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Research Article

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF HERBAL PREPARATION *BODHI VRIKSHKASHAYA* AND *AMRITAADIKWATH* IN THE MANAGEMENT OF *VATRAKTA* W.S.R GOUT

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KEYWORDS: *Bodhivrikshtwak,* Gouty Arthritis, *Amritaadi-kwath, Vatarakta*.

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ABSTRACT

Vatarakta is a disease which is encountered in the population leading to a sedentary lifestyle. The change in lifestyle is the main cause of many diseases, *Vatrakta* being one of these. Based on the causes, signs and symptoms, *Vatarakta* may be correlated to gouty arthritis in modern medicine. Gout is an abnormality of purine metabolism that causes hyperuricemia and deposition of monosodium urate crystal. Its prevalence has increased across the globe.2.1 million people are affected with gout worldwide. In India, it has been reported that the prevalence of gout is 2-6 per 1000. It is a potential signal for unrecognized co-morbidities like obesity, diabetes mellitus, hypertension and renal diseases. The purpose of this study is to explore and find out an effective, inexpensive, easily available and well accepted drug with minimal or no complications for this dreadful condition. 30 patients who were diagnosed with *Vatarakta* w.s.r Gouty Arthritis were allocated randomly into 2 groups. The test drug i.e., *Bodhi vriksh twak kashaya* 50ml B.I.D with *Madhu* was given to 15 patients of group A. The standard drug *Amritaadikwath* 50ml B.I.D, which was given to 15 patients of group B. The course of treatment was 60 days. Subjective parameters were assessed before and after the treatment as per the grade score. Serum uric acid was done before trial and on completion of trial i.e., 60th day. Data obtained during the trial was tabulated and statistically analyzed.

INTRODUCTION

Ayurveda, the "science of life" or longevity is the holistic alternative science since era. The whole philosophy of Ayurveda is based on achieving, maintaining and promoting positive health. The equilibrium of various structural and functional units of the body namely *Dosha, Dhatu, Mala, Agni* and *Mana* results in a healthy body. The life-style of modern society is proving to be a curse in promoting non-communicable diseases/ chronic diseases. These disorders are the result of a miss-matched relationship of people with their environment along with their lifestyle. *Vatarakta* also known as *Adhyavaat*[1] emerges from an inappropriate relationship of people with their diet, occupation and environment. The name of the disease itself represents that it is likely more prevalent among rich people.

Vatarakta is the major example of *Vata Vyadhi*, caused by the vitiation of *Vata* and *Rakta*.[2] *Rakta* is an important constituent of our body. It represents blood and associated metabolic products. *Sushruta* has considered *Rakta* as a fourth *Dosha*.[3] Aggravated *Vata* blocked by vitiated *Rakta*, in turn leads to further aggravation of *Vata*.

Thus, aggravated *Vata* vitiates the *Rakta* leading to the condition known as *Vatarakta*.[4] It has two stages i.e., *Uthana* and *Gambhira*. *Gambhira Vatrakta* mainly affects *Asthidhatu* and causes *Ruja*- which spread as *Aakhorvisha* (rat poison).[5]

Gout is a metabolic disorder and inflammatory response to the deposition of mono-

sodium-urate crystals in joints secondary to hyperuricemia[6]. In 21st century, gout is the most common inflammatory arthritis in men above 40 years of age and post-menopausal women.[7] The incidence of gout has been on the rise globally, potentially attributable to change in dietary habits, lifestyle, and greater use of medications causing hyperuricaemia. The annual incidence of gout is 2.68 per 1000 persons, with an overall prevalence of 2-26 per 1000.

Due to the remittent and relapsing nature of gout, there is no permanent cure for the disease, which is a challenge in the present era. Moreover, it is a potential signal for unrecognized co-morbidities like Metabolic Syndrome, Diabetes Mellitus, Coronary Artery Disease and Hypertension.

Although several drug regimens have been advised for its management in modern science like NSAID, Colchicine, Corticosteroids and Hypouricaemic drugs, their use is associated with adverse effects and certain limitations. Therefore, it is essential to find out some alternative therapeutics based on herbs with minimum health hazards. Both *Bodhi vriksha (Peepal) Kashaya* mentioned in *Charka Samhhita (Vatashonita Chikitsa Adhyayaya)* and *Amritaadi kwath* as mentioned in *Chakradatta* have been selected for the present study.

AIMS AND OBJECTIVES

1. To study the literature on *Vatarakta* and Gout in different Ayurvedic *Samhitas* and the modern era.
2. To study the etiopathogenesis of *Vatarakta*.
3. To evaluate the comparative clinical effectiveness of *Bodhi Vriksha Kashaya* and *Amritaadi kwath* in lowering the serum. Uric acid level and relief on clinical features in patients of *Vatarakta* (Gout).

MATERIAL AND METHOD

To fulfil all the aims and objectives of the study, the following material and methods were used.

PATIENTS AND METHODS

Selection of Patients

Patients fulfilling the diagnostic and inclusion criteria were selected randomly from O.P.D./I.P.D. of *Kayachikitsa* department of R.G.G.P.G. Ayurvedic Hospital, Paprola, Dist. Kangra (H.P.).

Diagnostic Criteria

The patients were diagnosed based on Ayurvedic and modern parameters.

Following signs and symptoms were considered for the diagnosis as mentioned in classical texts:-

1. *Sandhi Shoola* (Joint pain)
2. *Sandhi Shotha* (Swelling of joint)
3. *Sparsh Ashatvam* (Tenderness)
4. *Raaga* (Redness)
5. *Twaka Vaivarnya* (Discoloration of skin)
6. *Vidaha* (Burning sensation)
7. *Stabdhta* (Stiffness)

Serum uric acid was considered as investigation based diagnostic tool. Serum uric acid >7mg/dl in males and >6mg/dl in females was considered for diagnosis.

Inclusion Criteria

- Patients willing to participate in the trial
- Patients between the age group of 20-70 years of either sex or religion.
- Patients having serum uric acid >7mg/dl in males and >6mg/dl in females with or without any associate features like joint pain and inflammation.

Exclusion Criteria

- Patients unwilling to participate in the trial.
- Patients below the age of 20 years and above 70 years of age.
- Patients- suffering from chronic respiratory, cardiac, hepatic and hormonal disorder.
- Mentally unstable and substance abuse patients
- Any other patient considered unfit for the trial.

Investigations

1. Blood Investigations
   Routine- Hbgm%, TLC, DLC, ESR
   Biochemistry - FBS, B. Urea, S. Creatinine, RA Factor, Serum, Uric acid
2. Urine:

- Routine and microscopic examination.
- Radiological examination of the joint if required.

Trial Group

- Study was conducted on selected 30 patients in two groups
  - Group I: *Bodhivriksh (Peepal) Kashaya*
  - Group II: *Amritaadikwath*

Trial Drugs

***Bodhivriksha (Peepal) Kashaya (*Group 1)**

Dose- 50 ml twice daily

Route of administration- Oral

Time- After meals

Anupana- Madhu

*Amritaadikwath (*Group II)

Dose- 50ml twice daily

Route of administration - Oral

Time- After meal

viii) Trial Drugs Composition

(i) *Bodhi vriksha (Peepal) Kashaya* (Group 1) *Bodhivrikhatwak*

(ii) *Amritaadikwath* (Group II)

S.N.	Name	Botanical Name	Family	Parts Used	Proportion
1	*Amrita (guduchi)*	*Tinospora cordifolia*	Menispermaceae	Stem (*Kand*)	1 part
2	*Shunthi*	*Zingiber officinalis*	Zingiberaceae	Rhizome	1 part
3	*Danyak*	*Coriandrum sativum*	Umbelliferae	Fruit	1part

Method of Preparation

Ashwath Twak and *Amritaadi kwath yavkut churna* was added to water in the ratio 1:8 and *Kashaya* was prepared by reducing it to ¼th respectively.

Criteria of Assessment

Subjective parameters were assessed before and after the treatment as per the grade score.

Serum uric acid was done before trial, on the 30th day and completion of trial i.e., 60th day.

Subjective Criteria

Signs and Symptoms

The following signs and symptoms were assessed on the basis of Visual Analogue Scale (VAS) and grading was done.

1. *Sandhi Shoola* (Joint pain)
2. *Sandhi Shotha* (Swelling of joint)
3. *Sparsh Ashatvam* (Tenderness)
4. *Raaga* (Redness)
5. *Twaka Vaivarnya* (Discoloration of skin)
6. *Vidaha* (Burning sensation)
7. *Stabdhta* (Stiffness)

Table 1: Grading of Signs and Symptom

S. No.	Sign & Symptoms	Status	Grades
1.	***Sandhi Shoola* (Joint pain)**	No pain	0
		Mild pain/ Bearable	1
		Pain on movement & relieved on rest	2
		Constant pain	3
		Severe pain with disturbing sleep	4
2.	***Sandhi Shotha* (Joint swelling)**	No swelling	0
		Mild swelling	1
		Moderate swelling	2
		Severe swelling	3
		Severe swelling with loss of movement	4
3.	***Sparsh Asahatvam* (Tenderness)**	No tenderness	0
		Patient says joint is tender	1
		Patient says joint is tender and winces	2
		Patient winces and withdraws the affected joint	3
		Patient does not allow to touch the affected part	4
4.	***Raaga* (Redness)**	No redness	0
		Mild redness	1
		Moderate redness	2
		Severe redness	3
		Joint dusky red	4
5.	***TwakVaivarnya* (Discoloration)**	No discoloration of overlying skin	0
		Mild discoloration of overlying skin	1
		Moderate discoloration of overlying skin	2
		Severe discoloration with excoriation of skin	3
		Very severe discoloration of skin	4
6.	***Vidaha* (Burning**	No burning sensation	0

	sensation)	Mild burning sensation	1
		Moderate burning sensation	2
		Severe burning sensation	3
		Unbearable burning sensation	4
7.	***Stabdhata* (Stiffness)**	No stiffness	0
		Stiffness lasting for few minutes to one hour	1
		Stiffness lasting for 1 hour to half a day	2
		Stiffness lasting for more than half of day	3
		Stiffness throughout the day	4

Objective Criteria

Serum uric acid was done before trial, after 30 days and at the time of completion of trial i.e, -60 days. To assess the effect of therapy on objective parameters, serum uric acid level will be assessed before and after the treatment.

Final Assessment of Result

Statistical Analysis

Data obtained during the trial was tabulated and statistically analyzed using Student Paired 't' Test. The results were considered significant or insignificant based on the p- value.

- Highly significant- $p<0.001$
- Significant- $p<0.01$, $p<0.05$
- Insignificant- $p>0.05$

OBSERVATION AND RESULTS

Among 30 registered patients, maximum patients (36.66%) were between 30-40 years of age group and (23.33%) patients in the age group of 40 to 50 years. Based on gender, the majority of patients were males (53.33%) and (46.66%) were females. Maximum patients i.e. 83.33% were married and 16.66% were unmarried. It was observed here that the maximum numbers of patients i.e. 46.66% were under metric pass, 26.66% were metric. 36.66% patients had positive family history of gout and the rest 63.33% did not have familial history of the disease. 73.33% of the patients enrolled in the clinical trial belonged to a rural area. The majority of patients i.e. 66.66% had mixed dietary habits and 33.33% patients were vegetarians. Life-style distribution of 30 patients showed that 60% i.e. 18 patients had a sedentary life-style. 53.33% patients had predominant *Vata-pittaj prakriti*, followed by *Pitta-kaphaja* (26.66%) and *Vata-kaphaja prakriti* (10%). Symmetry wise distribution of joint involvement of 30 patients showed that 22 patients i.e. 73.33% had asymmetrical involvement of joints. Distribution of 30 patients based on the joints involved showed that MTP (Metatarsophalangeal joint) was involved in 17 i.e, 56.66% patients.

1. Subjective Parameters

Table 2: Table showing the incidence of signs and symptoms of gout in 30 patients

Sr. No.	Symptoms	Gr. - I		Gr. – II		Total	
		Pt.	%age	Pt.	%age	Pt.	%age
1.	*Sandhi Shoola*	13	86.66%	13	86.66%	26	86.66%
2.	*Sandhi Shotha*	11	73.33%	12	80.00%	23	76.66%
3.	*Sparsha Asahatvam*	13	86.66%	12	80.00%	25	83.33%
4.	*Raaga*	04	26.66%	05	33.33%	09	30.00%
5.	*Twak Vaivarnaya*	04	26.66%	03	20.00%	07	23.33%
6.	*Vidaha*	09	60.00%	09	60.00%	18	60.00%
7.	*Stabdhta* (stiffness)	12	80.00%	09	60.00%	21	70.00%

Effect of Therapy Based on Subjective Criteria

The effect of *Bodhi Vriksh Kashaya* in 15 patients on various assessment criteria was obtained after statistical analysis of the data obtained and is presented in tabular form (Table. 3).

Table 3: Effect of Therapy in 15 Patients of Group-I (paired t test)

Sr. No.	Symptoms	Mean		% relief		SD±	SE±	't'	'P'
		BT	AT	Diff.	% age				
1.	*Sandhi Shoola*	2.33	0.42	1.91	81.97%	0.65	0.16	5.91	<0.001
2.	*Sandhi Shotha*	1.33	0.33	1.00	75.18%	0.48	0.12	10.58	<0.001
3.	*Sparsh Asahtav*	2.00	0.40	1.60	80.00%	0.41	0.10	16.57	<0.001
4.	*Raga*	1.0	0.2	0.8	80.00%	0.44	0.20	4.00	<0.05
5.	*Twak Vaivarnya*	1.2	0.5	0.7	58.33%	0.50	0.25	3.00	>0.05
6.	*Vidaha*	1.4	0.3	1.1	78.57%	0.33	0.11	10.00	<.001
7.	*Stabdhta* (stiffness)	1.40	0.37	1.03	73.57%	0.63	0.163	8.57	<0.001

Fig.1: Effect of therapy in 15 patients of Group-I (paired t test)

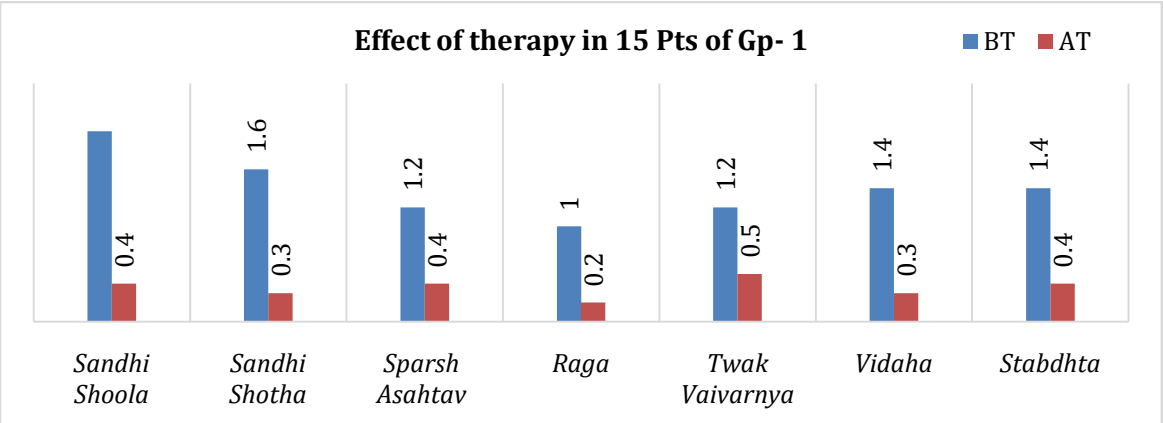

Figure 1 *BT (Before Treatment), AT (After Treatment)

Table 4: Effect of Therapy in 15 Patients of Group-II (paired t test)

Sr. No.	Symptoms	Mean		% relief		SD±	SE±	't'	'p'
		BT	AT	Diff.	% age				
1.	*Sandhi Shoola*	2.40	0.38	2.08	86.66%	0.594	0.153	6.95	<0.001
2.	*Sandhi Shotha*	1.40	0.24	1.16	82.85%	0.507	0.131	10.69	<0.001
3.	*Sparsh Asahtav*	2.86	0.33	2.53	88.46%	1.81	0.47	5.429	<0.001
4.	*Raga*	1.3	0.2	1.1	84.61%	0.64	0.22	4.96	<0.001
5.	*Twak Vaivarnya*	2.0	0.3	1.7	85.00%	0.57	0.33	5.00	<0.05
6.	*Vidaha*	1.8	0.3	1.5	82.33%	0.52	0.17	8.85	<0.001
7.	*Stabdhata*	1.33	0.18	1.15	86.46%	0.724	0.187	7.13	<0.001

Fig 2 : Effect of Therapy in 15 patients of Group-II (paired t test):

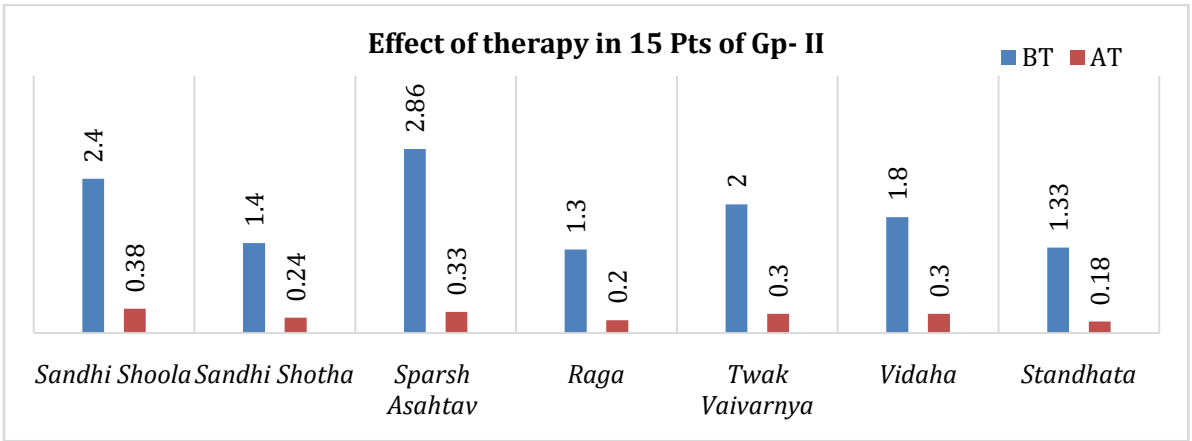

Figure 2.*BT (Before Treatment), AT (After Treatment)

Table 5: Inter- group comparison of subjective criteria (unpaired t test):

Sr. No.	Symptoms	% Relief		Diff. in %age	SD ±		SE ±		't'	'P'
		Gr.- I	Gr.II		Gr.-I	Gr.-II	Gr.-I	Gr-II		
1.	*Sandhi Shoola*	81.97%	86.66%	4.69%	0.62	0.59	0.16	0.15	0.76	>0.05
2.	*Sandhi Shotha*	75.18%	82.85%	7.67%	0.46	0.50	0.12	0.13	0.90	>0.05
3.	*Sparsh Asahtav*	80.00%	88.46%	8.46%	1.82	0.41	0.47	0.10	1.92	<.001
4.	*Raga*	80.00%	84.61%	4.61%	0.77	0.85	0.20	0.22	1.00	>0.05
5.	*Twak Vaivarnya*	58.33%	85.00%	26.67%	0.96	1.27	0.25	0.33	2.41	>0.05
6.	*Vidaha*	78.57%	82.33%	3.76%	0.19	0.42	0.06	0.27	1.94	>0.05
7.	*Stabdhata*	73.57%	86.46%	12.89%	0.63	0.72	0.16	0.18	0.48	>0.05

Fig.3: Inter- group comparison of subjective criteria (unpaired t test):

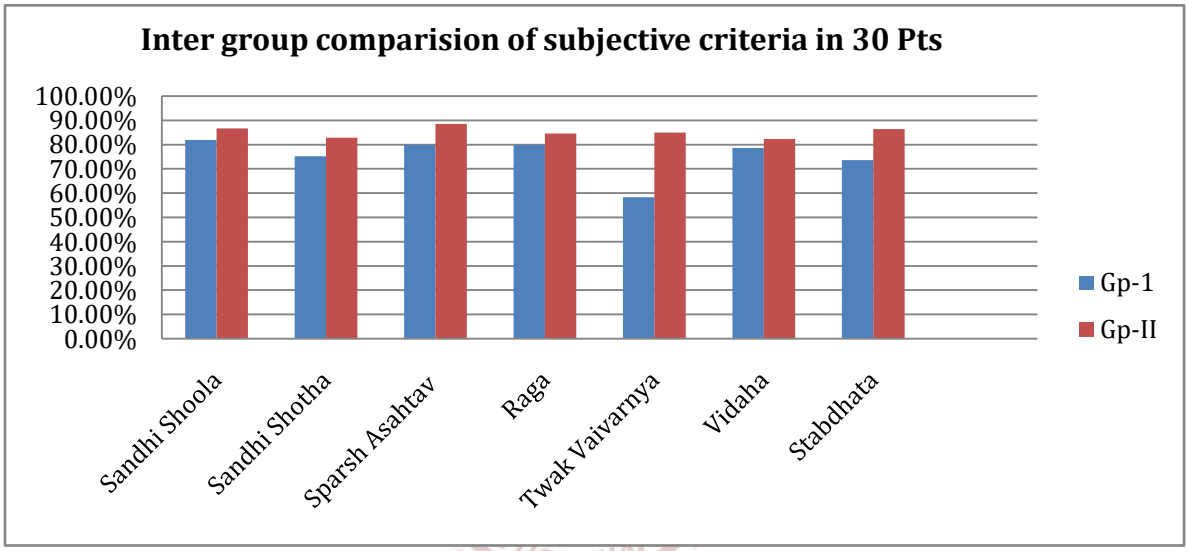

Fig.3:- Gp-I (Group-1), Gp-II(Group-Ii)

Effect of Therapy Based on Objective Criteria

Table 6: Effect of Therapy on Serum Uric Acid (GP-I)

Sr. No.	N.	Serum uric acid mean level		%age of reduction	SD±	SE±	t	P
		BT	AT					
1.	15	7.727	5.667	26.65%	0.280	0.072	4.983	<0.05

Fig. 4: Effect of Therapy on Serum Uric Acid (GP-I)

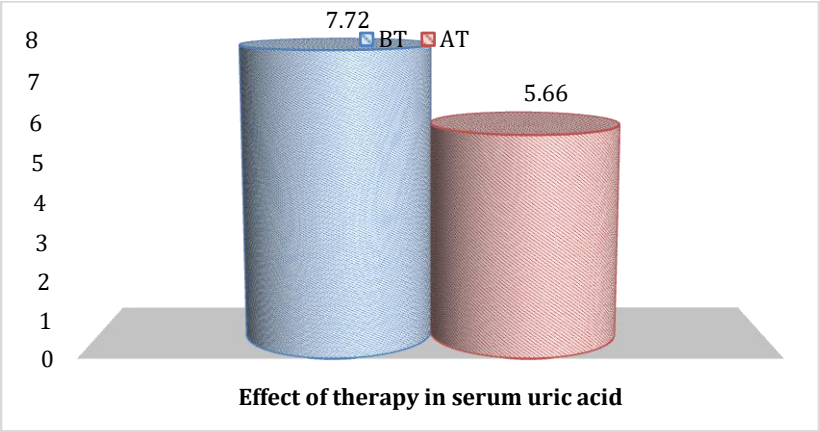

Figure 4.*BT (Before Treatment), AT (After Treatment),

Table 7: Effect of Therapy on Serum Uric Acid (GP-II)

S.No.	N	Serum uric acid Mean level		%age of Reduction	SD±	SE±	t	P
		BT	AT					
1	15	8.200	5.107	37.71%	0.675	0.174	6.278	<0.001

Fig 5: Effect of therapy on Serum Uric acid (GP-II)

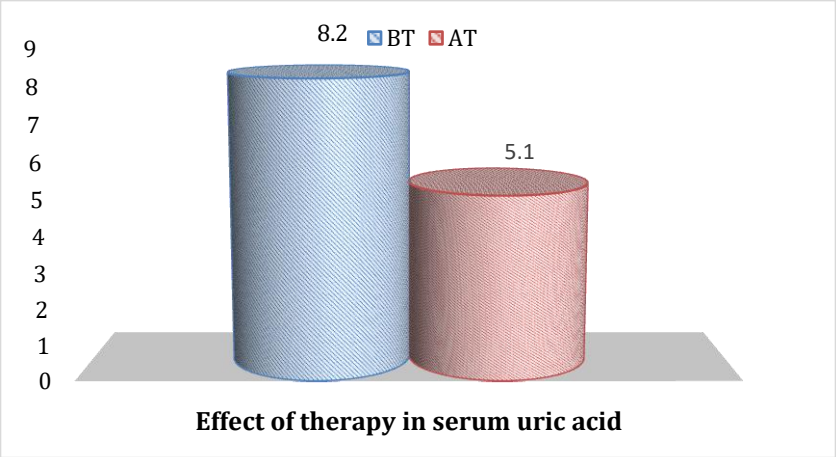

Figure 4.*BT (Before Treatment), AT (After Treatment)

Table 8: Inter group comparison of therapy on serum uric acid (unpaired t test)

Sr. No.	Signs and symptoms	% Relief		Diff. in %age	SD ±		SE±		't'	P
		Gr.-I	Gr.-II		Gr.-I	Gr.- II	Gr.- I	Gr.-II		
1.	Uric acid	26.65%	37.71%	11.06%	0.280	0.674	0.0722	0.174	1.380	>0.05

Fig 6: Inter group comparison of therapy on serum uric acid (unpaired t test)

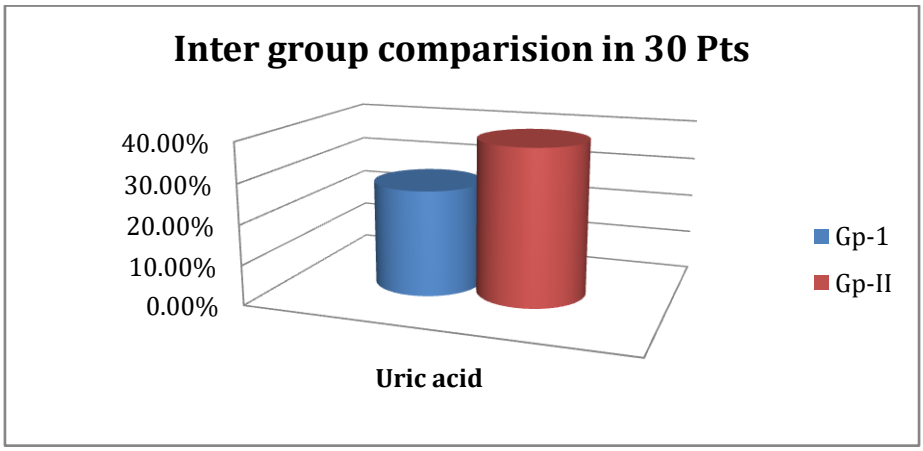

Fig 6: GP-I (Group-1), GP-II (Group-II)

Effect of Therapy

Subjective Criteria

Signs and Symptoms (Table. 2, 3, 4, 5)

86.66% patients included under clinical trial in both the groups were presented with *Sandhi Shoola.* 81.97% relief in Group-I patients and 86.66% relief in Group-II patients was found. The result was highly significant (p<0.001) for both groups.

Intergroup comparison shows that the effect of therapy on *Sandhi Shoola* was slightly better in Group- II patients, with 4.69% more relief than Group-I. This difference was insignificant (p>0.05).

75.18% relief in Group-I and 82.85% relief in Group-II was observed for *Sandhi Shotha*. The result was highly significant (p<0.001) for both groups.

Intergroup comparison shows that the effect of therapy on *Sandhi Shotha* was slightly better in Group- II patients, with 7.67% more relief

than Group-I. This difference was insignificant (p>0.05).

80% relief was observed in Group-I and 84.61% relief was found in Group-II for *Raga.* Result was significant in both the groups (p<0.05).

Intergroup comparison shows that the effect of therapy on *Raga* was slightly better in Group- II patients, with 4.61% more relief than Group- I. This difference was insignificant (p>0.05).

58.33% relief was observed in Group-I and 85.00% relief was found in Group-II for *Twaka Vaivarnya***.** Result was insignificant for Group-1 at (p>0.05) whereas it was found significant for Group-II at (p<0.05). This difference in result may be due to the variation in sample size as well as due to the small number of patients.

Intergroup comparison shows that the effect of the therapy on *Twaka Vaivarnya* was better in Group- II patients, with 26.67% more relief than Group-I. This difference was insignificant *(p>0.05).*

78.57 % relief was found in Group-I and 82.33% relief was observed in Group-II for *Vidaha*. Result was highly significant for both the groups (p<0.001).

Intergroup comparison shows that the effect of the therapy on *Vidaha* was slightly better in Group- II patients, with 3.76% more relief than Group-I. This difference was insignificant (p>0.05).

80.00 % relief in Group-I and 88.46 % relief in Group-II was assessed for *Sparsh ashayatav*. Result was highly significant for Group-I and Group-II (p<0.001).

Intergroup comparison shows that the effect of the therapy on *Sparsh ashayatav* was better in Group- II patients, with 8.46% more relief than Group-I. This difference was significant (p<0.001).

A highly significant relief i.e. around 73.57% in Group-I (*p<0.001*) and 86.46% in Group-II (*p<0.001*) was observed for *Stabdhata***.**

Intergroup comparison shows that the effect of therapy on *Stabdhata* was slightly better in Group- II patients, with 12.89% more relief than Group-I, however difference was insignificant (p>0.05).

Objective Criteria

Serum Uric Acid (Table 6,7,8)

The main laboratory criterion to assess the effect of the drug was the estimation of serum uric acid. After completion of treatment there was a significant reduction i.e. 26.65% (p<0.05) fall in serum uric acid level of Group-I patients whereas in Group-II, there was a highly significant reduction i.e. 37.71% (p<0.001) fall in serum uric acid level.

Intergroup comparison shows that the effect of the therapy on serum uric acid level was better in Group- II patients, with 11.06% more relief than Group- I, although difference was insignificant at p>0.05.

DISCUSSION

The tree *Ficus religiosa* contains terpenoids, flavonoids, tannins, glycosides and phenols[8]. The analgesic effect of the drug is due to its chemical constituents and is mediated via inhibition of cyclooxygenases leading to the inhibition of prostaglandin synthesis, which reduces the pain significantly.

Guduchi plant possesses *Snigdhaguna* and *Madhuravipaka*, and is *Tridoshahara*,[9] which helps in relieving pain mainly caused due to vitiation of *Vatadosha*. *Guduchi* possess alkaloids, glycosides, steroids and terpenoids. The analgesic effect of this drug can be attributed to these phytoconstituents, the flavonoids present may mediate the inhibition of prostaglandins. It also contains diterpenoid lactones, glycosides and polysaccharides which have a diuretic effect, because of which there is an additional reduction in *Sandhishotha* compared to *Bodhivrikshkashaya.* Apart from this, *Amrita* (*Guduchi)* also has properties, including *Rasayana* and *Srotovishodhana;* which helps in maintaining homeostasis in *Doshas and Dhatus*. Due to *Mutravirechana* property this drug also helps in excretion of excessive uric acid present in the blood.

Shunthi acts as carminative, appetizer, aphrodisiac, expectorant, analgesic, bronchodilator, anti-flatulent; anti-inflammatory, anti-tumorigenic, antiemetic, anti-hyperlipidemic, and antitussive. Ginger root inhibits the production of prostaglandins and leukotrienes, which are involved in pain and inflammation.[10]

Coriandrol is the major phytochemical present in *Coriandrum sativum L. (Dhanyak),* which is a very effective anti-inflammatory agent. It helps to reduce inflammation in various body parts and body joints. It also helps to reduce severe ache that is caused by inflammation.[11]

CONCLUSION

Bodhi vriksh kashaya contains flavanoids, which has a direct action on xanthine oxidase enzyme. As *Amrita* can inhibit the production of excess uric acid, while at the same time excrete excessive uric acid, this might be the reason, *Amritaadi kwath* shows better effect in reducing the uric acid levels in the blood.

While comparing the effect of *Bodhi Vriksha Kashaya* and *Amritaadi kwath* based on the subjective and objective criteria, it is found that the

net effect of both the trial drugs was significant, however, Group-II patients were more benefitted than Group-1 patients. Therefore, we believe that the effect of *Amritaadikwath* was more than *Bodhi Vriksh Kashaya.*

Patients who did not follow a proper diet; did not show much effect after the treatment. No major adverse effect of the therapy was noted during the entire trial and the follow-up period. However, a few patients complained of acidity after the intake of *Kashaya*.

REFRENCES

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