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TO EVALUATE THE COMPARATIVE EFFECT OF BODHI VRIKSHA KASHAYA AND GUDUCHI KASHAYA IN THE MANAGEMENT OF VATARAKTA W. S. R TO GOUT.

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ABSTRACT

The prevelance of gout ***(Vatarakt)*** is increasing day by day in indian population. Gout (*Vatarakt*) is a chronic and complex metabolic disorder of muscloskelton system. It is a disorder which cause inflammatory condition with pain and impairment in the locomotor function. It is a protein metabolism disorder. In *Ayurveda* every treatment is based on *Srotoshodhan Chiktsa* and *Tridosha Sidhant*. Therefore, *Guduchi Kashya* and *Bodhi Vriksha Kashaya* was having both these properties. Taking into the present study has been entitled "***To evaluate the comparative effect of Bodhi Vriksha Kashaya and Guduchi Kashaya in the management of Vatarakta w.s.r to Gout"***has been carried out to establish the efficacy of the treatment. In the present study minimum of 20 subjects diagnosed as *Vatarakta* were selected incidentally irrespective of caste, religion, sex, occupation& socioeconomic status and randomly categorized into 2 groups consisting of 10 patients in each group. Group 1: *Bodhi Vriksha Kashaya*, Group 2: *Guduchi kashaya*. The duration of trail was 45 days with follow up of 15 days. The observations obtained are analysed statistically and is observed that *Gaduchi kashaya* was found to be more effective than *Bodhi Vriksha Kashaya* individually.

KEYWORDS: *Gaduchi Kashaya, Bodhi Vriksha Kashaya, Vatrakat*.

INTRODUCTION

The word "*Anusandhana*" itself explanatory i.e. to add up the literal meaning of word *"Anu"* means *Paschat* (after) and *"Sandhana"* means adding up or joining. Here the present knowledge is subject to add with newly discovered facts. For revival and progress of any science, research is an essential practice. For convincing the people, it is essential to establish the facts by derived proofs after careful investigations, observations and experiments along with accurate statistical support. To confirm the efficacy of the drug, though experimental study plays an important role, yet a study remains incomplete unless it is supported by clinical trials. Thus the data obtained from the clinical study is useful in ascertaining the beneficial effect seen in experimental study. Clinical study adds and confirms the findings of the experimental study.

Vatarakta is a burning problem of the society due to irregular and improper food habits, busy and stressful life style. It is distressing and embarrassing to both the patient and the physician. This may compromise the quality of life of the patient due to permanent degenerative changes in joints, deformity of the joints and other tissues. In modern medicine, drugs are effective in relieving symptoms and agony of pain but associated with side effect that is why use for a longer period is cautionary. Here the present clinical work is undertaken to assess and evaluate the Comparative effect of *Bodhi Vriksha Kashaya* and *Guduchi Kashaya* in the Management of *Vatarakta* w.s.r. to Gout so that the progression of the disease can be controlled and quality of life can be improved.

AIMS AND OBJECTIVES

1. To study the literature pertaining to *Vatarakta* and Gout in different *Ayurvedic Samhitas* and modern era.
2. To study the etiopathogenesis of *Vatarakta.*
3. To evaluate the comparative effect of *Bodhi Vriksha Kashaya* and *Guduchi Kashaya in* lowering the S. uric acid level and relief on clinical features in patients of *Vatarakta* (Gout). It was an open trial with two groups. In this trial total 20 patients were diagnosed with *Vatarakta* and selected incidentally and randomly in two groups.

Ethical Clearance - No. Ayu/IEC/2015/1093
The proposed clinical study was presented in the form of a synopsis in front of the Institutional Ethics Committee. The clinical trial was started after the approval from the Chairman of Ethics committee.

PLAN OF STUDY/MATERIALS & METHODS

a) Clinical study
This was the main study of the present research work in which minimum sample of 20 patients was assessed during clinical trial.

b). Study design
Prospective and retrospective - Prospective
Randomizedor not - Randomized
Number of patients for trial - 20
Total duration of trial - 45 days
Follow-up visit - after 15 days

Protocol of Research
- The proposed work was an open and unicentral clinical trial.
- Patients were selected from Patients having clinical features of *Vatarakta*, according to *Ayurvedic Samhitas* as well as Modern science were selected from OPD/IPD of RGGPG Ayurvedic College & Hospital, Paprola (Kangra).Study was conducted on selected 20 patients in two groups
  - Group I - *Bodhivriksha (Peepal)Kashaya*
  - Group II - *Guduchi kashaya*

- **Trialdrug**[6,7,8]

Sr. No.	Name of Drug	Botanical Name	Family	Part Used
1.	Bodhi Vriksha	Ficus religiosa	Moraceae	Twak (Bark)
2.	Guduchi	Tinospora cordifolia	Menispermaceae	Kand (Stem)

- The raw drugs were taken from the *Baijnath* pharmaceuticals due to the unavailablability of these drugs in *Charaka* pharmacy Paprola and *Jogindernagar* pharmacy. The *Yavkut Churna* of these drugs was prepared in *Charaka* Pharmacy Paprola & was tested at Govt. Drug Testing Lab, Jogindernagar, Distt. Mandi.

- ***Kashaya preparation***

Patients were advised to take 40g of crude drug (*Yavkut Churna*) in a pot, add 320ml of water and boil it upto 1/4th reduction.

- ***Dosage of the drug***
  - *Bodhivriksha (Peepal) Kashaya* - 40ml. morning-evening.
  - *Guduchi Kashaya* - 40ml. morning-evening.

- ***Anupan***
  - *Bodhivriksha (Peepal)Kashaya* - *Madhu*
  - *Guduchi Kashaya*

Study Schedules
a. Screening
b. Enrollment
c. Follow up

a. Screening
The patients attending the OPD/IPD department with symptoms and signs of *Vatarakta* were considered for inclusion in the study.

Consent – Written and informed consent of patients was taken before inclusion in the trial.

b. Enrollment
Selection of patients
Patients were selected from the OPD/IPD of RGGPG Ayurvedic College & Hospital, Paprola (Kangra) randomly fulfilling the criteria of diagnosis.

Inclusion criteria
i. Patients willing to participate in trial.
ii. Patient in the age group between 20 – 70 years of either sex.
iii. Patients having serum uric acid level more than 6 mg/dl in male and more than 5 mg/ dl in female with or without any associate features like joint pain and inflammation.

Exclusion criteria
A. Patients not willing for the trial.
B. Patients below age of 20 years and above 70 years of age.
C. Any other inflammatory joint disorder like RA, tubercular arthritis etc.
D. Patients suffering from chronic respiratory, cardiac, hepatic and hormonal diseases.
E. Patients on chronic use of NSAIDS.
F. Patients having malignant disorder.
G. Any other patient considered unfit for inclusion in criteria.

Diagnostic criteria
The patients were diagnosed on the basis of *Ayurvedic* and Modern parameters. Clinical signs and symptoms as described in classical texts were considered for the diagnosis of *Vatarakta*. They are as follows:
1. *Sandhi Shoth* (Swelling of joint)
2. *Sandhi Shool* (Joint pain)

3. *Sparsha Asahatva* (Tenderness)
4. *Raga* (Redness)
5. *Twak Vaivarnaya* (Skin discoloration)
6. *Vidaha* (Burning sensation)
7. *Status of pain on Movement of Joint*
8. *Sandhi Vikriti* (Joint deformity)[1,2,3]

C. Follow up - 3 follow-ups after 15 days' interval
It was done every two weeks till the completion of therapy. After starting the therapy, the patients were examined in every visit for pulse, blood pressure, temperature, signs and symptoms, appetite, bowel habits and general condition. All the cases were subjected to clinical observation throughout the course of treatment to assess the efficacy of drug from time to time and also to note any adverse effect. After 45 days, when the trial was completed, thorough examination of the patient was carried out. After completion of therapy patient were also asked to come for post-trial follow up weekly for duration of 4 weeks to assess the sustenance of effects of the therapy and for any untoward effects of trial drugs.

Investigations

- Routine haematological
  - Hbgm%, TLC, DLC, ESR
- Biochemical investigations.
  - FBS, B. Urea, S. Creatinine, R.A factor, Uric acid
- Routine and microscopic urine examination.
- Radiological examination of the joint if required.

Dietary Instructions
All the patients were advised regarding their *Ahara* and *Vihara* during the trial period and follow up also.

They were advised to take low protein and high carbohydrate diet. Patients were advised to avoid meat, alcohol, cheese and pulses with intact outer coat (testa). *Ruksha* irritant astringent, salty and sour foods are also asked to be avoided.

Criteria of Assessment
Scoring system was adopted for assessment of various subjective features and grades from zero to three were accorded to various features according to the severity. The grading of various clinical features is as follows

During study period patients were thoroughly assessed on the basis of various subjective and objective parameters. Various subjective parameters were recorded grading on the basis of severity for the purpose of assessment. Patients were enquired about the growing feeling of physical and mental wellbeing during the study period. A special proforma was designed in-corporation following *Ayurvedic* parameters for the purpose of assessment.

Grading For Assessment
1. *Sandhi Shoola*
Grade Pain status
0 No pain at rest, No pain while working
1 No pain at rest, Mild tolerable pain while working
2 Mild pain at rest, Moderate and tolerable pain while working.
3 Moderate Pain at rest, Severe and intolerable pain while working.

2. *Sandhi Shotha*
Grade Swelling status
0 No swelling
1 Mild swelling
2 Moderate swelling without loss of movements
3 Severe swelling with loss of movements.

3. *Sparsha Asahatava*
Grade Tenderness status
0 No pain on palpation
1 Mild pain on palpation
2 Moderate pain on palpation
3 Patient do not allow to palpate

4. *Raga*
Grade Redness status
0 No redness
1 Mild redness
2 Moderate redness
3 Severe redness

5. *Twak vaivarnya*
Grade Discoloration status
0 No discoloration of skin
1 Mild discoloration
2 Moderate discoloration
3 Severe discoloration

6. *Vidaha*
Grade Burning sensation status
0 No burning sensation
1 Mild burning sensation
2 Moderate burning sensation
3 Severe burning sensation

7. Status of pain on Movement of Joint
Grade Status of pain on Movement of Joint
0 Minimal pain with Active Joint Movement
1 Moderate pain with Passive Joint Movement
2 Severe pain with Lesser Joint Movement
3 Severe Pain with No Joint Movement

8. *Sandhi vikriti*
Grade Deformity status
0 No deformity
1 Mild deformity of single joint
2 Deformity of 2 – 3 joints
3 Formation of tophi in multiple joints

Grade	Symptoms	Percentage
0	Absent /none	0
1	Mild	1 – 30
2	Moderate	31 – 60
3	Severe	61 – 100

Objective criteria
To assess the effect of therapy on objective parameters, serum uric acid level will be assessed before and after the treatment.

S. Uric acid

Fall in S. uric acid mg/dl	Grade
Fall in S. uric acid up to 0 mg/dl	0
Fall in S. uric acid up to 0.5 mg/dl	1
Fall in S. uric acid up to 1.0 mg/dl	2
Fall in S. uric acid up to 1.5 mg/dl	3
Fall in S. uric acid up to 2.5 mg/dl	4

Final Assessment of Results
Patients were assessed before and after the treatment for improvement in symptoms on the basis of above said scoring pattern and percentage improvement was calculated.

Statistical Analysis
The obtained data was analyzed statistically and expressed in terms of mean score before treatment (BT), after treatment (AT), difference of mean (BT – AT), standard deviation (SD) and standard error (SE).

Overall percentage improvement of each patient was calculated by the following formula

$$\frac{\text{Total BT} - \text{Total AT}}{\text{Total BT}} \times 100$$

Students paired 't' test was applied at $p > 0.05$, $p < 0.05$, $p < 0.01$, and $p < 0.001$, to observe significance of results obtained after treatment. The results were considered significant or insignificant depending upon the value of p.

- Extremely significant - $p < 0.0001$
- Highly significant - $p < 0.001$
- Moderately significant - $p < 0.01$
- Significant - $p < 0.05$
- Insignificant - $p > 0.05$

OBSERVATIONS AND RESULTS

In the present study, 20 patients were studied. These patients were treated in two groups. 10 patients in Group-I and 10 patients in Group-II were registered. Hence the demographic data is presented according to 20cases.

Result - Observation and results obtained were statistically analyzed by using student paired 't' test and unpaired 't' test and presented in the form of thesis.

Demographic Profile
Demographic data of all the 20 patients registered for clinical trial is shown here on the basis of Age, Sex, Marital status, Religion, Occupation, Education status, Economic status, habitat, lifestyle, family history, addiction, diet, nature of onset, distribution of joint involvement, No. of joints involved, *Prakriti* and chronicity.

Maximum number of patients i.e. 65% were in the age Group of 41- 60 years.

Sex Wise Distribution in 20 patients
Sex wise distribution shows that 55% patients were males and 45% were females.

Marital Status Wise Distribution in 20 patients
Maximum number of patients, i.e. 95.00% were married.

Religion Wise Distribution in 20 patients
The Hindu dominant population residing in and around the place of study.

Education Wise Distribution in 20 patients
It is observed here that maximum numbers of patients i.e. 40.00% were matric pass, 35.00% were under matric, 10%were illiterate, 10% were post graduate and 5% were graduate.

Occupation Wise Distribution in 20 patients
Occupation wise distribution of the patients shows that 60% patients were doing desk job, 20% were doing field work & 20% patients were housewives.

Socio-economic Status Wise Distribution in 20 patients
Socio economic status wise distribution of 20 patients shows that 30% patients were of low socio economic class, 70% patients were of middle class.

Familial History wise distribution in 20 patients
Family history wise distribution of gout showed that only 20% i.e. 04 patients had positive family history of gout and rest 80% did not have familial history of the disease.

Habitat Wise Distribution in 20 patients
Most patients i.e. 70% were residents of rural area and 30% were resident of semi-urban area.

Dietary Habits Wise Distribution in 20 patients - Majority of patients i.e. 70% had Mixed dietary habits and 30% patients were vegetarians.

Life style wise distribution in 20 patients
Life style distribution of 20 patients showed that 75% i.e.15 patients were having sedentary life style and only 25 % of patients i.e. 05 patients were leading an active life style.

Nature of onset wise distribution of 20 Patients Nature of onset wise distribution of 20 patients showed that 65% patients (13) had acute onset of disease and rest 35% or (7) patients had insidious nature of onset.

Prakriti Wise Distributionin 20 patients
60% patients had predominant *Vata-Pittaj Prakriti*, followed by *Pitta-Kaphaja* (30%) and *Vata-Kaphaja Prakriti(10%).*

Addiction wise distribution in 20 patients

Addiction wise distribution of 20 patients shows that 75 % of patients i.e. 15 patients had no addiction, 10% i.e. 02 patients were addicted to alcohol and 10% i.e. 02 patients were addicted to smoking.

Chronicity of Disease Wise Distribution
Duration of illness wise distribution of 20 patients showed that 10 patients (50%) presented with 2 months-2 years of chronicity, 8 patients (40%) presented with <2 Months of duration and 2 patients (10%) reported <2 months of chronicity.

Symmetry of joint involvement wise distribution in 20 Patient
Symmetry wise distribution of joint involvement of 20 patients showed that 13 patients i.e. 65% had asymmetrical involvement of joints and only 7(35%) patients reported symmetrical involvement of joints.

Type of joint involvement in 20 patients
Distribution of 20 patients on the basis of joints involved shows that MTP (Metatarsophalangeal) joints were involved in 17 patients (85%) out of 20 patients, ankle joints involvement was seen in 14 patients (70%), whereas wrist joints involvement was seen in 9 patients (45%), 8 patients (40%) presented with the involvement of knee joints. Next in order was the involvement of

M.C.P (Metacarpophalangeal) joints which was seen in 7 patients (35%) and 6 patients (30%) presented with I.P (interphalangeal) joints involvement.

CLINICAL OBSERVATIONS AND RESULTS

Table 18: Table showing incidence of signs and symptoms of gout in 20 patients.

Sr. No.	Symptoms	Gr. - I		Gr. – II		Total	
		Pt.	%age	Pt.	%age	Pt.	%age
1.	*Sandhi Shoola*	10	100%	10	100%	20	100%
2.	*Sandhi Shotha*	06	60%	07	70%	13	65%
3.	*Sparsha Asahatvam*	10	100%	10	100%	20	100%
4.	*Raga*	04	40%	07	70%	11	55%
5.	*Twak Vaivarnaya*	04	40%	03	30%	07	35%
6.	*Vidaha*	09	90%	09	90%	18	90%
7.	*Pain on joint movement*	10	100%	10	100%	20	100%
8.	*SandhiVikriti*	01	05%	01	05%	02	10%

Predominance of signs and symptoms of *Vatarakta*/gout were studied in 20 patients and it was observed that all the 20 patients presented with the complaint of *Sandhi Shoola, Sparsha Asahatvam and pain on joint movement. Vidaha* was observed in 18 patients (90%). 13 patients (65%) presented with the complaint of *Sandhi Shotha*. *Raga* was observed in 11 patients (55%). *Twak Vaivarnaya*was observed in 7 patients (35%). Only 2 patients (10%) complained of *Sandhi Vikriti*.

Effect of Therapy
All the patients were registered from OPD of R. G. G. P. G. Ayurvedic College and Hospital, Paprola. 20 patients were given the trial in two groups considering 10 patients in each group. Grading system was adopted for the assessment of effect of trial drug. 8 criteria of assessment were selected and their signs and symptoms were recorded on 1stand 45thday. The effect of therapy was studied on 20 patients.

Effect of Therapy on The Basis of Subjective Criteria
The effect of "*Bodhi Vriksha Kashaya*" in 10 patients on various assessment criteria was obtained after statistical analysis of the data obtained and is presented in tabular form (Table No. 20).

Table 19: Effect of therapy in 10 patients of Group-I (paired t test).

Sr. No.	Symptoms	Mean		% relief		SD±	SE±	't'	P
		BT	AT	Diff.	%age				
1.	*Sandhi Shoola*	2.0	0.4	1.6	80%	0.51	0.16	9.79	<.001
2.	*Sandhi Shotha*	1.6	0.3	1.3	81.25%	0.51	0.21	6.32	<.001
3.	*Sparsh Asahtav*	1.2	0.4	0.8	66.66%	0.42	0.13	6.00	<.001
4.	*Raga*	1.0	0.2	0.8	80%	0.44	0.20	4.00	<.05
5.	*Twak Vaivarnya*	1.2	0.5	0.7	58.33%	0.50	0.25	3.00	>.05
6.	*Vidaha*	1.4	0.3	1.1	78.57%	0.33	0.11	10.00	<.001
7.	*Status of pain on joint movement*	1.4	0.4	1.0	71.42%	0.47	0.14	6.70	<.001
8.	*Sandhi Vikriti*	3	1	2	33.33%	-	-	-	>.05

Fig. No. 19: Effect of therapy in 10 patients of Group-I (paired t test).

1. ***Sandhi Shoola*:** The mean gradation of *Sandhi Shoola* before treatment was 2.0 which reduced to 0.4 after the completion of the treatment. This 80% relief is statistically highly significant (p <0.001).
2. ***Sandhi Shotha*:** The mean gradation of *Sandhi Shoola* before treatment was 1.6 which reduced to 0.3 after the completion of the treatment. This 21.25% relief is statistically highly significant (p <0.001).
3. ***Sparsh Asahtav*:** The mean gradation of *Sparsh Asahtav* before treatment was 1.2 which decreased to 0.4 after completion of the treatment. This 66.66% relief is statistically highly significant (p <0.001).
4. ***Raga*:** The mean gradation of *Raga* before treatment was 1.0 which decreased to 0.2 after the completion of the treatment. This 80% relief is statistically significant (p <0.05).
5. ***Twak Vaivarnya*:** The mean gradient of *Twak Vaivarnya* was 1.2 which reduced to 0.5 after the completion of the treatment. This 58.33% relief is statistically non-significant (p >.05)
6. ***Vidaha*:** The mean gradation of *Vidaha* before treatment was 1.4 which reduced to 0.3 after the completion of the treatment. This 78.57% relief is statistically highly significant (p <0.001).
7. **Status of pain on joint movement:** The mean gradation of *Status of pain on joint movement* before treatment was 1.4 which reduced to 0.4after the completion of the treatment. This 71.42% relief is statistically highly significant (p <0.001).
8. ***Sandhi Vikriti*:** The mean gradation of *Sandhi Vikriti* before treatment was 3.0 which reduced to 1.0 after the completion of the treatment. This 33.33% relief is statistically non-significant (p >0.05).

Table 20: Effect of therapy in 10 patients of Group-II (paired t test).

Sr. No.	Symptoms	Mean		% Relief		SD±	SE±	't'	P
		BT	AT	Diff.	%age				
1.	*Sandhi Shoola*	2.0	0.3	1.7	85%	0.48	0.15	11.29	<.001
2.	*Sandhi Shotha*	1.5	0.2	1.3	86.66%	0.86	0.28	4.61	<.05
3.	*Sparsh Asahtav*	1.8	0.4	1.4	77.77%	0.51	0.16	8.57	<.05
4.	*Raga*	1.3	0.2	1.1	84.61%	0.64	0.22	4.96	<.05
5.	*Twak Vaivarnya*	2.0	0.3	1.7	85%	0.57	0.33	5.00	<.05
6.	*Vidaha*	1.8	0.3	1.5	82.33%	0.52	0.17	8.85	<.001
7.	Status of pain on joint movement	1.8	0.4	1.4	77.77%	0.51	0.16	8.57	<.001
8.	*Sandhi Vikriti*	2	1	1	50%	-	-	-	>.05

Table 21: Inter group comparison over criteria of assessment (unpaired t test).

Sr. No.	Symptoms	% Relief		Diff. in %age	SD ±	SE ±	't'	P
		Gr.- I	Gr. II					
1.	*Sandhi Shoola*	80%	85%	05%	0.03	0.01	0.45	>.05
2.	*Sandhi Shotha*	81.25%	86.66%	5.41%	0.03	0.02	0.36	>.05
3.	*Sparsh Asahtav*	66.66%	77.77%	11.77%	0.09	0.03	4.30	<.001
4.	*Raga*	80%	84.61%	4.6%	0.20	0.02	0.82	>.05
5.	*Twak Vaivarnya*	58.33%	85%	26.67%	0.07	0.07	2.47	>.05
6.	*Vidaha*	78.57%	82.33%	5.4%	0.19	0.06	1.94	>.05
7.	*Status of pain on joint movement*	71.42%	77.77%	6.3%	0.04	0.02	1.82	>.05
8	*Sandhi Vikriti*	33.33%	50%	16.67%	-	-	-	>.05

Overall Effect of Therapy (Subjective Criteria)

Table 22: Overall effect of therapy in 20 patients.

Total effect	Gr.- I		Gr.- II		Total	
	No. of pts.	% age	No. of pts.	% age	No. of pts.	% age
Cured (100% relief)	1	10	4	40	5	25%
Markedly Improved (76-99% relief)	4	40	4	40	8	40%
Moderately Improved (51-75% relief)	5	50	2	20	7	35%
Mildly Improved (25-50% relief)	0	0	0	0	0	0
Unchanged (<25% relief)	0	0	0	0	0	0

Overall effect of therapy in 20 patients

Group – I: Among 10 patientscompletely, 1 patient was cured, 5 patients were moderately improved, 4 patients were markedly improved, and none of the patient was mildly improved or remained unchanged on the basis of subjective criteria.

Group – II: Among 10 patients, 4 patients were cured completely, 2 patients were moderately improved, 4 patients were markedly improved, and none of the patient was mildly improved or remained unchanged on the basis of subjective criteria.

Overall effect of therapy shows that, 40% patients showed marked improvement, 35% patients were moderately improved, 25% patients cured completely.

Effect of Therapy on The Basis of Objective Criteria

Table 23: Effect of therapy on Serum Uric acid (GP-I).

S. No.	N	Serum uric acid Mean level		% age of Reduction	SD±	SE±	t	P
		BT	AT					
1	10	7.06	5.37	23.93%	1.63	0.51	3.26	<0.05

Table 24: 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	10	7.30	4.45	39.04%	1.17	0.37	7.68	<0.001

Table 25: Inter group comparison over criteria of assessment (unpaired t test).

Sr. No.	Signs and symptoms	% Relief		Diff. in %age	SD ±	SE ±	't'	P
		Gr.- I	Gr.-II					
1.	Uric acid	29.93%	39.04%	15.11%	0.46	0.14	1.82	>.05

Serum uric acid: Group-II showed 15.11 % more relief than Group-I, the difference was statistically insignificant at p>0.05.

Effect of Therapy on Blood Examinations

1. Effect of Therapy on Hb, TLC, FBS and ESR.

	Hb		TLC		ESR		FBS	
	Grp I	Grp II	Grp I	Grp II	Grp I	Grp II	Grp I	Grp II
Mean BT	12.69	12.77	6593	6127	19.2	13.9	85.70	96.20
Mean AT	13.03	13.10	5910	6360	16.2	*9.6*	97.00	94.00
S.D. ±	1.48	1.47	1721.49	1783.37	17.01	6.60	26.91	13.33
S.E. ±	0.46	0.46	544.38	563.95	5.38	2.08	8.51	4.21
t	-0.726	-0.710	1.255	-0.413	0.558	2.060	-1.328	0.522
p	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	<0.05

2. Effect of Therapy on B. Urea, S. Creatinine.

	B. Urea		S. Creatinine	
	Grp I	Grp II	Grp I	Grp II
Mean BT	22.90	28.20	0.86	0.86
Mean AT	22.90	24.50	0.91	0.91
S.D. ±	3.94	8.53	0.12	*0.30*
S.E. ±	1.24	2.70	0.04	*0.09*
t	0.00	1.37	-1.24	*-0.51*
p	>0.05	>0.05	>0.05	>0.05

3. Effect of Therapy on DLC.

	Neutrophils		Lymphocytes		Mixed	
	Grp I	Grp II	Grp I	Grp II	Grp I	Grp II
Mean BT	52.28	57.99	31.46	35.48	10.16	7.39
Mean AT	61.03	56.56	29.19	34.43	9.71	9.01
S.D. ±	3.73	8.88	5.23	9.49	4.12	3.11
S.E. ±	1.18	2.81	1.65	3.00	1.30	0.98
t	-2.32	*0.50*	1.37	0.35	0.34	-1.64
p	>0.05	>0.05.	>0.05	>0.05	>0.05	>0.05

4. Effect of Therapy on Lipid Profile.

	Cholesterol		TG		HDL		LDL		VLDL	
	Grp I	Grp II	Grp I	Grp II	Grp I	Grp II	Grp I	Grp II	Grp I	Grp II
Mean BT	175.9	172.4	148.5	133.5	49.30	46.00	96.9	99.70	29.70	26.70
Mean AT	186.1	184.5	157.4	147.0	52.50	50.40	102.2	104.7	31.50	29.40
S.D. ±	55.71	62.32	80.44	85.11	10.70	8.04	42.18	57.25	16.04	17.02
S.E. ±	17.61	19.70	25.44	26.91	3.38	2.54	13.34	18.10	5.07	5.38
T	-0.57	-0.61	-0.35	-0.50	-0.94	-1.73	-0.39	-0.27	-0.35	-0.50
P	>0.05	>0.05	>0.05	>0.05	>0.05	>. 05	>0.05	>. 05	>. 05	>. 05

Overall data shows that the effect of therapy on blood investigations was within normal limits in both the groups and the difference in the mean score values of blood investigations before and after treatment was statistically insignificant in both the groups (p >0.05).

DISCUSSION

Discussion is essential for proper understanding of various aspects of a subject. It adds to the quantum of knowledge and makes the approach regarding the research work more scientific and versatile. It also forms the basis for the future workers. It should be based on certain authentic classics, experiences and proofs. *Charaka* says that; **"Shastrasahitatarka"** (comments or discussion based on texts) is essential for *GyanSaadhana* (to attain the knowledge). The present era is of proofs and verifications. The research work should have a scientific basis well endorsed by proper experiments, observations and statistical analysis. The authenticity of a fact can be well established by a good reasoning and scientific explanation of the same. An idea becomes an established fact only after passing through series of examinations and reasoning.

The present study***"To Evaluate the Comparative Effect of Bodhi Vriksha Kashaya and Guduchi Kashaya in the Management of Vatarakta w.s.r. Gout"***has been conducted at RGGPGAyurvedic College and Hospital Paprola.

Vatarakta is elaborately mentioned in *Charaka Samhita* as an independent disease. The main causative factors for *Vatarakta* are excessive use of *Guru, Lavana*, astringent foodstuffs, excessive use of pulses, alcohol, meat, sedentary life style, psychological components such as excessive anger, emotional distress etc. Aggravated vitiated *Rakta* quickly obstructs the path of already aggravated *Vata*. On obstruction in the route of *Vata* its customary *Gati* is hindered leading to further aggravation. This vitiates the whole *Rakta* and manifests as *Vatarakta.*

Symptoms, signs and etiology of *Vatarakta* described in *Samhitas* are almost similar to that of Gout. Hence clinical features and estimation of uric acid was considered as the main criteria for the assessment of the effect of drug. In the present study 20 patients were enrolled in Two Groups. Total duration of the study was 45 days. At the time of admission patients were examined thoroughly. Hematological and biochemical investigations were done in the beginning and after every forty-five days of the trial. Serum uric acid estimation was done to assess the level after 45 days of the trial. These observations are presented on the basis of scoring system and other parameters and results are analyzed statistically. Inferences drawn are mentioned as under: -

Discussion on Demographic Profile

- ***Vatarakta* in relation to age:** The maximum numbers of patients i.e. 13 were in the age group of 41-60 years (65%).
- **Sex-** In the present study maximum patients were males (55%) and females were only 45% (Table No. 2).
- **Marital Status:** -95% of the patients were married (Table no 3).
- **Religion:** - 100% patients were Hindu (Table no 4).
- **Education-** Maximum (40%) patients were matric passed. 35% patients studied under matriculation, 10% were illiterate,10% were post graduate and 1 patient i.e.,5% was graduate (Table no 5).
- **Occupation-** In the present study, majority of the patients registered were persons doing desk jobs i.e., 60% and 20% were housewives (Table No.6).
- **Socio-Economic status-** Maximum patients (70%) were from middle-income group and 35% were from lower income group. (Table No. 7) Gout was earlier referred to as "disease of kings" or "Rich man disease.
- **Family History-** 80% of patients gave a negative family history. The present study could not confirm the familial tendency of *Vata-Rakta* (Table No. 8).
- **Habitat-** Maximum patients i.e., 70% belonged to rural area and 30 % patients were from semi-urban area. (Table no.9).
- **Dietary habits-** 70% of the patients had mixed diet. (Table No. 10). This is in accordance with the *Ayurvedic* and Modern point of view.
- **Life Style-**Maximum (75%) patients were leading sedentary life style where as 25% patients were having active life style (Table No.11).
- **Nature of Onset-** In present study, maximum i.e. 65 % patients registered with acute onset whereas 35% patients reported insidious onset of the disease (Table no 12).[10]
- ***Prakriti*-** It was observed that maximum patients (65%) were o*f Vata-Pitta Prakriti* (Table No. 13). It has been mentioned that in *Vatarakta*, both *Vata*

Dosha and *Rakta Dhatu* (having *Pitta Yoni*) are vitiated simultaneously.

- **Addiction-** It was observed that 75% patients were having no addiction whereas 10% patients were found addicted to alcohol and 10% patients were addicted to tea (Table No. 14).
- **Duration of Illness-** Chronicity wise data obtained from the registered patients revealed that maximum no. of patients (50%) were having2 months-2 years of duration, followed by 40% patients having <2 months of duration and 10% patients presented with 2-4 years of duration. (Table no 15).
- **Symmetry-** It was observed that 65% patients were having asymmetrical involvement of joints (Table No. 16).[13]
- **Involvement of Joints-** Present study showed that out of 20 patients, M.T.P joint was involved in 85% patients. (Table no 17).

Effect of the Therapy on Clinical Symptoms

1. ***Sandhi Shoola (joint pain):-*** Intergroup comparison shows that the effect of therapy on *Sandhi Shoolawas* slightlybetter in Group- II patients, with 5% more relief than Group-I. This difference was statistically insignificant at (p>0.05).
2. ***Sandhi Shotha (joint swelling):-*** Intergroup comparison shows that the effect of therapy on *Sandhi Shoolawas* slightly better in Group- II patients, with 5.41% more relief than Group-I. This difference was statistically insignificant at (p>0.05).
3. ***Sparsha Asahtava (tenderness):-*** Intergroup comparison shows that the effect of therapy on *Sandhi Shoola* was better in Group- II patients, with 11.77% more relief than Group-I. This difference was statistically significant at (p<0.001).
4. ***Raga (redness):-*** Intergroup comparison shows that the effect of therapy on *Raga* was slightly better in Group- II patients, with 4.6% more relief than Group-I. This difference was statistically insignificant at (p<0.001).
5. ***Twaka Vaivarnya (discolouration):-*** Intergroup comparison shows that the effect of therapy on *Twaka Vaivarnya*was *better* in Group- II patients, with 26.67% more relief than Group-I. This difference was statistically insignificant at (p<0.001).
6. ***Vidaha (burning sensation):-*** Intergroup comparison shows that the effect of therapy on *Vidaha*was slightly *better* in Group- II patients, with 5.4% more relief than Group-I. This difference was statistically insignificant at (p>.05).
7. ***Status of Pain on Joint Movement:-*** Intergroup comparison shows that the effect of therapy on *Status of pain on joint movement* was slightly better in Group- II patients, with 6.3% more relief than Group-I. This difference was statistically insignificant at (p>.05).
8. ***Sandhi Vikriti (joint deformity):-*** Intergroup comparison shows that the effect of therapy on *Sandhi Vikriti was* better in Group- II patients, with 16.67% more relief than Group-I. This difference was statistically insignificant at (p>.05).

Overall Effect of Therapy (Clinical Symptoms)

Group – I: Among 10 patients, 1 patient was cured completely, 5 patients were moderately improved, 4 patients were markedly improved and none of the patient was mildly improved or remained unchanged on the basis of subjective criteria.

Group – II: Among 10 patients,4 patients were cured completely, 2 patients were moderately improved, 4 patients were markedly improved, and none of the patient was mildly improved or remained unchanged on the basis of subjective criteria.

Overall effect of therapy shows that 25% patients cured completely, 40% patients showed marked improvement, 35% patients were moderately improved.

Effect of Therapy on Laboratory Investigations

Serum Uric Acid:- Intergroup comparison shows that the effect of therapy on Serum uric acid level was better in Group-II patients, with 15.11% more relief than Group-I. This difference was statistically insignificant at p>0.05.

Haematological Values

In the present study, no considerable change was recorded in haematological values like Hbgm%, TLC, DLC, ESR of the patients after completion of the therapy.

Biochemical Values

Certain Biochemical investigations, other than Uric acid were conducted before and after the treatment which, included FBS, B. Urea, Serum Creatinine, Total cholesterol, TG, HDL, LDL, VLDL and RA factor. No significant change was recorded during the trial.

Urine examination

No change was recorded in the routine and microscopic examination of urine of patients after completion of therapy

Probable Mode of Action of Drugs

Ayurvedic classics have unique way to explain the mode of action of drugs. The action of every drug is determined by the dominant pharmacodynamic factors in that particular drug and that may be *Rasa, Guna, Veerya, Vipaka and Prabhava*. The certain specific properties of drugs which cannot be explained on these principles are called *Prabhava.*

The fundamentals regarding treatment in *Ayurveda* are mainly based on the *Doshik Chikitsa*. These drugs act in combination as antagonist to the main morbid factors i.e. *Dosha* and *Dushya* to cause *Samprapti Vighatana* to allay the symptoms of the disease.[1,2]

Along with independent vitiation of *Vata Dosha* and *Rakta Dhatu*, excessive intake of *Ahita Ahara Vihara* leads to *Ama* formation which further causes *Jatharagni* as well as *Dhatvagni* (specifically *Raktadhatvagni*) *Mandyata*.

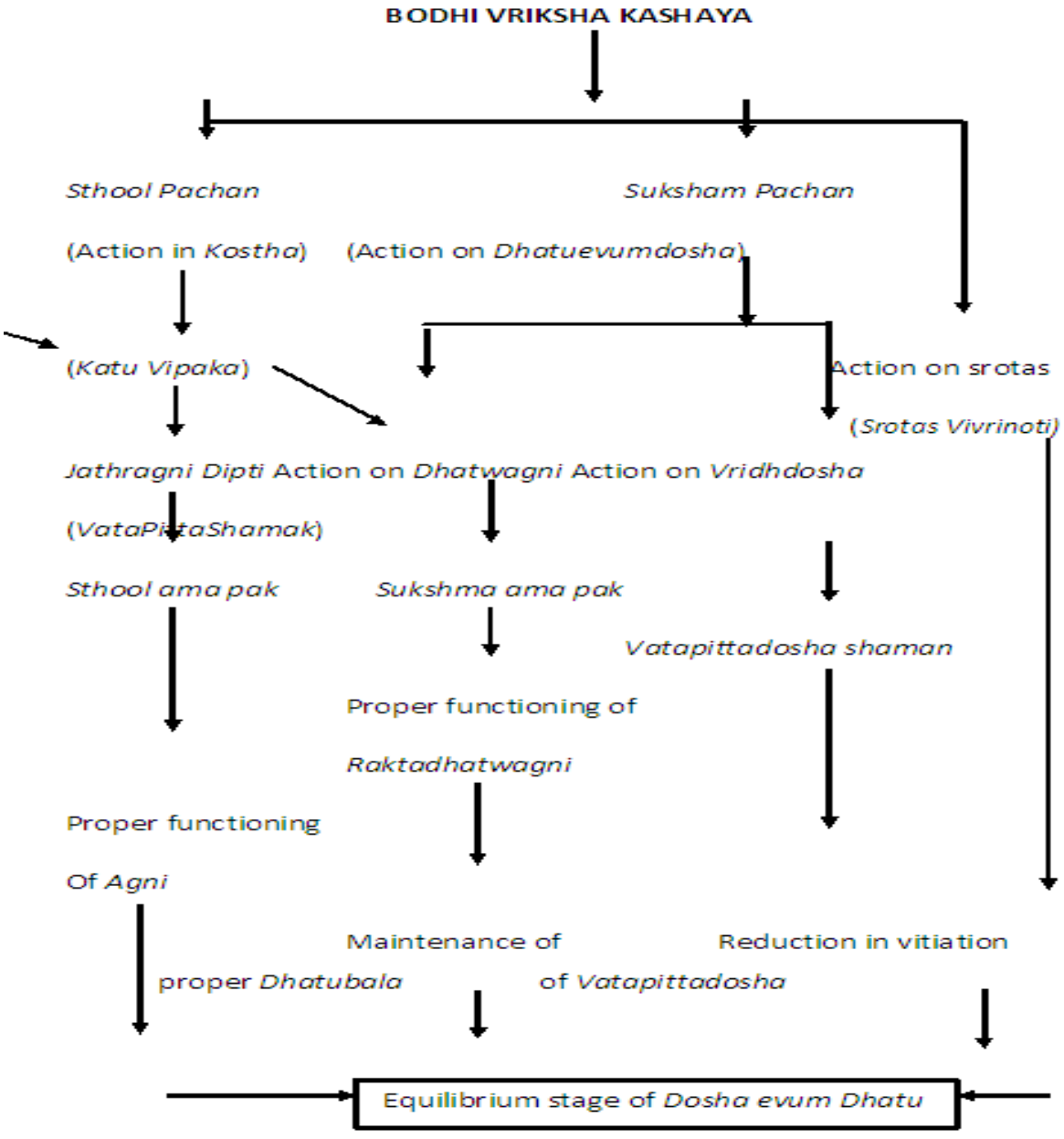
As there is involvement of *Ama* with *Rakta*, *Rakta Dhatu* gets vitiated. Normally, *Rakta* has *Drava* and *Laghuguna* but when associated with *Ama*, it becomes *Pichhila* and *Guru*, causing obstruction in the channels of *Vata*. Due to *Guru Guna* of *Sama Rakta*, obstructs the path of *Vridhh Vata* in its own *Ashaya i.e. Sandhi* of dependable body parts, in hands, feet and fingers.[4,5]

Along with *vata*, there is vitiation of R*aktadhatu* which is a *mala* of *pitta*. Involvement of *Pitta*is also there due to manifestation of all (*vata, pitta, rakta*and *ama*) the disease represents vitiation of *Tridosha*. When we consider its signs and symptoms, *Ruk* and *Toda* are caused due to vitiation of *Vata, Daha* is caused by *Ushnaguna* of *Pitta, Kandu* and *Kled i*s due to vitiated *Rakta,Guruta* and *Supti* is caused due to *Kapha* and *Ama*. So it can be concluded that this disease involves all the *Doshas.*

Probable mode of action of *Bodhi Vrisha Kashaya* can be explained on the following basis.

According to *Rasapanchaka*

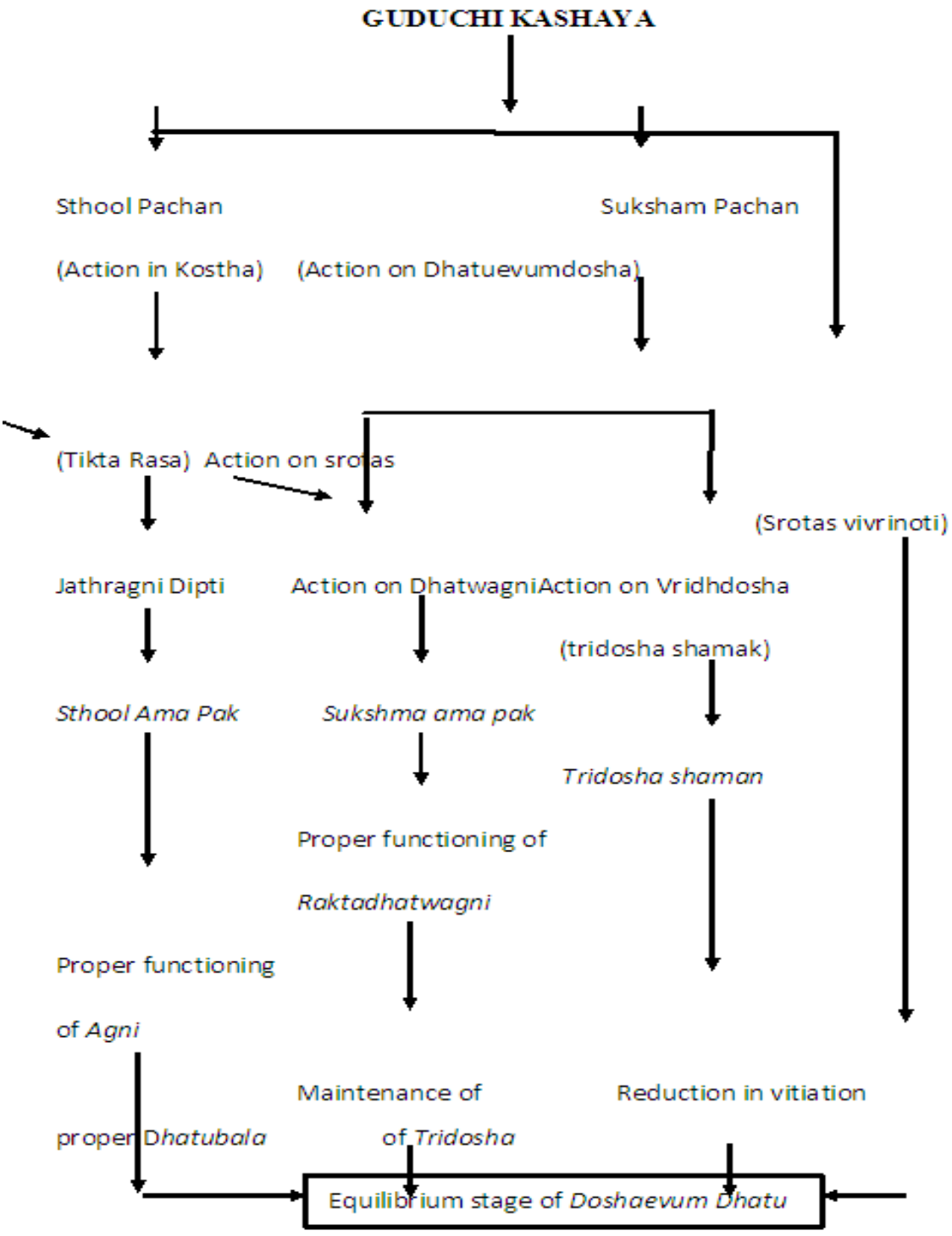
S. No.	***Name of drug***	***Rasa***	***Guna***	***Veerya***	***Vipaka***	***Dosha Karma***
1.	*Bodhi Vriksha (Peepal)*	*Kashaya, Madhura*	*Guru, Ruksha*	*Sheeta*	*Katu*	*Kaphapittashamaka*



Probable mode of action of ***Guduchi Kashaya*** can be explained on the following basis.

According to *Rasapanchaka*

S. No.	*Name of drug*	*Rasa*	*Guna*	*Veerya*	*Vipaka*	*Dosha Karma*
1.	*Guduchi*	*Tikta, Kashaya*	*Guru, Snigdha*	*Ushna*	*Madhur*	*Tridoshashamaka*



CONCLUSION

It may be concluded from the present research work that *Vatarakta* (Gout) is a disease of adults, which effects usually 3rd to 7th decade of life. After menopause due to lack of hormonal effect, females also become equally prone to this disease. Regarding etiological factors, it is found that high protein diet like non vegetarian diet, pulses etc., alcohol addiction, sedentary or stressful lifestyle are the most common factors which help in precipitating gouty attack. Gout is also called as "rich man's disease" but in present era, it affects the persons of

all socioeconomic groups who are able to afford the rich protein diet and spends sedentary lifestyles.

One of the trial drug used in the study was ***Bodhi Vriksha*** Kashaya (Group-1). According to *Doshakarmata* these drugs act as *Vatapittashamaka*. The other drug used in the study was ***Guduchi Kashaya* .** Along with this *Guduchi* also helps in pacifying vitiated *Tridoshas.* Statistically both the drugs showed highly significant results both on subjective and objective parameters. No adverse effect of the therapy was noted during the trial and in the follow up period.

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