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Research Article

RANDOMISED CONTROLLED CLINICAL STUDY OF *SHATYADI KWATHA* IN *AMAVATA* (RHEUMATOID ARTHRITIS)

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ABSTRACT

The disease *Amavata* simulate with Rheumatoid Arthritis (RA) in modern parlanceis a symmetric, inflammatory, peripheral polyarthritis of unknown etiology with systemic involvement caused by the impairment of *Agni* (digestive fire), formation of *Ama* (bio-toxin) and vitiation of *Vata Dosha*. The disease *Amavata* (rheumatoid arthritis) still is a challenge to the physician due to its chronicity, incurability, complications, morbidity and crippling nature. A clinical study was conducted for 45 days at V.Y.D.S Ayurved Mahavidyalaya, Khurja, on 30 patients divided them into two groups of 15 each, to compare the efficacy of *Shatyadi kwatha* with the well-established control drug *Maharasnadi Kwatha* in the management of *Amavata* (rheumatoid arthritis). The demographic data of this study reveals that *Amavata* (rheumatoid arthritis) can begin at any age, but incidence increases with age. It clearly shows the predominance of the disease in females, in housewives, in addiction of tea/coffee and in *Samashana* group (consuming suitable and unsuitable foods mixed together). The clinical data of this study reveals that, both the drugs were found capable to enforce relief, but based on % of improvement and clinical assessment of result, it can be concluded that control drug (*Maharasnadi Kwatha*) was more effective than trial drug (*Shatyadi kwatha*) in most of the sign and symptom of the disease at extremely significant level.

INTRODUCTION

Amavata is ailment of *Asthivaha* and *Rasavaha Strotas* which is mainly produced due to *Ama* and *Vata Dosha* vitiation[1]. The aetiological factors like *Guru Ahara, Viruddhahara, Viruddha Chesta, Mandagni, Snigdhabhuktattvata Vyayama* (*Vyayama* immediately after *Snigdha bhojana*) etc are responsible for *Àmavata*[2-5].

The *Ama* is carried by the vitiated *Vata dosha* and is deposited in *Sleshmasthanas* (seats of *Kapha* like joints etc) which then produces features like *Angamarda* (body ache), *Aruchi* (loss of appetite), *Thrishna* (thirst), *Alasya* (weakness), *Gaurav* (heaviness of body), *Jwara* (fever) with *Sandhishotha* (joint swelling), *Sandhiruk* (joint pain) like scorpion bite[6-9]. According to the clinical features *Amavata* very closely resembles with clinical features of rheumatoid arthritis. Rheumatoid arthritis is a chronic, progressive autoimmune arthropathy and characterized by bilateral symmetrical involvement of joints with systemic clinical features[10-11]. This disease affects mainly young population and the patients are gradually crippled physically as well as mentally due to bad prognosis of the disease[12]. *Maharshis* also highlight this by describing symptoms like *Jadyata, Sankocha* and *Khanja* etc which correlated with deformities[13]. Hence it is a most burning problem in the society.

In Ayurveda, *Nidana Parivarjana*[14] (avoidance of causative factors) is considered as the first and foremost line of management for any disease. *Virechana karma* is a *Shodhana* process (biological purification of the body) to balance the vitiated *Dosha* in general and *Pitta Dosha* in particular.[15] The specific line of treatment for *Amavata* laid down by Acharya Chakrapani denotes *Ama Pachana,* improve function of *Agni* and control of *Vata Dosha*. The

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treatment includes – *Langhanam* (light diet or fasting), *Swedanaam* (fomentation), use of *Tikta, Katu Rasa* drugs and *Deepana, Pachan* (appetizers, digestives and carminatives) action, *Virechana* (therapeutic purgation), *Snehapana* (oleation) and *Anuvasana* with *Saindhavadi* (therapeutic enema) as well as *Kshara Basti.*[16-17] *Rukshasweda* and *Upnaha* (type of hot dry fomentations) also added to the above said measures[18-19]. The *Shamana* drugs and *Ahara Vihara* (diet and regimen) which are having *Vatashamaka, Amapachaka, Ama Shoshaka*, *Kaphahara* and *Deepniya* properties can be used in the treatment of this disease. The drugs having *Katu, Tikta Rasa, Usna, Tikshna Guna* are *Pathya* (conducive)[20-21].

Keeping this in consider the present study entitled as "Randomised controlled clinical study of *Shatyadikwatha* in *Amavata* (Rheumatoid Arthritis)" was planned to establish the efficacy of *Shatyadi kwatha*[22] in the management of *Amavata* (rheumatoid arthritis). To compare the efficacy of the trial drug, the well-known preparation *Maharasnadi Kwatha*[23] was selected.

AIM AND OBJECTIVE OF THE STUDY

- To assess the effectiveness of *Shatyadikwatha.*
- To assess the effectiveness of *Maharasnadikwatha.*
- To compare the effectiveness of *Shatyadikwatha with Maharasnadi kwatha* in the treatment of *Amavata* (rheumatoid arthritis).

MATERIAL AND METHODS

Study Type: Randomized Clinical trial
Label: Open
Blinding/Masking: None
Randomization: Simple

Sample Size: 30

Place of Study- Clinical study was conducted on patients in OPD/IPD of Kayachikitsa Department, V.Y.D.S. Ayurveda Mahavidyalaya, Khurja.

Study Design: The selected patients were divided into two groups.

Group-A (Trial Group/TG)- 15 cases was treated with *Shatyadi Kwatha.*

Group-B (Control Group/CG)- 15 cases was treated with M*aharasnadi kwatha*.

Inclusion Criteria- Diagnosed cases of *Amavata* (rheumatoid arthritis) of both sex, between age group of 16 to 60 years who agreed for giving consent after making aware of the merits/demerits of the trial and having presence of cardinal clinical features like

- **Subjective Parameters** i.e., *Sandhi shoola* (continuous pain in joints like scorpion bites), *Sandhi-stabdhata* (joint stiffness), *Angamarda, Aruchi, Trishna, Alasya,*apaka along with tenderness in joints and joint swelling,
- **Objective Parameters** i.e., *Jwara* (fever), handgrip strength (right & left), foot press strength (right & left), DAS 28 response criteria

Exclusion Criteria

- Patients age below 16 and above 60 years.
- Patients who develop secondary complication of RA e.g. Pleuro-pericardial disease, extra articular arthritis, severely damaged joint with bed ridden patients.
- Any other serious illness e.g. Hepatic/renal failure, diabetes etc.
- Patient with diagnosed other arthritis like gouty arthritis, tuberculosis arthritis etc.
- Pregnancy, lactating mother

Lab Investigations

- DLC, TLC, ESR
- Rheumatoid factor (RA Factor)
- C-reactive protein (CRP)
- X-rays (if needed)
- Other related investigations according to necessity.

Drug Intervention

- **Trial drug**- ***Shatyadikwatha*** **(**Bhaisajyaratnavali, Amavatadhikara 21/22)
  - **Ingredients:** *Shati, Shunthi, Haritaki, Vacha, Devdaru, Ativisha, Amrita* (*Guduchi*) - each equal quantity mix with water in 1:16 ratio and heat until liquid remain 1/8th part.
  - **Dose:-**20ml *Kwatha* twice a day with lukewarm water after meal.
  - **Route of Administration:** Oral
- **Control drug: *Maharasnadi Kwatha*** (Sharangadhara Madhyamakhanda 2/89-95)
  - **Ingredients:** *Rasna* (2 parts), *Dhanvayasa*, *Bala, Eranda-mula, Devadaru, Shathi (Shati), Vacha, Vasaka (Vasa), Nagara (Sunthi), Pathya (Haritaki), Chavya, Musta, Punarnava, Guduchi, Vriddhadaru, Shatapushpa (Shatahva), Gokshura, Ashvagandha, Prativisha (Ativisha), Kritamala (Aragvadha), Shatavari, Krishna (Pippali), Sahacara, Dhanyaka, Kantakari, Brihati* (each 1 part).

    Prkshepadravya**:** *Shunthi Churna, Pippali Churna. Ajamodadi Churna, Eranda Taila.*
  - **Dose:** 20ml *Kwatha* twice a day with lukewarm water after meals.
  - **Route of Administration:** Oral

Duration of Treatment - 45 days

Follow Up: Every 15th day during trial period.

Assessment Criteria: In the present trial, age, sex etc. demographic parameters were analysed. The assessment was analyzed on subjective and objective parameters using Wilcoxon signed rank method and Paired 't' test respectively. Comparison of efficacy was done using Mann-whitney test in subjective parameters and unpaired-t test in objective parameters. Statistical analysis on the percentage of improvement in each parameter will evaluate by the formula: Average BT – Average AT * 100/Average BT.

Grading System Adopted for Assessment

Assessment Criteria for Subjective Parameters	
***Sandhishoola* (Joint pain)**	**Score**
No pain	0
Mild pain (Dose not interferes with most activities. Able to adopt to pain psychologically with medication or devices such as cushions)	1
Moderate pain (Interferes with many activities require life style changes but patient remain independent. Unable to adopt to pain)	2
Severe (Unable to engage in normal activities. Patient is disable and unable to function independently)	3
***Sandhi-stabdhata* (Morning stiffness)**	**Score**
None	0
Less than 30 minutes	1
30 to 60 minutes	2
More than 60 minutes	3
***Angamarda* (Body aches)**	**Score**
No body aches	0
Body aches getting better after a few minutes of activity	1
Body aches getting better after activity towards mid-day	2
Body aches persisting at all day	3
Aruchi	**Score**
Appreciates all *Rasas*	0
Appreciates any 4 *Rasas*	1
Appreciates any 2 *Rasas*	2
Doesn't appreciate taste of food	3
Trushna	**Score**
Quantity of water intake 0-2 liter per day	0
Quantity of water intake >2-3 liter per day	1
Quantity of water intake >3-4 liter per day	2
Quantity of water intake >4 liter per day	3
Aalasya	**Score**
Interested to do all activities	0
Can perform personal & other daily activities with little interest	1
Can perform only personal activities without interest	2
No interest in any activity	3
Apaka	**Score**
No indigestion	0
Heavy food not digested properly	1
Delayed digestion of lighter foods	2
Impaired digestion of even lighter foods	3
Tenderness in Joints	Score
No tenderness	0
Minimal (positive response to questioning)	1
Moderate (spontaneous response elicited)	2
Sever (withdrawal by patient on examination)	3
Joint Swelling	**Score**
No swelling	0
Mild (detectable synovial thickening without loss of bony contours)	1

Moderate (loss of distinctness of bony contours)	2
Sever (bulging synovial proliferation with cystic characteristics)	3
Assessment criteria for Objective parameters	
Jwara	**Score**
Absence of fever	0
Jwaralakshana, without rise in temperature	1
Jwaralakshana, temperature upto 100°F	2
Jwaralakshana, temperature >100°F	3
Handgrip Strength (Right & Left): Ability to compress the inflated ordinary sphygmomanometer cuff	**Score**
200mm/Hg or more	0
<200 to 120mm/Hg	1
<120 to 70mm/Hg	2
Under 70mm/Hg	3
Foot press strength (Right & Left): Ability of the patient to press a weighing machine	**Score**
25 to 21kg	0
20 to 16kg	1
15 to 10kg	2
Less than 10kg	3
DAS 28 response Criteria	**Score**
Remission (Score of less than 2.6)	0
Low activity (Score of 2.6 – 3.2)	1
Moderate activity (Score of 3.2 – 5.1)	2
High activity (Score of more than 5.1)	3

Observations on Demographic Data

Table 1: Incidence of Patients According to Age

Age Group	C.G.	T.G.	Total	%
16 - 30 yrs	1	1	2	6.67
31-40 yrs	4	3	7	23.33
41-50 yrs	5	6	11	36.67
51-60 yrs	5	5	10	33.33

Graph 1 - Age Group

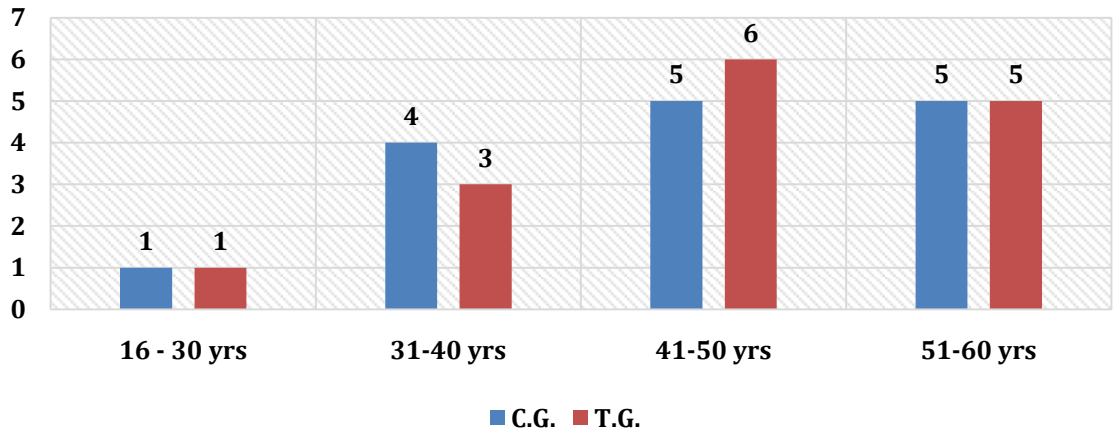


Table 2: Incidence of patients according to Gender

Gender	C.G.	T.G.	Total	%
Male	5	6	11	36.67

Female	10	9	19	63.33

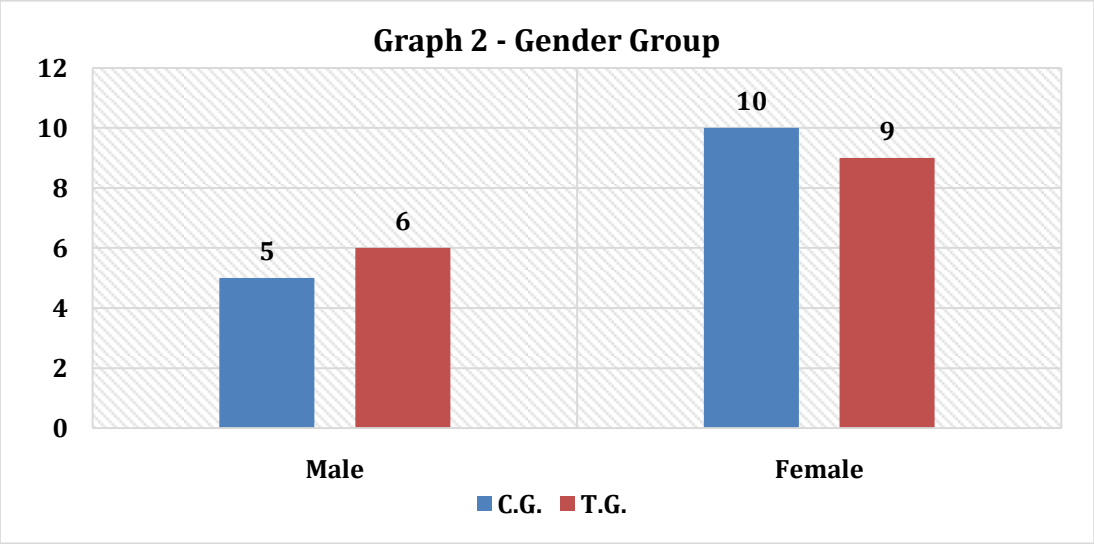


Table 3: Incidence of patients according to occupation

Occupation	C.G.	T.G.	Total	%
Housewife	8	4	12	40.00
Businessman	3	4	7	23.33
Labourer	1	2	3	10.00
Farmer	1	1	2	6.67
Students	0	0	0	0.00
Others	2	4	6	20.00

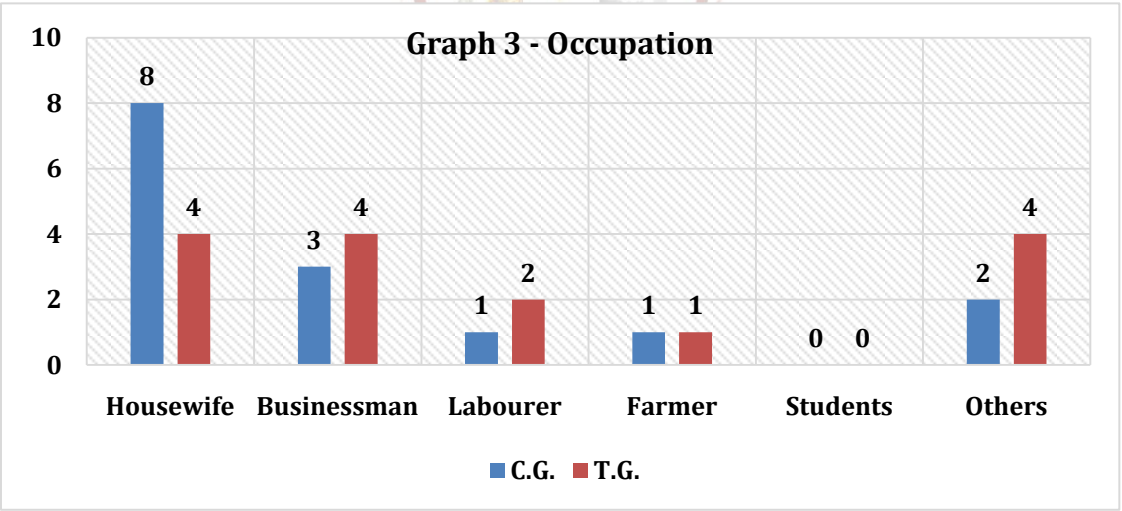


Table 4: Incidence of Patients According to Addiction (Multiple Responses)

Addiction	C.G.	T.G.	Total	%
Smoking	9	6	15	50.00
Tobacco	7	5	12	40.00
Alcohol	2	1	3	10.00
Tea/coffee	10	12	22	73.33
Others	0	1	1	3.33
No addiction	5	3	8	26.67

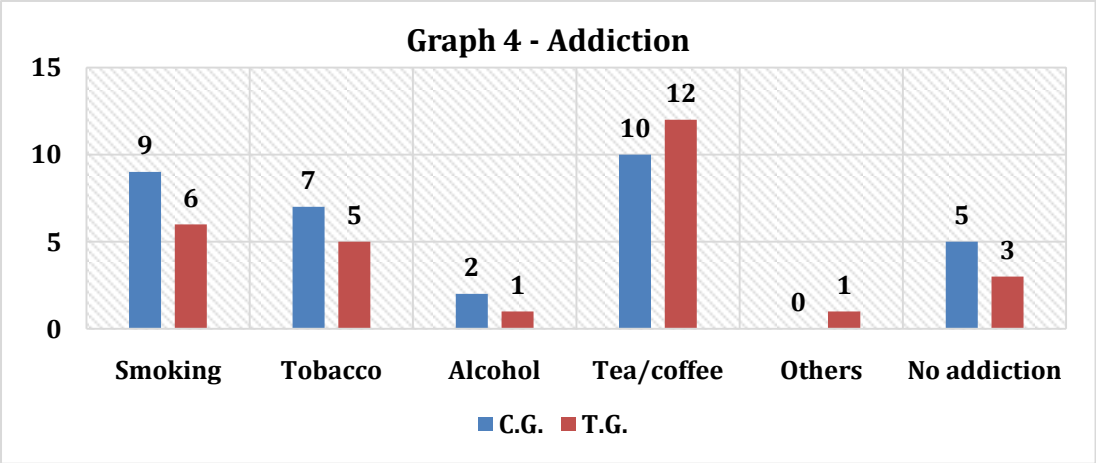
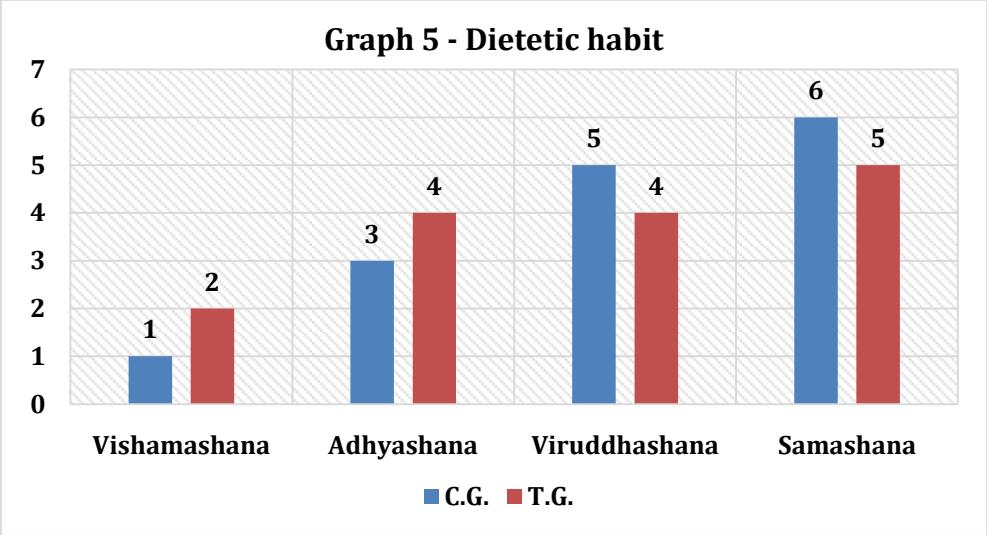


Table 5: Incidence of patients according to Dietetic habit

Dietetic habit	C.G.	T.G.	Total	%
Vishamashana	1	2	3	10.00
Adhyashana	3	4	7	23.33
Viruddhashana	5	4	9	30.00
Samashana	6	5	11	36.67



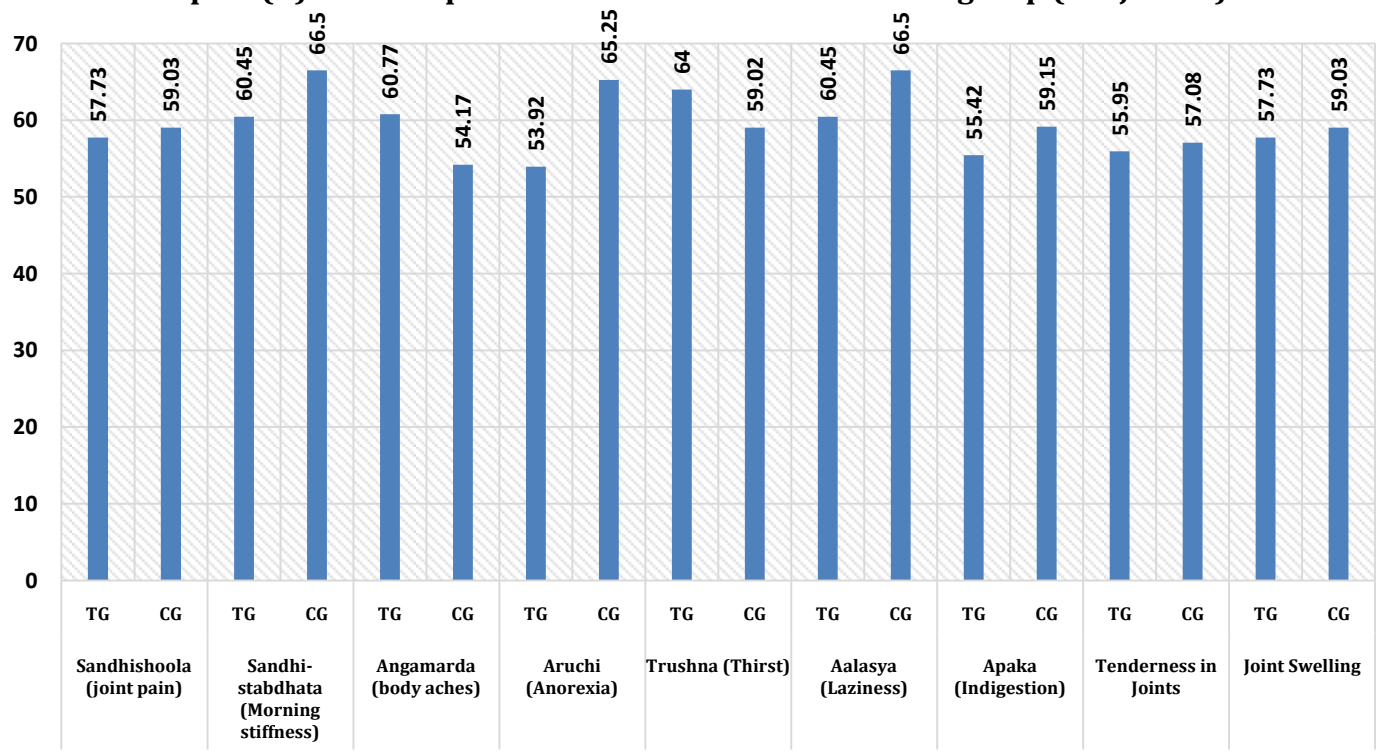
Observation on Statistical Data

Table 6: Statistical analysis showing the effectiveness of drugs in both groups

Sign & Symptoms		Mean Score		Mean diff.	% of improve	± S.D	± S.E.	w–Value	p - Value	Remark
		B.T.	A.T.							
Sandhishoola (joint pain)	TG	2.2	0.93	1.27	57.73	0.46	0.12	120	< 0.0001	E.S.
	CG	2.27	0.93	1.34	59.03	0.62	0.16	120	< 0.0001	E.S.
Sandhi-stabdhata (morning stiffness)	TG	2.2	0.87	1.33	60.45	0.49	0.13	120	< 0.0001	E.S.
	CG	2	0.67	1.33	66.50	0.62	0.16	120	< 0.0001	E.S.
Angamarda (body aches)	TG	2.09	0.82	1.27	60.77	0.47	0.14	66	0.001	E.S.
	CG	2.4	1.1	1.3	54.17	0.48	0.15	55	0.002	V.S.
Aruchi (Anorexia)	TG	2.17	1	1.17	53.92	0.41	0.17	21	0.0313	S.
	CG	2.36	0.82	1.54	65.25	0.69	0.21	66	0.001	E.S.

Trushna (Thirst)	TG	1.75	0.63	1.12	64.00	0.35	0.13	36	0.0078	V.S.
	CG	2.44	1	1.44	59.02	0.53	0.18	45	0.0039	V.S.
Aalasya (Laziness)	TG	2.2	0.87	1.33	60.45	0.49	0.13	120	< 0.0001	E.S.
	CG	2	0.67	1.33	66.50	0.62	0.16	120	< 0.0001	E.S.
Apaka (Indigestion)	TG	2.4	1.07	1.33	55.42	0.62	0.16	105	0.0001	E.S.
	CG	2.13	0.87	1.26	59.15	0.46	0.12	120	< 0.0001	E.S.
Tenderness in Joints	TG	2.27	1	1.27	55.95	0.59	0.15	120	< 0.0001	E.S.
	CG	2.33	1	1.33	57.08	0.49	0.13	120	< 0.0001	E.S.
Joint Swelling	TG	2.2	0.93	1.27	57.73	0.46	0.12	120	< 0.0001	E.S.
	CG	2.27	0.93	1.34	59.03	0.62	0.16	120	< 0.0001	E.S.
Jwara (Fever)	TG	100.52	98.54	1.98	1.97	0.6	0.18	10.96	< 0.0001	E.S.
	CG	99.81	98.4	1.41	1.41	0.38	0.13	10.524	< 0.0001	E.S.
Handgrip Strength (Right)	TG	120.7	159.7	39	32.31	20.5	8.13	2.05	< 0.001	V.S.
	CG	114	156.75	42.75	37.50	25.67	8.12	1.38	< 0.005	V.S.
Handgrip Strength (Left)	TG	102.13	142.67	40.54	39.69	29.69	7.67	7.9	< 0.0001	E.S.
	CG	103.73	146.67	42.94	41.40	32.83	8.48	7.43	< 0.0001	E.S.
Foot press strength (Right)	TG	14.4	22.4	8	55.56	8.27	2.61	3.8	< 0.001	V.S.
	CG	14.67	23.13	8.46	57.67	4.44	1.15	8.26	< 0.0001	E.S.
Foot press strength (Left)	TG	12.6	21.6	9	71.43	4.47	1.16	7.79	< 0.0001	E.S.
	CG	12.8	22.2	9.4	73.44	3.62	1.14	8.36	< 0.005	V.S.
DAS 28 response Criteria	TG	7.72	4.9	2.82	36.53	1.01	0.26	10.69	< 0.0001	E.S.
	CG	8.17	5.1	3.07	37.58	0.96	0.25	12.36	< 0.0001	E.S.
E.S– Extremely Significant, V.S– Very Significant, S– Significant										

Graph 6 (A) - % of improvement after treatment in both group (Subjective)



Graph 6 (B)- % of improvement after treatment in both group (Objective)

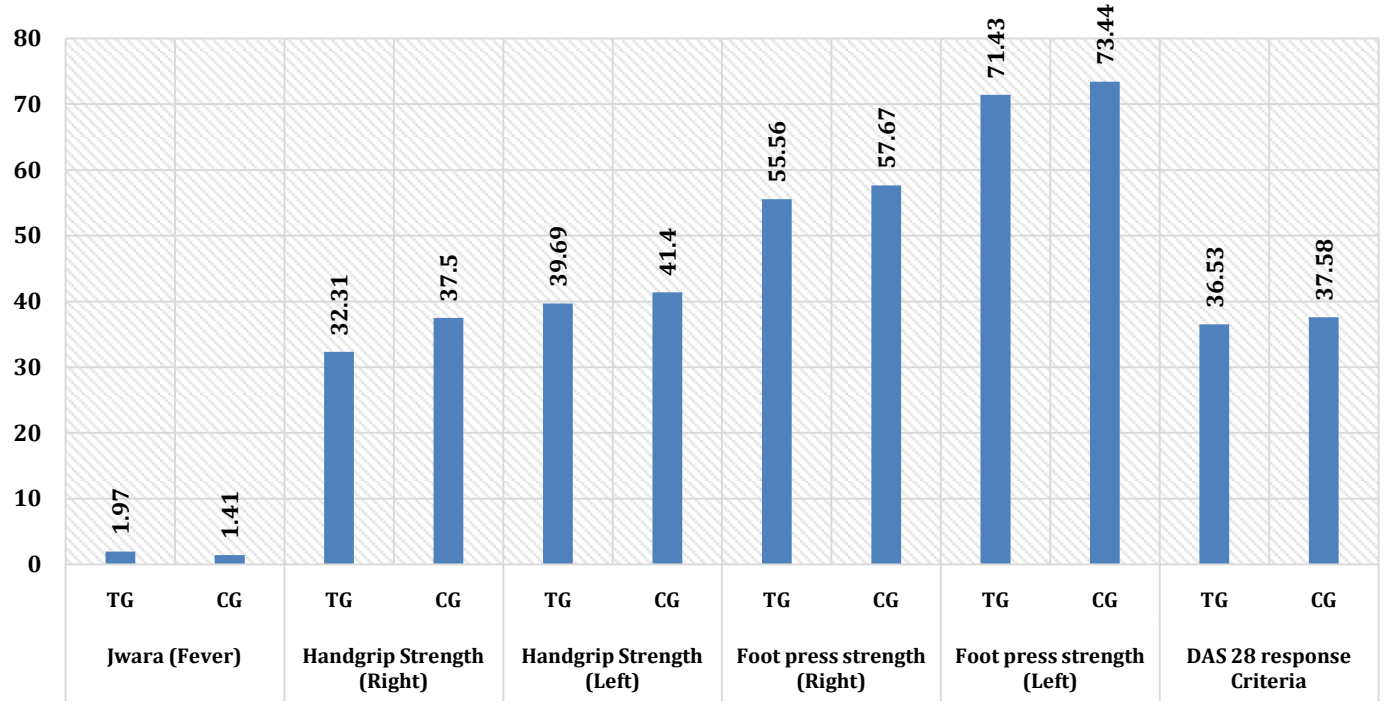


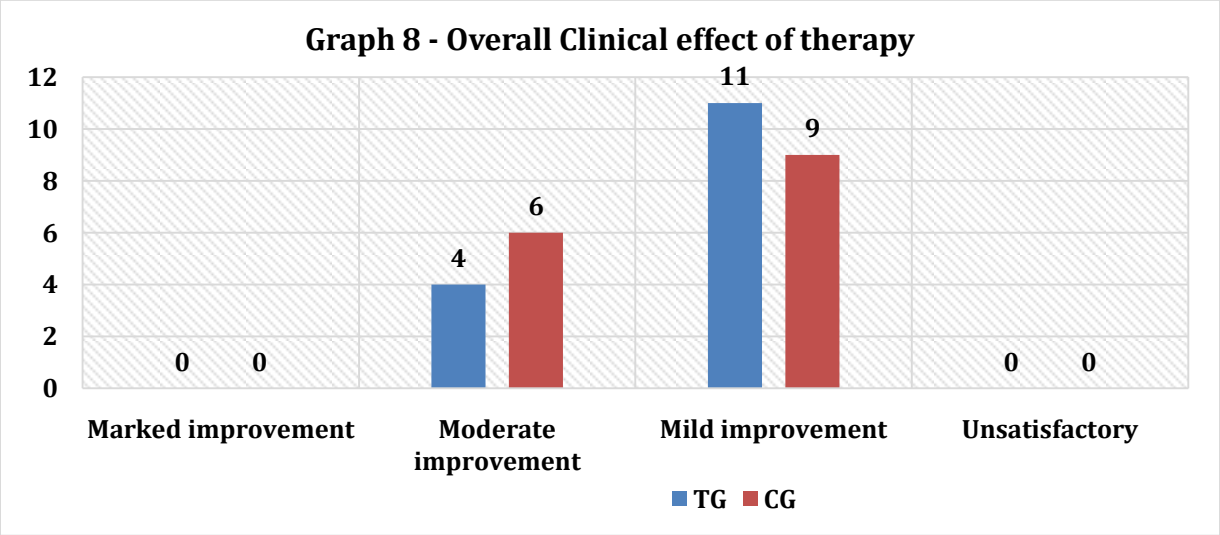
Table 7: Comparison of effects on different parameters of both drugs

Symptom		No of pts	Means	Mann-Whitney (U value)	p-Value	Remark
Sandhishoola (joint pain)	TG	15	1.27	110.5	0.9356	Not Significant
	CG	15	1.34			
Sandhi-stabdhata (Morning stiffness)	TG	15	1.33	107.5	0.8153	Not Significant
	CG	15	1.33			
Angamarda (body aches)	TG	11	1.27	51.5	0.8106	Not Significant
	CG	10	1.3			
Aruchi (Anorexia)	TG	6	1.17	26.5	0.4456	Not Significant
	CG	11	1.54			
Trushna (Thirst)	TG	8	1.12	35	0.9574	Not Significant
	CG	9	1.44			
A*alasya* (Laziness)	TG	15	1.33	107.5	0.8153	Not Significant
	CG	15	1.33			
A*paka* (Indigestion)	TG	15	1.33	103	0.6577	Not Significant
	CG	15	1.26			
Tenderness in Joints	TG	15	1.27	92.5	0.272	Not Significant
	CG	15	1.33			
Joint Swelling	TG	15	1.27	110.5	0.9356	Not Significant
	CG	15	1.34			
Jwara (Fever)	TG	11	1.98	0.3618	0.7244	Not Significant
	CG	8	1.41			
Handgrip Strength (Right)	TG	15	39	0.1793	0.859	Not Significant

	CG	15	42.75			
Handgrip Strength (Left)	TG	15	40.54	0.21	0.8352	Not Significant
	CG	15	42.94			
Foot press strength (Right)	TG	15	8	0.1253	0.9012	Not Significant
	CG	15	8.46			
Foot press strength (Left)	TG	15	9	0.2076	0.8371	Not Significant
	CG	15	9.4			
DAS 28 response Criteria	TG	15	2.82	0.7391	0.4662	Not Significant
	CG	15	3.07			

Table 8: Overall Clinical Effects of Therapy

Clinical effect of therapy	Overall Effect of therapy			
	TG		CG	
	f	%	*f*	%
Marked improvement (>75%)	0	0	0	0
Moderate improvement (>50 – 75%)	4	26.67	6	40
Mild improvement (>25 – 50%)	11	73.33	9	60
Unsatisfactory (<25%)	0	0	0	0



DISCUSSION

In this present study, *Shatyadikwatha* (Bhaisajyaratnavali, Amavatadhikara) is considered for clinical trial. It has 7 ingredients. Most of the *Dravyas* are having predominance of *Katu rasa* followed by *Tikta rasa,* predominance of *Laghu Guna*, *Katu Vipaka* and all have *Usna Virya* which is essential for management of *Amavata* as per treatment principle led down by Acharya Chakrapani. He was the pioneer in describing the principles of treatment of *Àmavata* which are *Langhana, Swedana*, drugs having *Tikta, Katu Rasa* and *Deepana* property,

Katu drugs are *Vayu Agni Pradhan* earning the properties of *Sodhan, Agni deepana*, *Bhuktaahara-soshana* helps to destroy *Ama*. *Katurasa* by virtue of *its Chhedana & Lekhana* properties helps to cure the *Dosa-Samurchhana* & *Srotabhisanga.* By virtue of *Laghu Guna*, *Ushna Virya*, it decreases *Kaphadosa*. *Tiktadravya* having predominancy of *Vayu* and *Akash mahabhuta* are opposite character of *Ama*. It has *Lekhna, Deepan, Pachana, Visaghna*. *Arochakghna* therefore preferable these are the regiment for the treatment of *Amavata.*

Normally the use of *Tikta* and *Katu Rasa* in vatic disorder is contra indicated as these are supposed to increase *Vatadosa*. But they are decisively indicated *in Amavata* because of the presence of *Ama*. They increases salivary and gastric secretion and improve intestinal motility acting as *Vatanulomak*. Stimulating of gastrointestinal function leads to better absorption. So the use of *Katu, Tikta* and *Deepan* drug

is justified as they increase the digestion and metabolism which is lowest in case of *Amavata*.

The well-known drug *Maharasnadi Kwatha (Sharangadhara Samhita/Sahasrayogam*, *Kashayayogha*) has been selected as a control drug. It is a polyherbal formulation proved to be safe and non-toxic potential for providing relief to arthritis patients. This formulation is prepared from parts of 26 different plants that are used in traditional medicine for a variety of purposes such as reduction of pain, reduction of inflammation and antipyretic activity.

The demographic data of this study reveals that *Amavata* (rheumatoid arthritis) can begin at any age, but incidence increases with age. It clearly shows the predominance of the disease in females, in housewives, in addiction of tea/coffee, in *Samashana* group (consuming suitable and unsuitable foods mixed together).

The clinical data in this study reveals that all patients belonging to TG & CG were found improved, which has been critically assessed in the language of percentage (Table 6/Graph 6 A & B). Control drug (*Maharasnadi Kwatha*) group has provided better relief in most of the cardinal features like in *Sandhishoola* (joint pain), *Sandhi-stabdhata* (morning stiffness), *Aruchi* (anorexia), *Aalasya* (laziness), *Apaka* (indigestion), tenderness in joints, joint swelling, handgrip strength (right & left), foot press strength (right & left) and in DAS 28 response criteria of the disease where as the trial drug (*Shatyadi kwatha*) provided comparatively better relief in symptoms of *Angamarda* (body aches*), Trushna* (thirst) and *Jwara* (fever). The statistical adjudication with suitable parameters shows that in maximum cases of both groups, both drugs (*Shatyadikwatha & Maharasnadi Kwatha*) were extremely significant with p-value <0.0001 on subjective and objective parameters.

On comparing the effect of two therapies in the language of percentage and on clinical assessment of results, it can be concluded that CG (*Maharasnadi Kwatha*) was more effective than TG (*Shatyadi kwatha*), but statistical Mann-whitney test and unpaired t - test for comparison of effect between TG and CG shows they were statistically not significant that means the result provided by both group was not so much differ.

Overall Clinical Assessment of Results

In TG (*Shatyadikwath* group) overall clinical effect was assessed as 4 (26.67%) patients were get moderate improvement while 11 (73.33%) patients were get mild improvement.

In CG *(Maharasnadi Kwatha* group), overall clinical effect was assessed as 6 (40%) patients were get moderate improvement while 9 (60%) patients were get mild improvement.

None of the patient was completely cured (100%) observed in both the groups.

CONCLUSION

Results of this study indicate that, the efficacy of the trial drug (*Shatyadi kwath*) found capable to enforce relief as a statistically significance response was obtained after the therapy in maximum symptoms and at the end of the study none of the case remained unchanged, but the cases achieved more benefit by control drug (*Maharasnadi Kwatha*).

The trial drug (*Shatyadikwath*) cannot be discarded inferior to control drug (*Maharasnadi Kwatha*) as the statistical comparison of effect of both drug on various symptoms shows the relief provided by both group was not so much differ.

This is a small group case study hence to prove its efficacy there is a need to conduct a study on large number of patients.

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