
xqYQ IfU/k	A (N-26)	1.73	1	0.731	42.21	0.777	0.152	W=139, (n=17) P = 0.0003, E.S
	B (N-23)	1.61	1.69	-0.087	-5.40	0.514	0.107	W= -7, (n=6) P = 0.5625, N.S
	Mann – Whitney U-statistic = 127.5 , U'= 470.5 , P = 0.0002 , H.S							
Tkkuq IfU/k	A (N-26)	2.46	1.30	1.154	46.87	0.613	0.120	W=300, (n=24) P < 0.0001, E.S
	B (N-23)	2.09	2.13	-0.043	-2.08	0.366	0.076	W= -2, (n=3) P = 0.7500, N.S
	Mann – Whitney U-statistic = 31.5 , U'= 566.5 , P < 0.0001 , H.S							
Oka{k.k IfU/k	A (N-26)	1.23	0.77	0.461	37.48	0.582	0.114	W=66, (n=11) P = 0.0010, E.S
	B (N-23)	0.95	1.13	-0.174	-18.18	0.491	0.102	W= -14, (n=6) P = 0.1563, N.S
	Mann – Whitney U-statistic = 147.5 , U'= 450.5 , P = 0.0003 , H.S							
f=d IfU/k	A (N-26)	1.11	0.57	0.538	48.29	0.647	0.127	W=78, (n=12) P = 0.0005, E.S
	B (N-23)	0.87	0.91	-0.043	-5	0.366	0.076	W= -2, (n=3) P = 0.7500, N.S
	Mann – Whitney U-statistic = 159 , U'= 439 , P = 0.0006 , H.S							
f'kjksxzhok IfU/k	A (N-26)	1.73	0.84	0.884	51.10	0.516	0.101	W=231, (n=21) P < 0.0001, E.S
	B (N-23)	1.39	1.43	-0.043	-3.12	0.366	0.074	W= -2, (n=3) P = 0.7500, N.S
	Mann – Whitney U-statistic = 64.5 , U'= 533.5 , P < 0.0001 , H.S							

Pathologic-al Investigati-on	Group	Mean		Differ-ence of Mean	% of Relief & Loss	SD	SE	Paired t- test & p-value
		BT	AT					
Hb%	A (N-26)	11.31	11.73	0.419	3.70	0.678	0.133	t = 3.152,(df=25) P = 0.0042, V.S
	B (N-23)	11.62	11.45	0.174	-1.49	0.445	0.093	t = 1.873,(df=22) P = 0.0745, N.S
	Unpaired t – test = 3.567, (d.f.= 47), P = 0.0008, H.S							
TLC	A (N-26)	9546.2	8121.2	1425	14.93	1478.1	289.9	t = 4.916,(df=25) P < 0.0001, E.S
	B (N-23)	8726.1	8578.2	147.8	1.69	1537.7	320.6	t = 0.461,(df=22) P = 0.6493, N.S
	Unpaired t – test = 2.962, (d.f.= 47), P = 0.0048, V.S							

ESR	A (N-26)	29.962	22.731	7.231	24.13	5.458	1.070	t = 6.756,(df=25) P < 0.0001, E.S
	B (N-23)	29.000	30.609	-1.61	-5.54	5.574	1.162	t = 1.384,(df=25) P = 0.1802, N.S
Unpaired t – test = 5.602, (d.f.= 47), P < 0.0001, H.S								
R.A Factor		jksxh;ksa ds izdkj + ve /- ve ds vk/kkj ij			BT		AT	
	A (N-26)	+ ve			5		4	
		- ve			21		22	
	B (N-23)	+ ve			4		4	
		- ve			19		19	

Symptoms	%of Relief	Result
Angmard	59.62%	Good (Markedly improved)
Aruchi	78.03%	Excellent (Complete remission)
Trishna	73.86%	Good (Markedly improved)
Aalasya	65.91%	Good (Markedly improved)
Gourav	70.31%	Good (Markedly improved)
Jwar	89.32%	Excellent (Complete remission)
Apaka	72.54%	Good (Markedly improved)
Angashotha	56.39%	Good (Markedly improved)
Sandhishoola	67.72%	Good (Markedly improved)
Hb%	3.70%	Poor (Mild Improved)
TLC	14.93%	Poor (Mild Improved)
ESR	24.13%	Poor (Mild Improved)

Overall effect of therapy in Patients

Effect	Group A=26		Group B=23	
	No. of patients	%	No. of patients	%
Complete remission	00	00	00	00
Markedly improved	03	11.53%	00	00
Moderately improved	23	88.46%	00	00
Mild Improved	00	00	00	00
Unchanged	00	00	05	21.73%

DISCUSSION

- Effect of trial drug *Shoolprashaman Mahakashaya* on various symptoms shows that there was a statistically extremely significant ($P < 0.0001$) improvement in *Angamard*, *Aruchi*, *Trishna*, *Aalasya*, *Gourav*, *Jwar*, *Apaka*, *Angashotha*, *Sandhishotha*, *Sandhishoola*, *TLC* & *ESR*.
- Due to most of ingredients were *Katu Rasa*, *Laghu Tikshana*, *Ruksha Gunas* and *Ushna Virya* in processed *Yavakutta kwath* of *Shoolprashaman Mahakashaya*. So it is found good *Kapha-Vatahara*. This *kwath* possesses the basic quality of *Deepan* and *Pachan* properties which improve *Jatharagni* and mild laxative too.
- By virtue of *Ushana Veerya*, it digests and absorbs the vitiated *Ama* by its *Shoshana Karma*. Scientifically, it has been proved that *Shoolprashaman Mahakashaya* possesses active principles of *Piperine*, *Rutine*, *Piperlongumine*, *gingerol*, *Cumin aldehyde*, *Zingiberene*, *Gingerin* & *Gingerol*, and they are potent inhibitors of *prostaglandin synthesis*, indicating the mechanism of an *anti-arthritis effect* & *analgesic effect*.
- Hence, taking the above points into consideration, the “*Shoolprashaman Mahakashaya*” has established properties like *Deepan*, *Pachan*, *Ama Nashan*, *Ama Shoshak*, and *Vata-Kaphahara*, which are all antagonists to the present entity. This drug is

effective in correcting the pathological condition of the disease *Amavata*.

Drug	Active Constituent	Action
Pippali Root of Pippali	Piperine	Anti-pyretic, Analgesic, Anti-inflammatory, Antioxidant
	Rutine	Stimulates the Digestive enzymes, immune system
	Piperlongumine cepharadione	Analgesic, Anti-inflammatory, Antioxidant
Chavya	Piplartine	Regulating lipid metabolism, Gastro protective, Antioxidant Property
	Sitosterol	Immunomodulator, Anti-inflammatory, Rheumatoid arthritis
Chitraka	Plumbagin	Anti-tumor activity, Anti-inflammatory, Antioxidant, Immunosuppressive
Sunthi	Zingiberene	Stimulate digestion Relieve constipation & Effects on the gastrointestinal tract
	Gingerin	Anti-oxidant, Anti-inflammatory
	Gingerol	Rheumatoid arthritis
	Shogaol	Anti-inflammatory, Antioxidant, Hepatic Disorder's
	Zingerone	Anti-oxidant, Neuroprotective Agent's, Free radical scavenging
Ajamoda	Limonene	Gastroesophageal reflux disease, Heart burn, Anthelmintic, Anti-rheumatic
	Sabinene	Anti-inflammatory agent
Maricha	Piperine	Antioxidant, Anti-spasmodic, Gastrointestinal motility disorder,
	Piperonol	Anti-inflammatory property
Ajaji	Cumin aldehyde	Neuroprotective, Anti-inflammatory, Antitumor, Anti-fibrillation activity
	γ - Terpinene	Anti-inflammatory properties, Antioxidant, Anti-proliferative property

CONCLUSIONS

- The present clinical study has been undertaken to evolve the treatment procedure for *Amavata* and to see the efficacy of "*Shoolprashaman Mahakashaya*". The study has revealed that a maximum numbers of patients had significant results in their signs and symptoms.
- "From the above-mentioned observations, it can be concluded that "*Shoolprashaman Mahakashaya*" can be used for 'Pain Management in all *Vatakapha Diseases*' and '*Deepana Pachana*' and improves the nonspecific immunity against *Amavata*.
- Finally it can be concluded that *Amavata* patients have got significant results with "*Shoolprashaman Mahakashaya*". To draw final conclusions, the trial requires more clinical data.