

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH

SJIF Impact Factor 8.084

Volume 11, Issue 9, 1779-1790.

Research Article

ISSN 2277-7105

A CLINICAL STUDY ON EVALUATION OF *RASNADI BASTI* IN THE MANAGEMENT OF *VATARAKTA* (GOUTY ARTHRITIS) – A STUDY PROTOCOL

Dr. Jaibir Singh*1 and Prof. Dr. Ashish Mehta2

¹PG Scholar, MD Scholar, Department of Panchkarma, Shri Krishna Govt. Ayurvedic College and Hospital, Kurukshetra, Haryana, India.

²Professor and Head, Department of Panchkarma, Shri Krishna Govt. Ayurvedic College & Hospital, Kurukshetra, Haryana, India.

Article Received on 21 May. 2022,

Revised on 11 June 2022, Accepted on 02 July 2022

DOI: 10.20959/wjpr202211-25138

*Corresponding Author Dr. Jaibir Singh

PG Scholar, MD Scholar,
Department of Panchkarma,
Shri Krishna Govt.
Ayurvedic College and
Hospital, Kurukshetra,
Haryana, India.

ABSTRACT

Background: Vatarakta is mentioned as a separate entity in Charaka Samhita. The main causative factors for Vatarakta are excessive use of Ruksa, Ushna, Laghu, Amla, Lavana & katu ahara, excessive use of pulses, alcohol, meat, emotional unstability etc. These factors causes aggaravation of Vata & Rakta simultaneously. Vitiated Rakta quickly obstructs the path of already aggravated Vata Dosha. On obstruction, Gati of Vata Dosha is hindered leading to further aggravation. This vitiates the whole Rakta and manifests as Vatarakta. Vatarakta can be correlated with Gouty Arthrirtis characterized by crystal deposition along with pain and swelling in first metatarsophalangeal joint followed by other joints. Acc. to Acharyas, Basti is the main treatment for Vata Vyadhi. So Rasnadi Niruha Basti will act by removing

vitiation of both Vata & Rakta. **Aim and Objectives:** To evaluate the comparative on the effect of *Rasnadi Basti* and Tab. Allopurinol 300mg in *Vatarakta* and to compare the effect of *Rasnadi Basti* and Tab. Allopurinol 300mg *on* CBC, E.S.R, CRP, Uric Acid and Urine Examination. **Methodology:** Sixty patients will be divided randomly into two groups (30 in each). Group A- 6 *Rasnadi Basti*, In morning (2nd,3rd,4th,5th,6th,7th) with dose 12 *prasarti* and 10 *Anuvasana Basti*, In morning (1st,8th,9th,10th) and In evening (2nd,3rd,4th,5th,6th,7th) with dose of 3 Pal will administer for 10 days Group B- Tab. Allopurinol 300mg HS will be given to 30 subjects for 10 days. **Results:** Changes will be observed in subjective and objective parameters. **Conclusion:** *Rasnadi Basti* may have better results in comparison to Tab.

Allopurinol not only on the symptoms of *Vatarakta* but also on the objective parameters.

KEYWORDS: Vatarakta, Gouty Arthritis, Vata Dosha, Rakta Dhatu, Rasnadi Niruha Basti.

INTRODUCTION

In modern era sedentary life style, unhealthy food practices, physical inactivity invites many metabolic disorders like hypertension, ischemic heart disease, diabetes, crystal arthropathy, arthritis and hyperuricemia etc. In ancient texts Acharayas have mentioned a disease Vatarakta. Vatarakta exhibits features of Gouty arthritis of modern science. The vitiation of Vata dosha and Rakta dhatu creates Vatarakta. Vatarakta is a Santarpana-Janya Vyadhi, In this disease Vayu vitiates due to nidan like ruksha, sheeta, alpa, laghu anna sevan, atyadhay, atilanghana, prajagran, diwaswapan, ativyavaya etc. and rakta dhatu vitiates by nidan like excessive intake of lavan, amla, katu, kshara etc. This imbalance of Vata dosha and Dushit Rakta is the cause of Vatarakta. Sandhi shula (Pain in Joints), Sandhi shotha (Swelling), Sparsh Asahatvam (Tenderness), Daha (Burning sensation), Raaga (Erythema), Twak Vaivarnya (Discoloration), Stabdhta (Stiffness) etc. are main symptoms of Vatarakta. [1] Gouty Arthritis is crystal arthropathy generally observed in middle age and elderly person males and post-menopausal females. Gout is derived from a Latin word "gutta", meaning drop, as it was believed in the past that poison falling in drops into the affected joints caused Gout. Sir Alfred Garrod linked Gout with hyperuricemia in 1848. [2] Incidence of Gouty arthritis is 0.2-2.5 per 1000. Overall prevalence is 2-26 per 1000. Hyperuicemia is a biochemical precursor of Gout in which Pain and swelling of metatarsophalangeal joint followed by other large joints are main characteristics. Gout is a disease characterized by severe pain, redness and tenderness in joints, sensitivity to touch, warmth and redness.

Gouty Arthritis also reported in young age due to malfunction of kidneys. There is abnormal elevation of uric acid in blood is due to uncontrolled production or less excretion of uric acid. Some pathological reactions in joints or tissues due to non-sodium uric acid monohydrate crystals may clinically cause inflammatory arthritis.^[3]

Vatarakta can be correlated with Gouty Arthritis of modern science on the basis of sign, symptoms like Sandhi ruja (pain), Sandhi shotha (joint swelling), Stabdhata (stiffness), Sancoch (tenderness) etc. In Ayurveda Texts, there are many different Treatment protocol are explained and Basti is advised as main treatment for Vatarakta, There is no therapeutic treatment equal to Basti in Vatarakta according to Aacharya Charak. Basti decreases the

disease progression by relieving sign and symptoms.

In Ayurveda, there are two types of methods of treatment for *Vatarakta-Shaman chikitsa* and *Shodhan chikitsa*. In Shaman *Chikitsa* medicines like formulations of *Guggulu, Guduchi, Rasna, Punarnava, Dashamul, Chopchini*, etc. are given orally. In *Shodhan Chikitsa -Vaman, Virechan, Basti, Nasya* and *Rakta-Mokshan*; purification and detoxification method of treatment applies. According to *Ayurveda Brihadtrayi* and *Laghutrayi* texts *Basti* is best treatment for *Vatarakta* (Gouty arthritis).^[4]

Etymology

Vatarakta is a disease where both Vata and Rakta are aggravated by many etiological factors. The vitiation of Vata dosha and Rakta dhatu creates Vatarakta. Vatarakta is a Santarpana-Janya Vyadhi, Aggravated Vata is blocked by vitiated Rakta, in turn leading to further aggravation of Vata. Thus aggravated Vata vitiates whole Rakta producing complex effects leading to the condition Vatarakta Acharya Sushruta described Vatarakta under Vatavyadhi named as Vatashonita (Ruja spreads as musak danh wat vedna). [5]

Gout is derived from a Latin word "gutta" meaning drop, as it was believed in the past that poison falling in drops into the affected joints caused Gout. Sir Alfred Garrod linked Gout with hyperuricemia in 1848.^[6]

REVIEW OF LITERATURE

All the Ayurveda classical literature including *Brihadtrayi*, *Laghutrayi* and *Nighantu* etc. along with modern text books will be reviewed for study. Website like PubMed, Google scholar, Scopes, Articles, Journals and Research papers etc. will be screened for the information regarding the subject.

REVIEW OF MODERN LITERATURE

According to Indian studies, 65% of patients of Gout are victims from middle socio economic class. In recent decades it becomes commonest disease in human being due to changes in life style, dietary habits and metabolism. Risk factors include male sex; obesity; hypertension; alcohol intake; diuretic use; a diet rich in meat and seafood; a diet heavy in fructose-rich food and beverages and patients of chronic kidney disease. In older males its chance are higher than others. Gout is an inflammatory response to the MSU crystals formed secondary to hyperuricaemia.^[7] Hyper-uricaemia is defined as a serum or plasma urate concentration is

>7.0 mg\dl in males and >6.0 mg\dl in female. Serum uric acid concentration is most important determination of risk of developing Gout. With normal renal function, its blood concentration depends mainly on break down of nuclear protein and dietary purine load. Provocative factors include alcohol, dietary excesses, surgery, trauma, sepsis, starvation, dehydration and drugs like diuretics, pyrazinamide and aspirin. The big toe first metatarsophalangeal joint [MTP] is the classical site of Gout. Acute attack starts in the night mainly due to lower body temperature and peaks within 24 hours of onset. The joint and surrounding tissues are swollen, hot, red, shiny and extremely painful. There is a mild fever with chills. Left untreated, the attack will start to improve in a week or two. In most of the patients, the next few episodes occur within one year. Gout is characterized by swelling, pain, or tenderness in a peripheral joint or bursa, including the development of a tophus. Tophi may develop after long time elevated uric acid levels with symptoms like hard, painless deposits of uric acid crystals. Due to bone erosion extensive tophi may lead to chronic arthritis and regularly elevated levels of uric acid for long time may cause kidneys stone and urate nephron pathology. Development of chronic tophaceous Gout depends on uncontrolled hyperuricaemia of long duration usually > 10 years. But tophi or chronic polyarthritis may occur as early as 3 year after the first attack. Tophi appear as firm, nodular or fusiform swellings. Arthrocentesis should be performed when suspicion for an underlying septic joint is present; synovial fluid or tophus analysis should be performed if the diagnosis is uncertain. Colchicine, non-steroidal anti-inflammatory drugs, and Corticosteroids relieve pain in adults with acute Gout episodes. Indications for long-term urate-lowering therapy include chronic kidney disease, two or more flare-ups per year, urolithiasis, the presence of tophus, chronic Gouty arthritis, and joint damage. Allopurinol and Febuxostat are used to prevent flare-ups, although Febuxostat is associated with an increase in all-cause and cardiovascular mortality and is therefore not routinely recommended. Levels of uric acid can be lowered via lifestyle changes when acute attack subsides. People with frequent attacks, Allopurinol or pro benecid can provide long-term relief. [8]

RATIONALE OF STUDY

In modern Science, treatmet of Gout is based on NSAIDs (Non-steroid Anti-inflammatory Drugs), Xanthine oxidase inhibitors (Allopurinol, Febuxostat), colchicine, Probenecids and Corticosteroids.

But these are having their own limitations & side effects like NSAIDs Xanthine oxidase

inhibitors and colchicine -risk of peptic ulcer disease, acute renal failure, stroke/myocardial infarction, skin rash, diarrhoea, nausea, changes in liver function test results, black, tarry stools, bloody nose, chest pain or discomfort, cloudy urine, dark urine, decreased frequency or amount of urine, cramping, abdominal pain, vomiting and Corticosteroids-Increased appetite, Weight gain, Changes in mood, Muscle weakness, Blurred vision, Increased growth of body hair, Easy bruising, Lower resistance to infection and Indomethacin- headache, dizziness, constipation, irritation of the rectum, constant feeling of the need to empty the bowel, ringing in the ear.^[9]

Keeping in view of the above limitations & side effects this study has been chosen to fill this gap of providing safe and effective line of treatment as *Ayurveda* provides multiple formulations and Panchkarma procedures for this. *Basti chikitsa* has been taken for this study keeping in mind about the importance of *Basti* because almost all the *Aacharyas* has considered *Basti* as equivalent to half of the treatment. [10]

SOURCE OF DATA

Patients visiting Shri Krishna Govt. Ayurvedic College and Hospital, Kurukshetra Haryana and full filling the inclusion criteria shall be enrolled for the study after obtaining informed consent.

AIM

Evaluation of *Rasnadi Basti* in the management of *Vatarakta* (Gouty Arthritis).

Primary Objective

To evaluate the efficacy of *Rasnadi Basti* in comparison to Allopurinol in the management of Vatarakta (Gouty Arthritis).

OBJECTIVES

- 1. To evaluate the effect of *Rasnadi Basti* on CBC, E.S.R, CRP, Uric Acid, Urine Examination.
- 2. To compare the effect of *Rasnadi Basti* and Tab. Allopurinol 300mg on CBC, E.S.R, CRP, Uric Acid, Urine Examination.

CASE DEFINITION

A diagnosed case of *Vatarakta* (Gouty Arthritis) with clinical symptoms of *Sandhi Shoola* (Joint pain), *Sandhi Shotha* (Joint swelling), *Sparsh Asahatvam* (Tenderness), *Daha* (Burning

sensation), Raaga (Erythema), Twak Vaivarnya (Discoloration), Stabdhata (Stiffness), Toda (Piercing sensation more than 6 months and less than 2 yrs.

Research Questions

Does Rasnadi Basti is as effective as Allopurinol in the management of Vatarakta (Gouty Arthritis).

Hypothesis

Research Hypothesis (H_1)

Rasnadi Basti is more effective than Allopurinol.

Null Hypothesis (H_0)

Rasnadi Basti is not as effective as Allopurinol in the management of Vatarakta (Gouty Arthritis).

Study Type –Interventional.

Study design: A Randomized controlled open clinical study.

Sampling procedure

Random sampling procedure will be applied.

Methodology Study Setting

The study will be conducted in Shri Krishna Govt. Ayurvedic College and Hospital, Kurukshetra Haryana.

Posology

Group A - Niruha Basti (Rasnadi) -12 prasarti and

Anuvasana Basti (Tila tailam) -3 Pal

Group B - Allopurinol -300mg

Inclusion criteria^[11]

- 1. Subjects presenting with clinical features of *Vatarakta* / Gouty Arthritis.
- 2. Subjects with chronicity of disease more than 6 months and less than 2 yrs.
- 3. Subjects of either sex between age group of 30-60 yrs.
- 4. The patients fit for *Basti Karma* (*Bastiyogya*).
- 5. Subject showing the uric acid level above 6mg/dl for females and 7mg/dl for males.

Exclusion criteria

- 1. Subjects presenting with clinical features other than Vatarakta/ Gouty Arthritis.
- 2. Subjects with chronicity of disease less than 6 months and above 2 yrs.
- 3. Subjects of either sex age below 30 years and above 60 years.
- 4. The patients unfit for *Basti Karma* (*Basti Ayogya*).
- 5. Subject showing the uric acid level above 9mg/dl.
- 6. All connective tissue disorders other than Gouty Arthritis.
- 7. Systemic Lupus Erythematous and other auto immune disorders.
- 8. Patients having systematic pathologies like cardiac disease, renal diseases and hypertension.
- 9. Subjects with uncontrolled diabetes, systemic disorders and endocrine disorders.
- 10. Patients having tuberculosis of spine, spinal tumors, vertebral fractures, surgical conditions and pregnant and lactating women.
- 11. Renal failure acute and chronic.

Table 1: Interventions of the groups.

s.n	Grouping	Group A		Group B
1.	Sample size	30		30
2.	Intervention	Niruha Basti (Rasnadi)	Anuvasana Basti (Tila tailam)	Allopurinol
3.	Dose	12prasarti	3 Pal	300mg
4.	Duration	10days		10days
5.	Follow up	11 th ,30 th 60 th day		11 th ,30 th 60 th day

Criteria for Discontinuing or Modifying Allocated Intervention

Patient will withdrawal from the study if there will be any adverse effect occurring and then he or she will be treated from the same in free of cost till becomes alright.

Follow up: 11th, 30th, 60th day.

Primary Outcome^[13]

The effect of *Rasnadi Basti* will be seen on *Sandhi Shoola* (Joint pain), *Sandhi Shotha* (Joint swelling), *Sparsh Asahatvam* (Tenderness), *Daha* (Burning sensation), *Raaga* (Erythema), *Twak Vaivarnya* (Discoloration), *Stabdhata* (Stiffness), *Toda* (Piercing sensation).

Secondary Outcome

The effect of Rasnadi Basti will be seen on CBC, E.S.R, CRP, Uric Acid, Urine Examination.

DISCUSSION

Vatarakta is a Santarpana-Janya Vyadhi, In this disease Vayu vitiates due to nidan like ruksha, sheeta, alpa, laghu anna sevan, atyadhav, atilanghana, prajagran, diwaswapan, ativyavaya etc. and Rakta dhatu vitiates by nidan like excessive intake of lavan, amla, katu, kshara etc. This imbalance of Vata dosha and Dushit Rakta is the cause of Vatarakta. Vitiated Vata and Rakta Dhatu goes downwards takes sthanasumshraya at the padangustha sandhi (big toe first metatarsophalangeal joint [MTP]) then it spreads all over the body with the help of vyanvayu by sukshma, sara guna of Vata Dosa and drava, sara guna of Rakta Dhatu. Sandhi shula (Pain in Joints), Sandhi shotha (Swelling), Sparsh asahatvam (Tenderness), Daha (Burning sensation), Raga (Erythema), Twak vaivarnya (Discoloration), Stabdhta (Stiffness) etc. are main symptoms of Vatarakta.

In Santarpana-Janya Vyadhi sodhan is srestha chikitsa and in shodhana chikitsa Basti is main treatment for Vata Vyadhi. Because almost all the Aacharyas has considered Basti as equivalent to half of the treatment and according to Aacharya Susruta Rasnadi Niruha Basti is srestha for Vatarakta chikitsa. In Rasnadi Niruha Basti kwath, kalka and all drwyas works on both Vitiated Vata dosha and Dushit Rakta and balance it in normal position.

- 1. *Rasna* is *kapha vata shmaka* and works on *vatarkta*, *Amavata* and *shopha* (inflammation), *shola* (pain), *udara*, *hikka kasa*, *visha*, *jwara*.
- 2. Amalatash is koshta shudhikar, mrudu rechak, Guru, Madhur, Shital in nature mainly works on pitta indirectly works on Rakta dhatu.
- 3. *Poonarnava* is *kapha pitta nashak, vishaghna, pandughna, shothhar* property mainly works on *pitta* indirectly works on *Rakta dhatu*.
- 4. *Katuki* is also *rechan* and *koshta shodhniya* property.
- 5. Trayamana is tikta Kashaya rasyukta pittakpha nashak, hradyrog harnam in property mainly works on pitta indirectly works on Rakta dhatu.
- 6. Guduchi is tridosha samak balya, Rasayan, sanghni, agni deepana, dahahara, used in jawara, pandu, vatarakta, amavata etc.
- 7. *Yatimadhu kalk* is *vrishya*, *shothhar*, *rasayan* in nature.
- 8. Indrayav kalk is vrishya, Balya, rakta sangrahak property.
- 9. Rasanjan kalk is Rasayan in nature.
- 10. Priyangu kalk is Shit viryatmak, Bala karak, Sangrahi property
- 11. Laghu panchmool is Vatapitta hara, Tikta, Kasaya, Madhur Rasa, Laghu Guna, Anusna Virya Madhur Vipaka and it is used in Vatarakta, Paksaghat, Sandhigata vata, Amavata,

Asmari, Jwara etc.

- 12. Bala is sheet virya, dhatu pushtikar and praja sthapa.
- 13. Saindhava Lavana by Sukshma and Tikshna guna helps the Basti dravya to reach up to the molecular level and liquefies the viscid matter and it breaks into small particles.
- 14. *Ghrit* is used for *pita hara* property.
- 15. Mansa Rasa is also added in this Basti for vata harnam in property.

STATISTICAL DESIGN

Uric acid will be up to 9.0 mg/dl before Therapy Vs after Therapy will be assessed.

Statistical Analysis

Data will be analyzed on the basis of appropriate statistics Paired t-test, unpaired test and Chi square test by using SPSS software, 24.0 version and Graph Pad Prism 7.0 version and p<0.05. will considered as level of significance.

Time Duration till Follow up

In both groups initially 10 days of treatment and follow upperiod 11th, 30th, 60th day.

Time Schedule of Enrolment, Interventions^[12]

Six Rasnadi Basti, In morning (2nd,3rd,4th,5th,6th,7th) with dose 12prasarti and 10 Anuvasana Basti, In morning $(1^{st}, 8^{th}, 9^{th}, 10^{th})$ and In evening $(2^{nd}, 3^{rd}, 4^{th}, 5^{th}, 6^{th}, 7^{th})$ with dose 3 Pal will be given after CTRI registration.

Recruitment

Thirty (in each group, Group A and Group B) will be recruited randomizing sampling method. Total 60 Subjects (30subjects in each group)

Group A

Sixteen *Basti* will be administered to 30 subjects as per Kala Basti schedule for 10 days.

Group B

Tab. Allopurinol 300mg will be given to 30 subjects for 10 days.

Data Collections Method

Randomized sampling.

Subjective Parameters

Sandhi Shoola (Joint pain)

Sandhi Shotha (Joint swelling)

Sparsh Asahatvam (Tenderness)

Daha (Burning sensation)

Raaga (Erythema)

Twak Vaivarnya (Discoloration)

Stabdhata (Stiffness)

Toda (Piercing sensation)

Objective Parameters

- 1. Range of movement
- 2. VAS scale- for pain assessment
- 3. CBC
- 4. ESR
- 5. CRP
- 6. Serum uric acid
- 7. Urine Examination.

Data Management

Data coding will be done by Principal investigators.

Statistical Methods

Paired t- test and unpaired for objectives parameters, non- parametric and Chi square test for subjective parameters.

Ethics and Dissemination

Research ethical approval, after critical evaluation and presentation the ethical committee has taken the research topic.

Consent or Assent

Subjects will be given detail information regarding their treatment in their own language. Then written consent will be taken from patients before starting the study.

Dissemination Policy

Will be in the form of paper publication, presentation and Monograph.

Strengths

If proposed study will result in the positive outcome, then it will be established new mode of management for the *Vatarakta* (Gouty Arthritis).

In society, we will be provided economical and effective for pain reduction and stiffness.

Limitations

Will be convincing the patients for Basti procedure and for hospitalization.

CONCLUSION

Conclusion will be mentioned after the analyzing data.

RESULTS

Results of the treatment will be tabulated and analysed statistically with relevant tests and level of significance will be reported.

REFERENCES

- 1. A Comparative study of Vatarakta w.s.r to Gout by Vikas Rana et al.
- 2. Ayurvedic Management of Vatarakta-A Case Study- Poorva G. Kadam and V.J. Tiwari.
- 3. Charaka Samhita (Vidyotini Hindi Commentary), Kashinath Pandey Shastri and Dr. Gorakhnath Chaturvedi editors. Revised ed. Varanasi: Chaukhamba Bharti Academy; Chikitsa Sthana, 2020; 29: 747-765.
- 4. Gout: An Asia-Pacific update- Binoy J.Paul, Reeta James- first published: 05 June 2017.
- 5. Sushruta Samhita (Ayurveda tatva Sandipika Hindi Vyakhya), Kaviraj Ambika dutta Shastri, editor. 1st ed. Varanasi: Chowkhamba Sanskrit Sansthana; 2010; 1. Nidana Sthana, 38/71-76, 1/48.P.214-215, P.232.
- 6. API Text Book of Medicine, 10th ed. Mumbai: The Association of Physicians of India; 2015.
- 7. Ayurvedic management of gouty arthritis: A case report Aswathi Rajan V.K. Devipriya Soman, Mahesh C. Kundago, James Chacko.
- 8. Harrison's Principals of internal Medicine 16th ed., vol. 2, Dennis 1. Kasper, E. Braunwald, Anthony S. Fauci, at el. MCGraw-Hill medical publishing divison.
- 9. API Text Book of Medicine, 10th ed. Mumbai: The Association of Physicians of India;

20158.

- Charaka Samhita (Vidyotini Hindi Commentary), Kashinath Pandey Shastri and Dr. Gorakhnath Chaturvedi editors. Revised ed. Varanasi: Chaukhamba Bharti Academy; Chikitsa Sthana, 2020; 29: 747-765.
- 11. API Text Book of Medicine, 10th ed. Mumbai: The Association of Physicians of India, 2015.
- 12. Sushruta Samhita (Ayurveda tatva Sandipika Hindi Vyakhya), Vol. 1, Kaviraj Ambika dutta Shastri, editor. 1st ed. Varanasi: Chowkhamba Sanskrit Sansthana; 2010. Nidana Sthana, 38/71-76, 1/48.P.214-215, 232.
- 13. Charaka Samhita (Vidyotini Hindi Commentary), Kashinath Pandey Shastri and Dr. Gorakhnath Chaturvedi editors. Revised ed. Varanasi: Chaukhamba Bharti Academy; Chikitsa Sthana, 2020; 29: 747-765.
- 14. Davidson's Principals & Practice of Medicine Editor, Nicholas A. Boon, Nicki R. Coledge, Brian R. Walker, John A.A. Hunter, editor, 20th ed., New York; Churchill Livingstone Elsevier, 2006.