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Research Article

CLINICAL EVALUATION OF THE ROLE OF *SINGHASYADI KWATHA* IN THE MANAGEMENT OF *VATARAKTA* (GOUT)

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ABSTRACT

Vatarakta is a disease where both *Vata* and *Rakta* are afflicted by distinct etiological factors. *Vatarakta* is a *Vatapradhana Tridoshaja Vyadhi* in which *Rakta* is main *Dushya*. In modern science, it corresponds to gout. While synthetic drugs offer quick relief, they often cause adverse reactions. As a result, many are turning to Ayurveda, which has effective formulations for *Vatarakta* and a proven track record, providing hope for better relief to those suffering. **Aims:** Clinical evaluation of '*Singhasyadi Kwatha*' in the management of *Vatarakta* (gout). **Materials & Methods:** In this interventional clinical trial, the purpose is to assess the treatment efficacy of *Singhasyadi Kwatha* for *Vatarakta* (gout). The study involves a randomized allocation of 30 patients into a single group with open label masking. The assignment is parallel, determined through computer-generated randomization. The study follows a prospective timeline with a total study period of 30 days for each patient. There is preparatory period of 7 days followed by 45 days treatment period. After completion of treatment, participants were monitored during a follow-up period occurring every 15 days to evaluate both efficacy and safety of the intervention. **Result:** Overall, the drug exhibited significant relief for several key symptoms including *Sandhi Shoola* (pain in joints), *Sandhi Shotha* (swelling of joints), *Vidaha* (burning sensation), *Raga* (redness), *Toda* (pricking sensation), *Twakvaivarnya* (discoloration of skin), *Vikriti* (deformity of joints). Although all the symptoms didn't show statistically significant improvement, the findings of study collectively demonstrate the positive impact of the drug on *Vatarakta* symptoms highlighting its potential as a therapeutic intervention for the condition under investigation. **Conclusion:** this research emphasizes the importance of utilizing traditional herbal remedies in treating non communicable conditions like *Vatarakta*. This herbal formulation can serve as potent alternatives or complementary options alongside modern medications, showcasing their effectiveness in managing the disease.

INTRODUCTION

Despite major advancements in modern technology, a number of diseases still afflict people. It is really upsetting to have a *Vatarakta* disease because of how it recurs frequently and is intermittent. One of the unique metabolic disorders is known as *Vatarakta*.

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Vatarakta has described under *Vatavyadhi* by *Acharya Sushruta* while *Acharya Charaka* and *Acharya Vagbhatta* explained it in separate chapter. *Vatarakta* may also termed as "*Vata Dushtam Raktam Yatra Roga Vishesha*"[1]. Inflammatory joint disease is most prevalent in men and elderly women[2]. Based on causes, signs and symptoms, *Vatarakta* may be related to gouty. Gouty arthritis is a metabolic disorder of purine protein metabolism characterized by hyperuricemia and deposition of monosodium urate crystals in Joints. Gout affects 2.68 out of every 1000 people annually [3]. Multiple diseases manifest largely as a result of how human lifestyles, including diet and behaviour patterns, are changing. Numerous illnesses

are caused by the union of vitiated *Vata Dosha* and *Rakta Dhatu.* One of them is called *Vatarakta*. As the name implies, *Vata Dosha* and *Rakta Dhatu* are involved. The pathophysiology of the illness starts in the blood, moves through the blood vessels, and then settles in the joints. Vitiated *Vata Dosha* gets *Avruta* with vitiated and *Dushta Rakta Dhatu,* producing complex effects in the joints.

Vatarakta, a more general word for the variety of health problems caused by the conjugation of vitiated *Vata* and *Rakta*, is the result of these diseases. In the *Brihattrayi* and other ancient scriptures, *Vatarakta* is described. It mentions *Nidanas* such as *Katu, Amla*, *Ushna, Vidahi Aaharas, Gaja*, and *Ushtra Yaana*. '*Lavana Amla Katu Kshara Kupyate Vatashonitam*'[4]. *Utthana* and *Gambheera* are its two stages. The main complaint of the patient is severe joint pain, which starts at *Hasta Pada Mulagata Sandhi* and spreads to all other joints in a manner resembling the spread of *Akhorvisha* [5].

AIMS AND OBJECTIVES

1. To assess the clinical efficacy of *Singhasyadi Kwatha* in the management of *Vatarakta* (Gout).
2. To evaluate the safety, efficacy, sustainability and adverse drug reactions of the trial drug.

MATERIAL AND METHODS

Following materials and methods will be adopted for conducting the present research project.

Conceptual Study

There will be in depth view of relevant literature from Ayurvedic classics, journals, previous research and internet for drug and disease review.

Clinical Study

Selection of Cases

Confirmed and well-diagnosed 30 patients with *Vatarakta* (gout) were selected randomly from the O.P.D. and I.P.D. departments of the P.G. Department of Kayachikitsa in PGIA, hospital. The selection of patients was made on the basis of diagnostic and inclusion criteria after taking the patient's consent in the prescribed format.

Ethical Clearance

This study was approved by Institutional Ethical Committee (IEC) DSRRAU, Jodhpur vide letter no. Sr. No./DSRRAU/UPGIAS&R/IEC/20-21/397 on dated 12/06/2022.

CTRI Registration [CTRI No. - CTRI/2022/11/ 047494 registered on 21/11/2022]

Selection Criteria

Inclusion Criteria

1 Patients of either sex in the age group between 20-70 years
2 Diagnosed and confirmed case of *Vatarakta* (Gout).
3 Patients having serum uric acid level more than 6mg/dl with or without any associated features like joint inflammation.
4 Willing to participate and able to provide signed informed consent.

Exclusion Criteria

1 Patients below 20 years and above 70 years of age.
2 Patients suffering with other forms of arthritis like rheumatoid arthritis, ankylosing spondylitis, infective arthritis, osteoarthritis, etc.
3 Pregnant and lactating mother.
4 Patients having any malignancy or any other severe systemic disorders.

Administration of Drug

30 clinically diagnosed and well confirmed patients of *Vatarakta* (Gout) registered for clinical trial will be administered with *Singhasyadi Kwatha* orally 20ml twice a day for 45 days.

Follow Up

1. Patients will be followed up on each 15th day.
2. Improvement and other effects will be noted.
3. Laboratorial and radiological investigation will be repeated for the assessment.

Study Design

Study Type: Interventional (Clinical Study)
Purpose: Treatment
Allocation: Randomized
Masking: Open label
Timing: Prospective
End Point: Efficacy & Safety
No. of Groups: 1
Participants: 30
Total Study Period: 45 days
Follow-Up Period: 15 days

Drug Selection

Singhasyadi Kwatha [6]

Dose: 20ml orally twice a day (10gm of coarse powder then boil it with 16 times of water to make *Kwatha* and reduce to 1/8th and filtered. Then add 10ml *Eranda taila,* 500mg *Hingu* and 1gm *Saindhava lavana)*

Table 1: Ingredients of *Singhasyadi Kwatha*

S. No.	Constituents	Latin Name	Used Part	Proportion
1	*Vasa*	*Adhatoda vasica*	*Pushpa*	1 part
2	*Brihati*	*Solanum indicum*	*Phala*	1 part
3	*Kantkari*	*Solanum surattense*	*Panchanga*	1 part
4	*Shalparni*	*Desmodium gangeticum*	*Panchanga*	1 part
5	*Prishniparni*	*Uraria picta*	*Moola*	1 part
6	*Gokshura*	*Tribulus terristris*	*Phala*	1 part
7	*Guduchi*	*Tinospora cordifolia*	*Kaanda*	1 part
8	*Eranda*	*Ricinus communis*	*Moola*	1 part

Prakshepa Dravya

S. No.	Constitution	Latin Name	Used Part	Proportion
1	*Eranda*	*Ricinus communis*	*Taila*	10 ml
2	*Ramatha*	*Ferula narthex*	*Niryasha*	500 mg
3	*Saindhava*	Rock salt	*Choorna*	1 gm

Assessment Criteria

The effects of trial drugs will be assessed in terms of subjective and objective criteria.

Subjective Criteria

The patients will be diagnosed on the basis of Ayurvedic and modern parameters following clinical signs & symptoms as described in classical texts will be considered for the diagnosis of *Vatarakta* e.g., *Sandhi Shoola* (pain in joints), *Sandhi Shotha* (swelling of joints), *Vidaha* (burning sensation), *Raga* (redness), *Toda* (pricking sensation), *Twakvaivarnya,* (discoloration of skin), *Sandhi Vikriti* (deformity status). Different signs and symptoms will be graded on the basis of scores ranging from 0 to 3.

Table 2: Grading of Subjective Criteria

***Sandhi Shoola* (Pain in joints)**	**Grading**
No pain	0
Mild pain (nagging, annoying, interfering little with activities of daily living)	1–3
Moderate pain (interferes significantly with activities of daily living)	4–6
Severe pain (disabling; unable to perform activities of daily living)	7–10
***Sandhi Shotha* (Swelling over joints)**	
No swelling	0
Mild swelling (seen with very careful observation)	1
Moderate swelling	2
Bulky swelling	3
***Vidaha* (Burning sensation)**	
Absent	0
Transient, no approach of its aversion	1
Frequent, self-approach for its aversion	2
Regular, seeking medical advice	3
***Raga* (Redness in joints)**	
No Redness	0
Mild Redness	1
Moderate Redness	2
Severe Redness	3

***Toda* (Pricking sensation)**	
No pricking sensation	0
Mild pricking sensation	1
Moderate pricking sensation	2
Severe pricking sensation	3
***Twakvaivarnya (*Discoloration)**	
No discoloration	0
Mild discoloration of the skin	1
Moderate discoloration of the skin	2
Severe discoloration of the skin	3
***Sandhi Vikriti (*Deformity Status)**	
No deformity	0
Mild deformity of single joint	1
Deformity of 2-3 joints	2
Formation of tophi in multiple joints	3

Objective Criteria

Laboratory profile: Following investigation will be assessed for objects assessment- CBC, ESR, Serum uric acid, CRP, Urine complete, R.A Factor, Radiological investigation - X-ray of affected joint

OBSERVATION AND RESULT

Total 30 patients of of *Vatarakta* (Gout) were studied in the present study. They were in the age between 20-70 years with maximum 09 patients in the age group of 41-50 years (30%). In this series maximum numbers of patients were male (63.33%), Hindu (100%), having graduate in education level (30%), from upper middle class (47.5%), house wife (17.5%), addicted to alcohol (30%) and Married (93.33%).

Dashavidha Pariksha biostatistics revealed that maximum numbers of the patients were having *Vata-Pittaja Deha Prakriti* (50%), *Rajasika Mansika Prakriti* (50%), *Madhyama Satva* (56.67%) *Mamsa Sara* (56.67%), *Vyamishra Satmaya* (60%), *Madhyama Samhanana* (56.67%) *Madhyama Vyayama Shakti* (50%), *Madhyama Abhyavaharana Shakti* (50%) and *Madhyama Jarana Shakti* (50%).

Table 3: Relative incidence of various symptoms (*Lakshanas*) seen in *Vatarakta* (Gout) (in present study (N=30)

Sr. No.	Symptoms	Total Patients	%
1	*Sandhi Shoola* (Pain in joints)	30	100
2	*Sandhi Shotha* (Swelling over joints)	25	83.33
3	*Vidaha* (Burning sensation)	20	66.67
4	*Raga* (Redness in joints)	24	80.00
5	*Toda* (Pricking sensation)	22	73.33
6	*Twakvaivarnya* (Discoloration)	27	90
7	*Sandhi Vikriti* (Deformity status)	0	0

Intra-group study: For Non-parametric Data Wilcoxon signed rank test was used while for Parametric Data paired t Test was used and results were calculated in this present study.

Table 4: Effect of therapeutic trial on Subjective Parameters

Variable	No of Pt.	Mean		Mean Diff	% Relief	S.D.	S.E.	P-Value	Result
		BT	AT						
***Sandhi Shoola* (Pain in joints)**	30	2.700	0.935	1.765	65.370	0.681	0.124	0.0000013	ES
***Sandhi Shotha* (Swelling in joints)**	30	2.300	0.764	1.536	66.783	0.711	0.130	0.0000108	ES
***Vidaha* (Burning sensation)**	30	2.233	0.982	1.251	56.030	0.498	0.091	0.0011941	S

***Raga* (Redness in joints)**	30	1.333	0.584	0.749	56.200	0.803	0.147	0.0018022	S
***Toda* (Pricking sensation)**	30	2.200	0.933	1.267	57.576	0.691	0.126	0.0025727	S
***Twakvaivarnya* (Discoloration)**	30	2.033	1.272	0.761	37.443	0.740	0.135	0.0643559	NS
***Sandhi Vikriti* (Deformity Status)**	0	0.000	0.000	0.000	NA	0.000	0.000	NA	NA

Effect of Therapy on Subjective criteria

***Sandhi Shoola* (Pain in joints):** In present study, mean score before treatment was 2.700 which reduced to 0.935 after treatment, with SD±0.681 giving a relief of 65.370% which is statistically extremely significant (P<0.001).

***Sandhi Shotha* (Swelling over joints):** In present study, mean score before treatment was 2.300 which reduced to 0.764 after treatment, with SD±0.711 giving a relief of 66.783% which is statistically extremely significant (P<0.001).

Vidaha (Burning sensation): In present study, mean score before treatment was 2.233 which reduced to 0.982 after treatment, with SD±0.498 giving a relief of 56.030% which is statistically significant (P<0.05).

***Raga* (Redness in joints):** In present study, mean score before treatment was 1.333 which reduced to 0.584 after treatment, with SD±0.803 giving a relief of 56.200% which is statistically significant (P<0.05).

***Toda* (Pricking sensation):** In present study, mean score before treatment was 2.200 which reduced to 0.933 after treatment, with SD±0.691 giving a relief of 57.576% which is statistically significant (P<0.05).

***Twakvaivarnya* (Discoloration):** In present study, mean score before treatment was 2.033 which reduced to 1.272 after treatment, with SD±0.740 giving a relief of 37.443% which is statistically non-significant (P<0.05).

***Sandhi Vikriti* (Deformity in joints):** *Sandhi Vikriti* was not present in any of the patients hence, statistical test is not applicable.

Table 5: Effect of therapeutic trial on Objective Parameters

Objective Parameters		Mean	N	SD	SE	t-Value	P-Value	% Relief	Result
Hb	**BT**	11.87	30	1.76	0.32	-1.395	0.173	4.58	NS
	AT	12.41	30	1.95	0.36				
TLC	**BT**	9293.67	30	1828.10	333.76	6.400	<0.001	55.00	ES
	AT	4182.37	30	822.59	150.18				
Serum Uric Acid	**BT**	8.09	30	0.90	0.16	23.181	<0.001	51.67	ES
	AT	3.91	30	0.58	0.11				
ESR	**BT**	56.40	30	16.80	3.07	10.982	<0.001	59.40	ES
	AT	22.90	30	4.92	0.90				
CRP	**BT**	7.13	30	1.85	0.34	13.889	<0.001	55.61	ES
	AT	3.17	30	0.87	0.16				

Effect of Therapy on Objective Criteria

Hb: In present study, mean score before treatment was 11.87 which increased to 12.41 after treatment, with SD±1.95 giving a relief of 4.58% which is statistically not significant (P>0.05).

TLC: In present study, mean score before treatment was 9293.67 which reduced to 4182.37after treatment, with SD±822.59 giving a relief of 55% which is statistically extremely significant (P<0.001).

Serum Uric Acid: In present study, mean score before treatment was 8.09 which reduced to 3.91 after treatment, with SD±0.58 giving a relief of 51.67% which is statistically extremely significant (P<0.001).

ESR: In present study, mean score before treatment was 56.40 which reduced to 22.90 after treatment, with SD±4.92 giving a relief of 59.40% which is statistically extremely significant (P<0.001).

CRP: In present study, mean score before treatment was 7.13 which reduced to 3.17 after treatment, with SD±0.87 giving a relief of 55.61% which is statistically extremely significant (P<0.001).

Table 6: Showing the % relief on Subjective Parameters

Sr. No.	Subjective Parameters	% Relief
1	*Sandhi Shoola* (Pain in joints)	65.37
2	*Sandhi Shotha* (Swelling over joints)	66.78
3	*Vidaha* (Burning sensation)	56.03
4	*Raga* (Redness in joints)	56.20
5	*Toda* (Pricking sensation)	57.58
6	*Twakvaivarnya* (Discoloration)	37.44
7	*Sandhi Vikriti* (Deformity Status)	NA
	Total	56.57

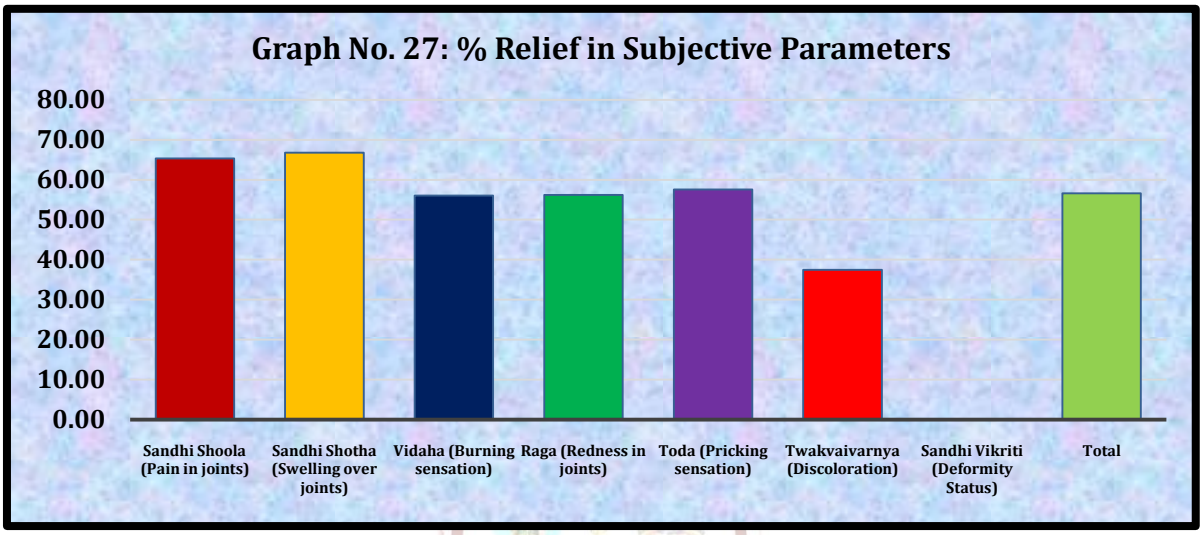
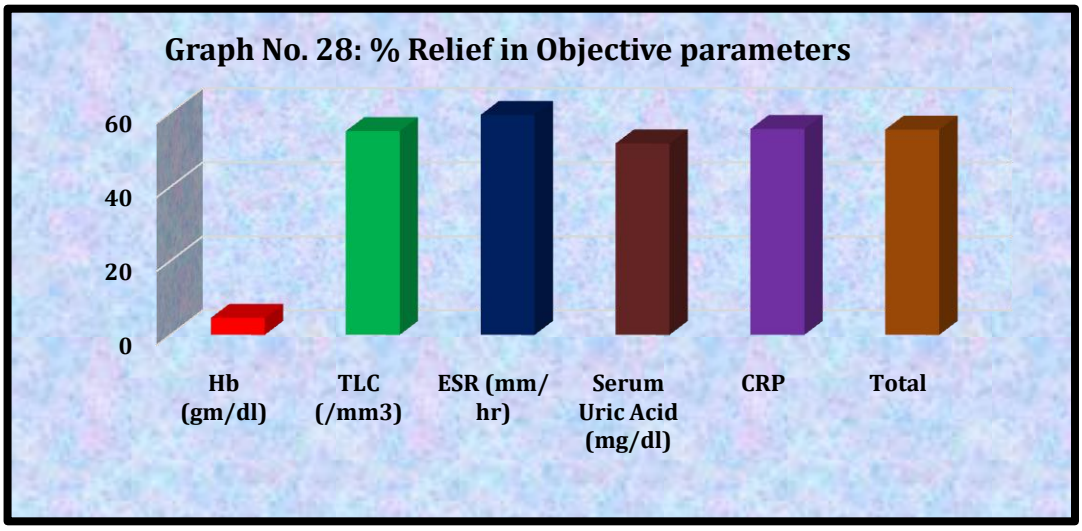


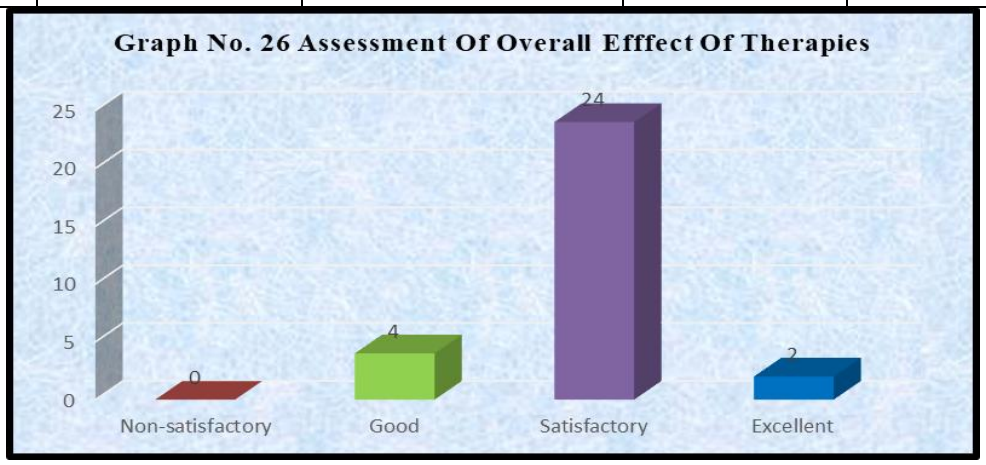
Table 7: Showing the % relief on Objective Parameters

Sr.No.	Objective Parameters	% Relief
1	Hb (gm/dl)	4.58
2	TLC (/mm$^{3)}$	55
3	ESR (mm/ hr)	59.4
4	Serum Uric Acid (mg/dl)	51.67
5	CRP	55.61
	Total	55.42



Assessment of overall effect of the therapies

Sr.No.	Symptoms	Grading	No of Patients	Percentage
1	Less than 25%	Non-satisfactory	0	0.00
2	25% to 50%	Good	4	13.33
3	50% to 75%	Satisfactory	24	80.00
4	75% to 100%	Excellent	2	6.67



DISCUSSION

Probable Mode of Action

Singhasayadi Kwatha, which consists of ingredients like *Guduchi, Shalparni*, *Prashniparni, Gokshura, Eranda,* etc., poses *Sothhara*, *Vedna Sthapaka, Raktashodhaka* [7], properties, by reducing the obstruction in the path of *Vata* caused by *Dushita Rakta. Amrita, Prishniparni, and Saindhava* have *Tridosha Nashaka* properties. It has the qualities of *Vatanulomana* and aids in reducing the *Vatadushti* brought on by *Vatarakta*.

Most of these drugs show a characteristic of *Ushna Veerya* (hot potency) with *Laghu* (easily digestible), *Ruksha* (dry), and *Tikshna Guna* (qualities), which helps in easy assimilation of the drug in the body, whereas *Shalaparni, Gokshura,* and *Guduchi* [8] are *Guru* (hard to digest) and *Snigdha* (oily), which further helps in the *Vatahara* action of the drugs. The *Vipaka* (post-digestive effect) characteristic of *Amrita, Shalaparni, Prishniparni, Gokshura, Eranda*[9], and *Saindhva* is *Madhura* (sweet), which has *Vata-Pitta Shamaka* (pacifying) property. The *Rasa* of *Eranda Taila* is *Madhura Katu Tikta Kashaya, Vipaka Madhura, Virya Ushna* and *Gunas Guru and Teekshna*. The action is *Deepana, Vrishya, Twachya, Vayasthapana, Varnya, Saraka*. Because of *Sookshma* and *Teekshna* properties *Eranda Taila* removes obstructions in *Srotasas* and possesses *Srotovivaranya* [10] property. Out of 10 ingredients, 2 gradients show the property of *Vatarakta Shamaka,* which finds a solid base for the treatment of *Vatarakta* (gout) with raised uric acid.

Overall, the aforesaid Ayurvedic therapeutics conclude that the preparation of *Simhasyadi Kwatha* with all ingredients is enriched for the properties that certainly prove better in *Vatarakta* as well as in other *Vata* diseases.

CONCLUSION

In lifestyle diseases, Ayurveda is the best treatment option. *Singhasyadi Kwath*a was selected for this inquiry due to the predominance of *Vata* and *Rakta* vitiation in *Vatarakta,* which is evident in *Bhavprakasha* in *Vatarakta Prakarana*. These drugs have *Vatashamaka, Raktaprasadaka* and *Raktashodhaka* (blood purifiers), *Vedanahara, Anulomana,* and *Shothhara* properties, according to *Ayurvedic* texts. On the basis of this single case study, it can be concluded that *Singhasyadi Kwatha* had been effective in the management of *Vatarakta* (gout). There were no adverse effects of the therapy noted during the entire trial period. On the same disease, I'll plan more research.

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