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A clinical study to evaluate the effect of *Guduchyadi Ksheerabasti* in Hyperuricemia

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ABSTRACT

Background: Hyperuricemia affects approximately 5.9% of men and 2.0% of women and around 12% of overall population. *Vatarakta* is correlated with hyperuricemia is a acute/chronic inflammatory condition of joint takes place predominantly where serum uric acid is raised beyond 6.8 mg/dL. **Aims and Objectives:** Assessment of *Guduchyadi Ksheera Basti* in the management of Hyperuricemia. **Methodology:** The 23 patients of either sex belonging to age between 20-70 years having signs and symptoms of Hyperuricemia and confirmatory haematological investigations, were selected and after local massage and fomentation, were administered *Ksheera Basti* through anal route for a period of 8 days (*Kala Basti* Schedule) *Niruha* and *Anuvasana* given on the same day. Results were statistically analysed by using paired 't' test and Wilcoxon signed rank test. **Observations and Results:** *Ksheera Basti* provided statistically highly Significant effect ($p < 0.001$) in improving in almost all the cardinal symptoms of Hyperuricemia. It also provided statistically highly significant results in improving all the given parameter in Visual Analogue Scale (VAS), Numerical rating scale (NRS), Verbal Rating Scale (VRS), status of serum uric acid, Bodily pain assessment, due to nourishing, rejuvenating, anti-inflammatory, immunomodulatory and analgesic properties of ingredients. **Conclusion:** *Guduchyadi Ksheera Basti* yields good clinical improvement in pacifying *Vatadhika*, *Pittadhika* *Vatarakta*.

Key words: Hyperuricemia, *Ksheerabasti*, *Vatarakta*, Ayurveda, *Guduchyadi Ksheera Basti*

INTRODUCTION

The clinical challenges presented by hyperuricemia, its catastrophic injury potential, severe level of disability it may occur and its complex mechanical behaviour makes it, arguably, most interesting effects on smaller as well as bigger joints which leads to intolerable pain, stiffness, degenerative joint disorders even various

vascular diseases. The disease selected for the study is Hyperuricemia, because of two reasons, first is increasing incidence of hyperuricemia which affecting the quality of life and second is degenerative joint disorders associated with intense pain, which is leading to decreased amount of working hours and more stress on daily routine as well as personal and social life. Hyperuricemia can be defined as increased serum uric acid levels beyond its normal range i.e., above

7.0 $\mu\text{mol/l}$. Increased serum uric acid level is a common lab finding with significant clinical implications, easily detected but mechanisms may not be clearly elucidated. About 45 diseases or categories of conditions, 20 drugs and 9 states of intoxications have been surveyed. Hyperuricemia can be a multifactorial genetic disorder or a discrete response to a specific stimulus.^[1]

Conditions have both increased production of uric acid as well as decreased renal outflow. Although the

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incidence of hyperuricemia in apparently healthy subjects between 4.5% and 12% in the overall population, has become high as 15.5%. commonest of numerous aetiologies of hyperuricemia appears to be renal failure, ketoacidosis and use of diuretics. Recently increasing rate of joint disorder like gouty arthritis, avascular necrosis of femur, sacroiliitis which further lands up in degeneration of joints.

Now a days due to occupation nature, changed food habits, sedentary life styles *Vata* as well as *Rakta Dushti Janya Vikaras* are consistently rising up. Early degenerative joint disorders associated with *Raktadushti* are taking place. Usually people will go for the symptomatic line of management which includes NSAIDS, steroids, even surgical intervention which again not favourable for the patient. Acharyas have told *Yapana Basti* as a very effective treatment. As in *Asthigatavta* of *Vata* takes place, *Tiktaksheera Basti* has been told as best line of treatment. In *Vatadhika Vatarakta*, *Ksheerabasti* is the best line of management told by *Acharyas*.^[2] The study entitled "The clinical study to evaluate the effect of *Guduchyadi Ksheerabasti* in hyperuricemia" was selected to scrutinize the effect of *Basti* and put some light on *Acharyas* assertions and evaluate each process on scientific background like, pharmacology, biochemistry and pharmaceuticals etc. to develop a uniform protocol for this era and acceptable to the whole scientific community as well as practically assessable to the physician and patients without hampering the basic concepts of *Ayurveda*. Considering classical reference of efficacy of *Ksheera Basti* in hyperuricemia (*Vatarakta*), a open label, clinical study was initiated.

AIMS AND OBJECTIVES

Assessment of effect of *Guduchyadi Ksheera Basti* in the management of Hyperuricemia.

MATERIALS AND METHODS

Study type - Interventional

Design - Treatment, efficacy, Quality of life trial

Plan of study

An open label clinical trial was conducted on the patients, where the patients were given treatment

with specific duration with fortnightly follow-up. Patients were given specific instructions on diet and life style modifications.

Ethical committee clearance

Freely given informed written consent had been obtained from every subject prior to research participation in accordance with the applicable law. As this is a clinical research, Institutional Ethical Committee (IEC) approval was requested for the protocol prior to initiation of research.

Then the available data was assessed using suitable statistical analysis method i.e., paired 't'- test where ever required.

MATERIALS

Selection of patients

Patients who report to OPD and IPD of Shree Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi.

Drug source - Shree Dharmasthala Manjunatheshwara Ayurveda Pharmacy, Udupi.

Diagnostic criteria

Patients having the clinical picture of pain in multiple joints lasts more than 6 months, aggravating after physical work, burning sensation, stiffness associated with numbness degenerative changes.

Inclusion criteria

1. Patients of either sex and of age between 25 - 70 years.
2. Fulfilling the diagnostic criteria, having signs and symptoms of Hyperuricemia and radiological early degenerative changes. raised level of serum uric acid more than 7 µg/L
3. Fulfilling the symptoms mentioned in hyperuricemia and scoring visual analogue scale more than 5-6 and numerical rating scale more than 40
4. Willing to sign the consent for study participation.
5. Able / willing to comply with the treatment schedule.

Exclusion criteria

1. Patients having diabetes, hypertension, tumor pathologies, malignant diseases of the kidney, tuberculosis of vertebral bodies, recent joint region surgery or implanted instrumentation /prostheses other chronic metabolic pathologies i.e., Ankylosing Spondylosis, Rheumatoid Arthritis, rheumatic fever, Psoriatic Arthritis, pregnancy, Epilepsy or any other serious systemic illness etc. were excluded from the study.
2. Investigations were done before and after treatment.
3. Routine haematological investigations, i.e., HB%, ESR, TC, DC, PCV, CRP etc.
4. Routine and microscopic examination of urine
5. Routine biochemical investigations i.e., FBS, S. Cholestrerol, S. Triglycerides, etc. Lipid profile, S. Uric acid, RAF, ASLO factor etc.
6. Digital x-ray, AP view and lateral view of the joint affected.

Selection of the drug/medicines**Ingredients of Niruha Basti****Table 1: Ingredients of Kashaya Dravya: quantity 480ml**

Sanskrit name	Botanical name	Part used	Proportion
Guduchi ^[4]	<i>Tinospora cordifolia</i>	Kanda	1 part

Table 2: Ingredients of Kalka (herbal paste): quantity 40 gms

Sanskrit name	Botanical name	Part and form	Proportion
Madanaphala	<i>Randia spinosa</i>	Madanapippali	1 part
Shatapushpa	<i>Anethum graveolens</i>	Patra Choorna	1 part

Remaining ingredients

Sanskrit name	English term	Proportion
Moorchita Tila Taila	Sesame oil	80ml
Saindhava	Rock salt	5gms
Madhu ^[5]	Honey	80ml

Total amount of *Ksheera Basti Dravya* is 660 ml

Ingredients of Anuvasana Basti

Dhanwantara Taila - 100 ml

Saindhava Lavana - 1 Karsha

***Ksheerapaka Vidhi*^[6]**

Kshira Paka was prepared as per description available in classics. The usual dose of *Kshira Paka* is 200ml. In the present study to equalize the quantity of drug administered *Guduchi* 50 gms + 200 ml milk + 1600 ml milk was added and heated up to 200 ml.

METHODOLOGY**Drug, Dosage and duration****Intervention and dosage pattern**

Abhyanga with *Murchita Tila Taila*, *Nadi Swedana* with plain steam.

Guduchyadi Ksheerabasti (660ml) and *Anuvasana Basti* (100ml) on alternate days following the *Kala Basti* schedule (15days).

Duration of the therapy

07 days (*Kala Basti*) - *Niruha Basti* and *Anuvasana Basti* was given on the same day.

Follow-up

After 15 days (increased accordingly)

Method of preparation of drugs under trial:***Guduchyadi Ksheera Basti***

In preparation of *Niruha*, Rock salt, honey, sesame oil, herbal paste and medicated decoction containing milk were taken in the mentioned quantity and consequently mixed in a clean mortar with pestle;

mono directional triturating was done till uniform and stable mixture was formed. Oil and decoction were lukewarm at the time of adding to the mixture. Total of *Niruha Dravya* was 660ml.

In preparation of *Anuvasana Basti*, 100ml *Taila* was made lukewarm and a pinch of rock salt was added.

Method of application of therapy: *Guduchyadi Ksheera Basti*

Purva Karma

Patient was given local massage with sesame oil and fomentation with plain steam after observing for symptoms of well digested previous meal.

Pradhana Karma

After clearing natural urges, patient was instructed to lie on left lateral position and after per rectal examination to eliminate rectal pathologies, luke warm *Basti* material was administered per rectum. *Anuvasana Basti* was administered with disposable glycerine syringe (100ml) and *Niruha Basti* was administered with plastic enema can (660ml).

The patient was asked to lie down in supine position gradually and buttocks were tapped slowly and gently 3-4 times. Patient was instructed to evacuate the material when urge arises. The patients were given a questionnaire after careful instructions, which was to be duly filled up after each *Basti* session. *Samyak Lakshana* was assessed and observed daily.

Pashcat Karma

Evacuation time of *Basti* material and any untoward effects were observed and noted. One *Muhurta* (48 min) and three *Yaama* (9 hours) is the maximum period of time in which the evacuation of *Niruha* and *Anuvasana Basti* respectively should occur. The patients were explained and instructed to adhere to *Pariharya Vishaya* (code of conduct) specifically indicated for *Yapana Basti*.

Criteria for assessment

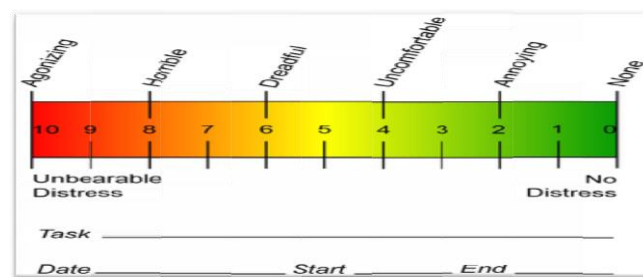
- Patients were examined throughout the week. Changes in symptoms as well as general condition of patients were noted and following points were

taken in to consideration for the assessment of the results.

- Clinical features of Hyperuricemia were assessed during the treatment till end of the treatment.
- Improvement in *Rogabala* along with *Deha*, *Agni* and *Chetasa Bala* were considered for assessment.
- Changes in serum uric acid were taken before and after the treatment.
- Visual analogue scale, numerical rating scale, verbal rating scale were taken as an assessment parameters.
- Laboratory investigations were carried out before and after treatment.

Objective criteria

- Serum uric acid before 7 days and after 14 days of treatment.
- Visual Analogue Scale



Numerical Rating Scale (NRS)

Asked patients to select between 0 - 100 as per severity of pain

Bodily pain assessment - SF 36

Activities	Range of activity		
	Min	Mod.	Severe
Vigorous activities	1	2	3
Moderate activities	1	2	3
Lifting groceries	1	2	3
Climbing stairs one / several	1	2	3
Bending kneeling	1	2	3
Walking	1	2	3

Wheeling	1	2	3
Bathing yourself	1	2	3

Along with these the Score on NRS scale, VAS and SF-36 pain scale put together were used for overall assessment.

Complete remission : 100% relief in chief complaints, relief in associated symptoms along with more than 20 points decrease in numerical pain scale, more than 5 points reduction in VAS and slight changes in X- ray (if needed), with normal range of serum uric acid.

Marked improvement : Above 75% relief in chief complaints, relief in associated symptoms along with more than 20 points decrease in numerical pain scale, more than 4 points reduction in VAS and, with marked decreased range of serum uric acid.

Moderate improvement : Above 50% but less than 75% relief in the chief complaints, relief in associated symptoms along with more than 3points reduction in VAS and no changes in X- ray.

Improved : More than 25% but less than 50% relief in the chief complaints with slight presence of associate symptoms, more than 2 point reduction in VAS and no improvement on X-ray.

Mild Improvement : Less than 25% relief in the chief complaints with slight improvement in associate symptoms, less than 2 points reduction in VAS and no improvement on X-ray.

Unchanged : No relief in any of the signs and symptoms

OBSERVATIONS

In the present study, total 23 patients were registered. Out of which 20 patients completed the treatment with follow-up. Out of 3 dropouts 1 patient didn't come for follow-up and 2 patients discontinued treatment due to travelling problem.

Demographic data

Maximum number of patients were from age group 51-60 years (30%), closely followed by 41-50 age group (26%). Remaining (21%) patients were from the age group of 31-40 years followed by 20-30 years of age group (13%). And only 8% patients were from age group of 61-70 years.

Dasha Vidha Pariksha

On examination it was found that maximum number of patients were having *Vata Pitta Prakriti* (39.13%) followed by *Vata* predominant *Prakriti* in 34.78% of patients. *Madhyama* and *Avara Dhatu Sara* were observed in 18.39% and 4.34% patients respectively. Maximum number of patients (78.73%) were having *Madhyama Samhanana*, followed by 21.73% with *Pravara Samhanana* and none of them with *Avara Samhanana*. Maximum number of patients (91.30%) were having *Madhyama Satmya*, followed by 8.69 % having *Pravara Satmya* and no one having *Avara Sathmya*. Maximum number of patients i.e., 65.21% were having *Madhyama Satva*, followed by 21.73% with *Avara Satva* and 13.34% with *Pravara Satva*. Maximum number of patients (69.56%) were having *Madhyama Abhyavaharana Shakti*, followed by 21.73% having *Avara Abhyavaharana Shakti* and 8.69% with *Avara Abhyavaharana Shakti*. Maximum number of patients (56.21%) were having *Madhyama Jarana Shakti*, followed by 39.13% having *Avara Jarana Shakti* and 4.34% *Pravara Jarana Shakti*. *Mandagni* was observed in 82.60% patients, followed by while *Vishamagni* was found in 13.34% and *Tikshagni* in 4.34% patients. Maximum number of patients i.e., 78.23% were having *Madhyama Vyayama Shakti*, followed by 21.73% with *Avara Vyayama Shakti*.

Maximum number of patients had *Madhyama Vaya Pramana* (56.21%) followed by 30.43% having *Avara Vaya* and 13.21% having *Pravara Vaya*.

Nidana^[7]

Greenpeas, chickpeas, potatoes, cauliflower, spinach was consumed by maximum patients i.e., 91.30%. *Shushka Shaka* by 78.26%, whereas more patients 26.08% are habitual to consume *Shushka Mamsa*. 78.26% of patients were consuming bakery food frequently closely followed by 65.21% of patients who are consuming fast food. 08.69% of people takes aerated drinks occasionally. 37.78% patients had history of food intake which is predominant in *Ruksha* (Dry), *Laghu* (Light) *Guna* and 39.13% were consuming *Sheeta* (Cold) *Guna*. 82.60% of patients have history of *Katu Rasa Ahara Pradhana* food, 47.82% consumed *Lavanadhika* and 21.39% consumed *Madhuradhika*

Ahara. Patients 13.04% have history of consuming *Vishtambhi Ahara* whereas 73.91% of *Vidahi Ahara* closely followed by *Vishamanshana* (91.23%) and 26.08% of *Adhyadhana*. In the present study, *Ratri Jagarana* was observed in 43.47% of patients while *Diva Swapna* was reported in 65.21% and *Swapna Viparya* in 21.73% related to irregularities in sleeping habits. Related to actions, *Bhara Harana* (lifting and carrying heavy weights) was observed in 08.69% of patients. Long time driving was found in 73.91% of patients. *Vega Dharana* was found in 100% of patients (*Mootravega Dharana* and *Purisha Vegadharana*) and *Vega Udirana* (ex. *Purisha Vega Udirana* in patients who had constipation) was found in 17.39% of patients. It was interesting to note that 69.56% of patients had history of insufficient intake of water. Minimum percentage i.e., 34.78% of patients were found with history of *Atapasevana* Due to nature of working. And in some patients i.e., 52.17% and 08.69% were found history of *Krodha* and *Bhaya* respectively. *Ativyavaya Nidana* not was found in any of patients.

Sudden jerks to the lumbar spine and knee joint were found in 26.08% of patients and 21.73% of patients gave the history of a fall or slipping (*Prapatana*) whereas 08.69% of patients had the history of *Marma Abhighata* in the form of trauma.

Parameters related to Guduchyadi Ksheerabasti

The average retention time for *Anuvasana Basti* on day 1 was 2 hours, where as it was 3.25 hours on day 2, 4hrs on day 3, 5.05 hours on day 4, 5.85 hours on day 5, 5.45 hours on day 6, 4.5, 3.95 hours on day 7 and 8 respectively. The average amount of *Niruha* retained by patients on day 2, 3, 4, 5, 6 and 7 were 355ml, 410ml, 445ml, 420 ml, 430ml and 450 ml.

Effect of Guduchyadi Ksheera Basti

Table 1: Effect on Rogabala, Dehabala, Chetasabala

Symptoms (n-20)	Mean values		Mean D. F.	% change	S. D.	S. E.	't'	p	Significance
	B. T.	A. T.							
<i>Agni Bala</i>	14.2	8.6	5.6	39.44	2.14	0.48	11.72	<0.001	HS

<i>Deha Bala</i>	7.15	4.4	2.85	39.86	0.81	0.18	15.68	<0.001	HS
<i>Chetasa Bala</i>	7.55	3.75	3.85	50.99	1.39	0.33	12.41	<0.001	HS

Effect on Doshas

Guduchyadi Ksheerabasti provided statistically significant ($p < 0.001$) in specifically on *Pittadosha* followed by *Vatadosha*.

Effect on Srotas

Guduchyadi Ksheera Basti provided statistically highly significant results in improving symptoms considered under all the *Srotas*.

Table 2: Effect on Serum uric acid

N	BT Mean		Dif f	%	Paired t test				
					SD	SE M	P	Significant	
20	7.84	A	7.41	0.43	1.27	0.55	0.12	<0.001	ES
		F	6.81	1.02	59.80	0.61	0.14	<0.001	ES

Guduchyadi Ksheera Basti showed statistically highly significant result in status of serum uric acid after *Basti Chikitsa* ($p < 0.0001$).

Table 3: Effect in visual analogue scale

N	BT Mean		Dif f	%	Wilcoxon rank test				
					SD	SE M	P	Significant	
20	7.4	A	5.3	2.10	67.14	1.41	0.31	<0.001	ES
		F	3.35	4.05	46.66	1.89	0.42	<0.001	ES

Guduchyadi Ksheera Basti showed statistically highly significant result in Visual analogue Scale (VAS), reduction in pain intensity after *Basti Chikitsa* ($p < 0.0001$).

Effect on bodily pain assessment

Guduchyadi Ksheera Basti showed statistically highly significant result in vigorous activities (lifting weight), moderate activities such as moving table after *Basti Chikitsa* ($p < 0.0001$).

It is clinically not statistically significant in lifting weight and walking more than a kilometer.

Total effect of therapy

In the present study 60% patients achieved marked improvement, 25% of patients achieved mild improvement and no one showed complete remission and moderate improvement in 15% of patients.

DISCUSSION

Dietary habits and life style modalities plays a major role in the causation of *Vatarakta*. Also, the morbidity of *Kapha* and *Medas* can cause different pathogenesis. *Prameha*, *Shonitadushti*, *Hridroga* and *Vatavyadhi* etc. all are found to be due to incriminatory effect of *Kapha* and *Medas*, it is emphasized in *Margavarana Samprapti* like rheumatoid arthritis, second one is *Dhatukashajanya* i.e., chronicity where *Dosha* resides in *Asthi- Majja* and causes *Bala Kshaya*. It is a common finding in above 50 age patients and also in postmenopausal woman. In these cases, increased level of sr. uric acid is a common lab finding which is frequently ignored. Ignorance of treatment can further lead to a chronic degenerative joint disorders. *Charaka Acharya*, *Vagbhatacharya* had both noted *Guduchyadi Ksheera Basti* as beneficial for *Vatarakta* and *Guduchi* has been mentioned as prime drug of choice while treating *Vatarakta*.^[3] Keeping these classical references as base these two treatments were chosen for present study for assessing their clinical efficacy.

CONCLUSION

It has been clearly seen that *Guduchyadi Ksheerabasti* holds a promising hope in the treatment of Hyperuricemia. *Guduchyadi Ksheera Basti* yields better results in pacifying pure *Vataja* or *Vata Pittaja* type of *Vatarakta*. In *Pitta* predominant patients symptoms may aggravate, due to *Ushna Virya* property of ingredients. *Yapana Basti* is a good alternative to

classical *Dvadasha Prastiti* etc. *Niruha* which is not well tolerated by today's delicate and weak patients. Further, mild restricted code of conduct makes it an ideal therapy for today's fast paced society.



Fig. 1: Madhu + Saindhava trituration



Fig. 2: Addition of Sneha



Fig. 3: Kalka addition after Sneha



Fig. 4: Ksheerapaka and Kwatha addition

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