

Clinical Evaluation of Ashwattha Siddha Ksheera Kala Basti and Ashwattha Siddha Tailamatra Basti in Vatarakta WSR to Gout

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ABSTRACT

Vitiated Vata obstructs the path of Vitiated Rakta which further vitiates the Rakta, this complete process is called Vatarakta. The signs and symptoms of Vatarakta can be compared with that of Gout. The pain stabilized by NSAID's, corticosteroids, is a rational treatment regimen practiced today. But they produce adverse effects on renal functions. There is a need to find a better curative and cost-effective treatment regimen. Many previous studies have been conducted on different treatments on Vatarakta such as Snehana, Virechana, Basti, Raktamokshana, Lepa, Parisheka, etc. In the present study, the attempt was made to study the possible pharmacological action of Ashwattha Siddha Ksheera Basti with Ashwattha Siddha Taila Matra Basti as Shothagna, Shoolaghna, Rakta Shodhaka, Vata Shamaka and also its effect on serum uric acid levels. Results were recorded and analyzed statistically. All the recorded results were significantly good.

INTRODUCTION

Ayurveda is the oldest documented medical science in the world of medicine. In Ayurveda, there are three main pillars of the human body mentioned namely, Dosha, Dhatu, Mala. These three along with Agni in the equilibrium stage called Swastha-healthy people. Locomotion is the best gift that every human being has got. With the help of locomotory organs, we can perform our day-to-day functions very easily. Locomotory organs include mainly joints; these

joints are responsible for easy movements and free movements also. Joints are also said to be the main seat of Vata Dosha. Vitiating of Vata Dosha causes deformities in joints. Ayurveda has explained a unique concept of gata Vata and Avruta Vata, mentioning about covering of one Dosha to Vata Dosha and the covering of Dhatu to Vata Dosha. Vitiated Vata obstructs the path of Vitiated Rakta in the beginning and further vitiates the Rakta this complete process is called Vatarakta [1].

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Vatarakta can be compared with Gout. Gout is one of the musculoskeletal diseases and it is the second most common in arthritis affecting almost all joints especially superfine function performing lumbrical joints. Gout affects around 1%-2% of the Western population at some point in their lifetimes and is becoming more common. Some 5.8 million people were affected in 2013. Rates of gout approximately doubled between 1990 and 2010. This rise is believed to be due to increasing life expectancy, changes in diet, and an increase in diseases associated with gout, such as metabolic syndrome and high blood pressure. Factors that influence rates of gout include age, race, and the season of the year. In men over 30 and women over 50, rates are 2% [2]. In Vatarakta, the pain is so severe that it can be compared to rat-bite pain (Akhu visha). There is joint stiffness mostly early morning, locally raised temperature (Daha), discoloration of joint spaces (Vaivarnya), tingling (Chimachimayana), numbness (Supti). These all affect joint and hence day to day functioning also gets hampered. The pain stabilized by NSAID's, corticosteroids, is a rational treatment regimen practiced today. But they produce adverse effects on renal functions. There is a need to find a better curative and cost-effective treatment regimen. In Vatarakta Chikitsa Adhyaya, Snehana, Virechana, Basti, Raktamokshana, Lepa, Parisheka is the mentioned line of treatment by Charakacharya. Basti is mentioned best treatment for Vata Dosha in all Samhitas, hence it is used in this study. Kala Basti is the format of the Basti regimen given for 15 days mentioned by Charakacharya. It includes oil enemas (MatraBasti) and also decoction enemas (NiruhaBasti) given alternatively. Ashwattha (*Ficus religiosa Linn.*) is used in this study. It is astringent (Kashaya) to taste and Katu Vipaki. It has the property of Rakta Shodhana by its tannin contents. According to Acharya Vagbhatta there is no alternate treatment as ksheer basti for Vatarakta [3]. According to Acharya Charak Ksheer basti removes all dushit doshas in Vatarakta.

The need of this study is to attribute the possible pharmacological action of Ashwattha Siddha Ksheera Basti with Ashwattha Siddha Taila Matra Basti as Shothagna, Shoolaghna, Rakta Shodhaka, Vata Shamaka and also effect on Serum uric acid levels. So, the study has been carried out to evaluate the efficacy of Ashwattha Siddha Ksheera Basti and Ashwattha SiddhaTaila Matra Basti on Vatarakta [4].

MATERIALS AND METHODS

Materials

Drug

Ashwattha SiddhaTaila and Ashwattha Siddha Ksheera have been prepared in Ayurved Pharmacy of attached hospital Ashwattha SiddhaTaila, Kalka: Sneha (til tail): Decoction (Ashwattha kwath) 1:4:16 Ashwattha Siddha Ksheera paka was prepared by Ksheera paka method mentioned in Sharangadhara Samhita [5].

Content	Pramana
Ksheera paka	6 prasruta - 480 ml
Ghrita	½ prasruta - 40 ml
Tila Taila	½ prasruta - 40 ml
Madhu	1 prasruta - 80 ml
Saindhava	5 grams

Methodology

Study type

Simple open prospective clinical trial.

Sampling method

Non-probability sampling method.

- 30 Patients of Vatarakta have been selected from OPD/IPD irrespective of gender, economic status, religion, occupation.
- 1 patient from the group was excluded due to the development of adverse effects of Basti treatment (loose motions, abdominal pain). Patient was given internal medication with Shankha vati 250 mg Vyanodana, Kutaja Parpati Vati 125 mg Vyanodana for 3 days.

- Total 31 patients completed the trial.

Inclusion criteria

1. Patient showing Classical sign and symptoms of Vatarakta.
2. Age Group: 20 years - 60 years.
3. Basi Arha.
4. Patient who will give written consent.

Exclusion criteria

1. Pregnancy and lactation.
2. All other arthritic diseases than Vatarakta.
3. Patients having any systemic and metabolic disorders.
4. Basti Anarha.
5. Patients taking some other therapy or internal medicine for Vatarakta.

Treatment not permitted

During the trial any medication like;

- a. Analgesic, Local application containing steroids, Narcotics, sedatives, Tranquilizers, anti-depressants are not permitted.
- b. Self-medications and oral ayurvedic medicine are also not permitted.

Note: Upon questioning, if any subject is found to be using medications in no permitted categories, he/she will be withdrawn from the trial.

Assessment criteria

Subjective criteria

Joint score

The no. of clinically active joints will be determined on the basis of tenderness on pressure or painful passive movements.

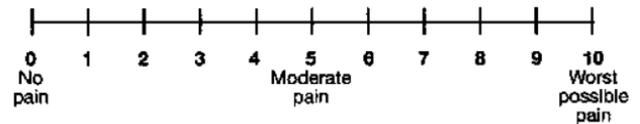
Score	Number of Joints Involved
3	More than 5
2	Between 3-5
1	At least 2
0	No Joint Involvement

Tenderness

Score	
3	Severe
2	Moderate
1	Mild
0	Absent

Pain, swelling, local temperature and burning

By visual analogue scale.



Episode of numbness

1	Present
0	Absent

Functional score

Score	Ability to Perform Joint Function
3	Unable
2	With the Help of Other Person
1	Able to do with Difficulty
0	Able to do with Ease

Overall score

1-8	Mild - Grade 1
9-16	Moderate - Grade 2
17-24	Severe - Grade 3

Objective criteria

Grip strength

Will be measured by recording the pressure that patient can exert for squeezing a partially inflated cuff (20 mmHg) of a standard sphygmomanometer for hand fingers only.

Poor	Below 38 mm Hg
Moderate	40 mm Hg - 140 mm Hg
Mild	142 mm Hg - 280 mm Hg
Normal	Above 280 mm Hg

Lab investigations

	Before Treatment	After Treatment
Hb%		
Wbc Count		
Neutrophil Count		
ESR		
Serum Uric Acid		

Standard operating procedure (S.O.P) of administration of Basti

Form	Ksheera Basti, Anuvasana Basti
Route	Per Rectum
Dosage	Ksheera Basti - 640 ml
	Anuvasana Basti - 60ml
Kala of Ksheera Basti	On Empty Stomach
Kala of Anuvasana Basti	After Meals
Duration of Therapy	15 days
Follow up	7 th days, 15 th days, 30 th days
Duration of Study	30 days

A) Purva Karma

- Pachana was given by Musta churna for 2-gram Vyanodan Kala (after meals)
- On the day of Basti, Sarvanga Snehana with sesame oil and Sarvanga Swedana was done.

B) Pradhan Karma

- Position-left lateral position (Vama Parshwa) with right leg folded and left leg straight.
- Basti Netra (simple rubber catheter no-10/11) was attached to Basti Putaka (enema pot). The Column of catheter was filled with Basti Dravya and air was removed.
- Simple rubber catheter and anal region was lubricated with sesame oil. 4 Angula of rubber catheter was introduced per rectum.
- The patient was then asked to take deep inspiration. Then the enema pot was kept higher than the table so as to allow Basti to enter into the rectum.

- Little quantity of medicine was left behind at the end to avoid savata basti dana.
- Taila Matra Basti was also given in same way.

C) Paschat Karma

- The patient was asked to lie down comfortably in supine position.
- Sphik Tadana was done.
- Basti Pratyagama was observed by Prashna Pariksha.
- After Basti Pratyagama patient was advised to take bath with Sukhoshna Jala
- Laghu Bhojan was advised.

OBSERVATION AND RESULTS

Subjective Criteria Analysis

Joint score

The effect of Basti on a joint score.

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Joint Score	Median		Wilcoxon Signed-Rank W	P-Value	% Effect	Result
	B	A				
	T	T				
	3	0	-4.996 ^a	0.000	90.5	Significant

Since observations are on an ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From the above table, we can observe that P-Value is less than 0.05 hence we conclude that the effect observed is significant.

Pain

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Pain	Median		Wilcoxon Signed-Rank W	P-Value	% Effect	Result
	B	A				
	T	T				
	8	1	-4.910 ^a	0.000	88.3	Significant

Since observations are on an ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From the above table, we can observe that P-Value is less than 0.05 hence we conclude that the effect observed is significant.

Tenderness

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Tenderness	Median		Wilcoxon Signed-Rank W	P-Value	% Effect	Result
	B	A				
	T	T				
3	0	-5.015 ^a	0.000	91.6	Significant	

Since observations are on an ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From the above table we can observe that P-Value is less than 0.05 hence we conclude that the effect observed is significant.

Swelling

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Swelling	Median		Wilcoxon Signed-Rank W	P-Value	% Effect	Result
	B	A				
	T	T				
7	1	-4.931	0.000	89.0	Significant	

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From the above table, we can observe that P-Value is less than 0.05 hence we conclude that the effect observed is significant.

Temperature

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Temperature	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	B	A				
	T	T				
7	1	-4.915 ^a	0.000	91.6	Significant	

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From above table we can observe that P-Value is less than 0.05 hence we conclude that effect observed is significant.

Functional score

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Functional score	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	B	A				
	T	T				
2	0	-5.092 ^a	0.000	90.8	Significant	

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From above table, we can observe that P-Value is less than 0.05 hence we conclude that the effect observed is significant.

Total score

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Total score	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	B	A				
	T	T				
29	3	-4.871 ^a	0.000	89.9	Significant	

Since observations are on an ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From the above table, we can observe that P-Value is less

than 0.05 hence we conclude that effect observed is significant.

Grip strength

Data was collected from 31 patients on the 0th day, 7th days, 15th days, 30th days.

Grip Strength	Median	N	SD	SE	Z - Value	P- value
BT	35.5	31	20.14	3.62	-8.171	0.000
AT	118.8	31	30.4	5.46		

Since observations are quantitative sample size greater than 30, we have used Z-test to test the efficacy. From the above table, we can observe that P-Value is less than 0.05 hence we conclude that effect observed is significant.

Objective Criteria Analysis

Uric acid

Data was collected from 31 patients on 0th day and 30th days i.e. before treatment and after treatment.

Grip strength	Median	N	SD	SE	Z - Value	P- value
BT	7.0	31	0.76	0.14	-9.050	0.000
AT	4.3	31	0.76	0.14		

Since observations are quantitative sample size greater than 30, we have used Z-test to test the efficacy. From above table we can observe that P Value is less than 0.05 hence we conclude that effect observed is significant.

Hb%

Data was collected from 31 patients on 0th day and 30th days i.e., before treatment and after treatment.

Grip Strength	Median	N	SD	SE	Z - Value	P- value
BT	11.3	31	2.19	0.39	-2.865	0.002
AT	11.5	31	1.98	0.36		

Since observations are quantitative sample size greater than 30, we have used Z-test to test the efficacy. From above table we can observe that P Value is less than 0.05 hence we conclude that effect observed is significant.

WBC

Data was collected from 31 patients on 0th day and 30th days i.e., before treatment and after treatment.

Grip Strength	Median	N	SD	SE	Z - Value	P- value
BT	10323.9	31	3251.23	583.94	-6.805	0.000
AT	5556.1	31	1615.92	290.23		

Since observations are quantitative sample size greater than 30, we have used Z-test to test the efficacy. From the above table, we can observe that P-Value is less than 0.05 hence we conclude that the effect observed is significant.

ESR

Data was collected from 31 patients on 0th day and 30th days i.e., before treatment and after treatment.

Grip Strength	Median	N	SD	SE	Z - Value	P- value
BT	12.7	31	2.41	0.43	-8.516	0.000
AT	5.6	31	2.26	0.41		

Since observations are quantitative sample size greater than 30, we have used Z-test to test the efficacy. From the above table, we can observe that P-Value is less than 0.05 hence we conclude that the effect observed is significant.

Follow-up wise result of treatment

Grade	Day 0	Day 7	Day 15	Day 30
Grade 3	31 (100%)	30 (96.7%)	1 (3.3%)	0 (0%)
Grade 2	0 (0%)	1 (3.3%)	28 (90.3%)	0 (0%)
Grade 1	0 (0%)	0 (0%)	2 (6.4%)	30 (96.7%)
Grade 0	0 (0%)	0 (0%)	0 (0%)	1 (3.3%)

To test the significance of the result day we have used the Chi-square test. P-Value is less than 0.05 hence effect is significant.

DF	Chi-Square	P-Value
3	8.203	0.042

DISCUSSION

Discussion on Drugs

Among the drugs of Ashwattha Siddha Ksheera Basti, Ashwattha is Kashaya Madhura Rasatmaka, Katu Vipaki, Sheeta Veerya, Guru Gunatmaka, Kapha-Pitta hara drug. Ashwattha is Rakta shodhak, Rakta prasadak with shola hara, and shotha hara properties. Due to above-mentioned properties of Ashwattha it has been used in the present study.

Effect of Ashwattha on Local Temperature and Grip Strength

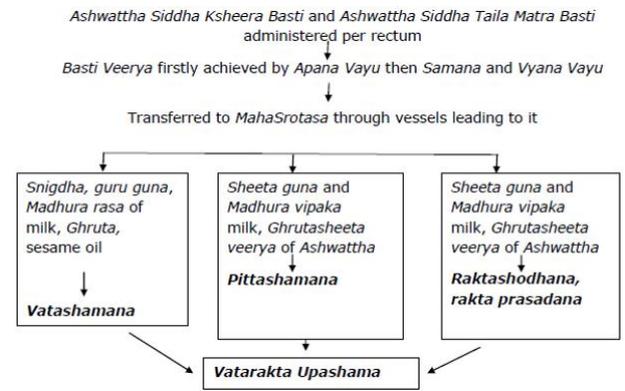
Local temperature (Ushna sparsha)

Localized raised temperature is an effect of inflammation in Vatarakta. It was observed in present study, local temperature reduced after Basti administration due to Sheeta veerya of Basti.

Grip strength

Lack of grip strength is due to loss of function of joints which is enlisted as sign of inflammation. Ashwattha has the property to work as antioxidant and to reduce inflammation. In the present study, it was observed that grip strength increased after Basti administration. It also helped to raise the functional score of joints.

Discussion on Procedure



CONCLUSION

- Ashwattha Siddha Ksheera Basti and Ashwattha Siddha Taila Matra Basti in Kala Basti format is effective as Shothahara, Shoolahara and Raktaprasadana in Vatarakta.
- Ashwattha Siddha Ksheera Basti and Ashwattha Siddha Taila Matra Basti in Kala Basti format is effective in reducing Uric acid levels in Vatarakta.

SCOPE OF STUDY

- As the study showed effect on pain, swelling, local temperature, grip strength, uric acid levels, WBC count, ESR, it can be carried out on larger sample size with altered environmental conditions.
- Biochemical changes happening due to Gout are observed, there is a need to work on the MSU crystals formed in joint spaces and also the effect of herbal drugs on uric acid excretion through urine.

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