



# A Randomised Controlled Clinical Study to Evaluate the Effect of *Vardhamana Pippali Rasayana* in the Management of *Vatarakta* w.s.r. to Gouty Arthritis

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## ABSTRACT

*Vatarakta* is a painful disease that initially involves small joints. This disease is caused due to consumption of *rakta pradoshaka ahara vihara* along with *vataprakopaka nidanas*, both *rakta* and *vata* gets vitiated. In modern science a condition called Gouty arthritis had similar presenting features hence it can be co-related to *Vatarakta*. The main involvement of causative factor here is *Vata* and *Rakta*. *Naimittika Rasayana* is one of the important therapeutic concepts in *Ayurveda* that is helpful in treating the disease and rebuilding the damaged tissue thus helping to recover from prevailing disease. A randomised controlled clinical study was conducted to evaluate the effect of *vardhamana pippali rasayana* in the management of *vatarakta*. **Objective:** To compare the efficacy of *Guduchi Rasayana* and *Vardhamana Pippali Rasayana* in *Vatarakta*. In this study *vardhamana Pippali Rasayana* which is also having *vata-shleshmahara, deepana, vrushya* action is administrated. Minimal research has been conducted on effect of *Rasayana* on *Vatarakta* hence the present research work was carried out. **Study design:** Randomized open controlled clinical study on patients having signs and symptoms of *vataakta/Gouty arthritis* with pre-test and post-test on 30 patients divided in two groups A and B. **Result:** when results were obtained it showed marked improvement in the overall signs and symptoms as per the statistical analysis. **Conclusion:** Both *vardhamana pippali Rasayana* and *Guduchi* are found to be effective in the treatment of *Vatarakta*.

**Key Words:** *Vatarakta, vardhamana pippali, Rasayana, Gout*

## INTRODUCTION

*Vatarakta* is one of the major diseases mentioned under *Vatavyadhi* caused due to vitiation of *Vata* and *Rakta* by their own *nidanas*. The word *Vatarakta* is made up of two words, '*Vata*' and '*Rakta*'. Even though it is mentioned under *Vatavyadhi*, a separate chapter has been dealt for

this disease by Charaka because of importance of *vishesa sampraptighataka* of both *Vata* and *Rakta*. Different other synonyms have been mentioned in classics like *adhyavata, khudavata* and *vatabalasa* based on its importance, *lakshana, upadrava* and *vyaktasthana*. *Vata* having the quality of *chala guna* helps in the movement of all



dosha and dhatu. Rakta is a circulatory dhatu which provides nourishment to all cells of the body. Due to consumption of *rakta pradoshaka ahara vihara* along with *vataprakopaka nidanas*, *vata* and *rakta* independently gets aggravated by its own *nidanas*, *rakta* further obstructs the *vata* dosha and produce the disease<sup>1</sup>. *Raktavaha srotas* is mainly exaggerated in this disease. *Vatarakta* mainly affects the lower extremities and the peripheral blood vessels in the initial stage.

*Vatarakta* is also caused by *margavarana* of *vayu* by *medas* resulting in *medasavruta vata*. So it is also considered as *avaranajanya vyadhi*. It is also called as *kudavata*, *adyavata* and *vatabalasa* on the basis of its severity and importance.

In the view of western medicine *Vatarakta* has similar features of multiple disorders including arterial as well as venous diseases, collectively correlated as peripheral vascular diseases and an arthritis called as Gouty arthritis.

Gout is a true crystal deposition disease. It refers to a disease which occurs in response to the presence of monosodium urate (MSU) crystals in joints, bones and soft tissues. It may result in acute arthritis and a chronic arthropathy. MSU crystals preferentially deposit in peripheral connective tissues in and around synovial joints, initially favouring lower rather than upper limbs and especially targeting the first metatarsophalangeal joint and small joints of feet and hands. Hyperuricemia is a common pathogenic factor in the development of gout. Initially affects first metatarsophalangeal joint, but may become polyarticular in later episodes. It leads to

significant pain and afflicts patient's health related quality of life<sup>2</sup>.

Gout is the common inflammatory disease in men aged more than 50yrs. Globally, gout affects 1-2% of the population with strong male predominance of ratio >5:1. By 2013 a report showed that about 8.3 million people suffered from this disease<sup>3</sup>. In India, Gout is the most common form of inflammatory arthritis. It is commonly seen in men than in women. The incidence rate in men is 5-27 per 1000men. Gout rarely occurs in children and in women before menopause<sup>4</sup>. Raised uric acid in children is in-born errors of metabolism.

*Ayurveda* plays an important role in treating metabolic disorders. It targets the whole system ensuring to treat the root cause of the disease. *Rasayana chikitsa* is a form of *chikitsa* in which both prevention as well as treatment of disease is explained with different formulations. *Vayasthapana*, *ayushkara*, *balakara* and *jaravyadhinashana* are the important clinical functions of *Rasayana*. It not only improves the health but also helps in longevity. *Naimittika Rasayana* is one of the important therapeutic concepts in *Ayurveda* explained under the concept of *Rasayana*, helpful in treating the disease and rebuilding the damaged tissue thus helps to recover from prevailing disease.

*Pippali* having *katu rasa*, *ushna veerya*, *madhura vipaka* with *laghu*, *snighda* and *teekshna guna* which is having *vata-shleshmahara*, *deepana*, *vrushya* and *Rasayana* action<sup>5</sup>. It is mainly indicated in *shoola*. *Vardhamana Pippali Rasayana* is indicated in *vatashonita vikara*<sup>6</sup>.



*Guduchi* is a drug of choice and it acts as *Rasayana* in *Vatarakta*<sup>7</sup>. There is minimal research conducted on *Rasayana* effect on *Vatarakta* hence this research work is carried out.

## AIMS AND OBJECTIVES

- To study *Vatarakta* and gouty arthritis in detail.
- To evaluate the efficacy of *Vardhamana Pippali Rasayana* in the management of *Vatarakta*.
- To compare the efficacy of *Guduchi Rasayana* and *Vardhamana Pippali Rasayana* in *Vatarakta*.
- To evaluate the therapeutic effect of *Rasayana* on quality of life in patients suffering from *Vatarakta*

## MATERIALS AND METHODS

### Source of Data:

A. Literary Source: Reference of *Vatarakta* from Ayurvedic classical text books, Journals, Research Articles and References of Gouty arthritis from updated modern text books

B. Clinical Source: Patients suffering from *Vatarakta* will be selected from OPD/IPD of Shri JGCHS Ayurvedic Medical College and Hospital Ghataprabha, from Medical Camps and other sources.

C. Drug Source: Drugs will be collected after authentication from the Dept of *Dravyaguna*.

### Method of Collection of Data:

### Study Design

Randomized open controlled clinical study with pre-test and post-test on 30 patients divided in two groups A and B.

### Diagnostic Criteria:

Diagnosis was established on the Basis of History, Inspection, Signs and Symptoms of *Vatarakta*

### Inclusion Criteria

- Patients of Either Sex Between the age group from 20 to 60 Yrs
- Patients Presenting with clinical features of *vatarakta*
- Patients presenting clinical features of Gouty arthritis with Hyperuricemia.

### Exclusion Criteria

- Patients with Uncontrolled Diabetes Mellitus, Systemic Disorder and Endocrine Disorder.
- Patients with Auto-Immune Disorders Of Joints, infective and reactive arthritis.
- Patients with Severe Toxicity, Ulceration, Progressive Gangrenous Changes.
- Patients with Infections and Communicable Diseases.
- Pregnant Women and Lactating Mother.

### Duration of the Study

Treatment duration: 34 to 40 days

Follow up: 30 days

Total duration: 64 to 70 days

Patients are assessed before treatment, after *Shodhana*, after *Rasayana* and once in every 15days for a month during follow up.

### Intervention

### Method of Administration

It is a clinical interventional study on 30 patients divided in to two groups a and b. Subjects are selected on the basis of classical signs and symptoms of *Vatarakta* with detail history taking and physical examination as per case proforma.



➤ Details of administration of drugs in trial

group A is mentioned in Table 1

**Table 1** Method of administration of drugs in Trial Group A

1. Group A- Trial Group							
Day	Procedure	Drugs	Ingredients	Dosage	Anupana		
1-3	Deepana and Pachana	Shiva Kshara Pachana Choorna <sup>8</sup>	Hingwastaka Churna Haritaki Churna Sarja Kshara	2gms twice daily before food	Sukoshna Jala		
4-10	Shodhana	Snehapana	Amrita Ghrita <sup>9</sup> (Guduchi and Shunti)	Arohana Krama upto	Sukoshna Jala		
		Abhyanga	Tila Taila	Q.S	-		
		Bhashpasweda	Dashamoola Kashaya	Q.S	-		
		Virechaka	Haritakyadi Yoga <sup>10</sup>	Depending upon Koshta.	Sukoshna Jala		
11-15	Samsarjana Karma	Diet	-	-	-		
16-34	Rasayana	Vardhamana Pippali Rasayana	Pippali	Vardhamana dosage	Dugdha		
	Pathya	Shashtika Shali with Dugdha and Ghrita	-	Depending upon koshta	-		

### Vardhamana Pippali Rasayana Dosage<sup>11</sup>

Ingredient: Pippali (Piper longum) , dosage is shown in Table 2

**Table 2** Dosage of pippali

Days	Qty In No.	Grams	Anupana	Days	Quantity In No.	Grams	Anupana
D1	3	1	Dugdha 200ml	D11	27	9	Dugdha 200ml
D2	6	2	Dugdha 200ml	D12	24	8	Dugdha 200ml
D3	9	3	Dugdha 200ml	D13	21	7	Dugdha 200ml
D4	12	4	Dugdha 200ml	D14	18	6	Dugdha 200ml
D5	15	5	Dugdha 200ml	D15	15	5	Dugdha 200ml
D6	18	6	Dugdha 200ml	D16	12	4	Dugdha 200ml
D7	21	7	Dugdha 200ml	D17	9	3	Dugdha 200ml
D8	24	8	Dugdha 200ml	D18	6	2	Dugdha 200ml
D9	27	9	Dugdha 200ml	D19	3	1	Dugdha 200ml
D10	30	10	Dugdha 200ml				

➤ Details of administration of drugs in trial group B is mentioned in Table 3

**Table 3** Method of administration of drugs in control Group B

Group B – Control Group							
Day	Procedure	Drugs	Ingredients	Dosage	Anupana		
1-3	Deepana and Pachana	Shiva Kshara Pachana Choorna	Hingwastaka Churna Haritaki Churna Sarja Kshara	2gms twice daily before Food	Sukoshna Jala		
4-10	Shodhana	Snehapana	Amrita ghrita (guduchi and shunti)	Starting With 50ml upto Adhastad Sneha Darshana and Samya Siddha Laxana	Sukoshna Jala		
		Abhyanga	Tila Taila	Q.S	-		
		Bhashpasweda	Dashamoola Kashaya	Q.S	-		
		Virechaka	Haritakyadi Yoga	Initial 1 karsha(12gm) and increased depending upon koshta.	Sukoshna Jala		



11-15	Samsarjana Karma	Diet	-	-	-
16-34	Rasayana Pathya	Guduchi Rasayana Pathya mentioned in vatarakta.	Guduchi Khanda Churna	6gms <sup>12</sup> OD	Dugdha
			-	Depending upon koshta	-

### Assesment Criteria

#### Subjective Parameters

- Sandhi Graham
- Sandhi Shoola
- Spurana
- Sandhi Shotha
- Daha
- Sparsha Asahishnuta
- Twak Vaivarnya
- Functional ability and disability

#### Objective Parameters

- Esr
- Serum Uric Acid

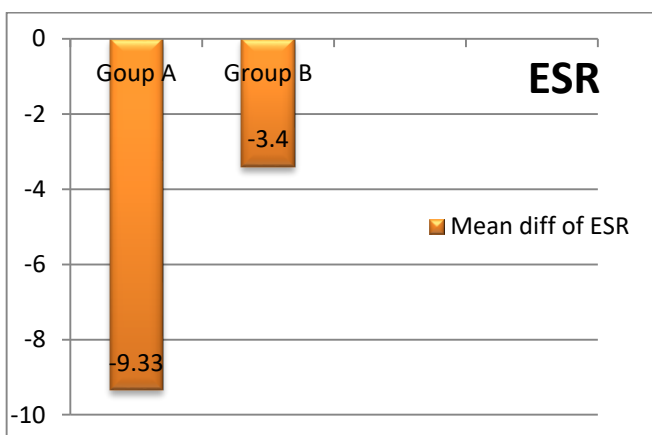
### OBSERVATIONS AND RESULT

#### Statistical analysis of the Objective Criteria by unpaired 't' Test between the Group A and Group B

➤ Statistical analysis between the Group A and Group B effect of therapy on ESR Before treatment and after treatment by showing their mean score values is showed in Table 4 and Figure 1.

**Table 4** Between the Group A and Group B effect of therapy on ESR Before treatment and after treatment by showing their mean score values

ESR	N	Mean	SD	SE	df	't' Value	P Value
<b>Group A</b>	12	-9.33	7.96964	2.30064	25	-2.501	0.019
<b>Group B</b>	15	-3.40	4.1369	1.06815	25	-2.339	0.033



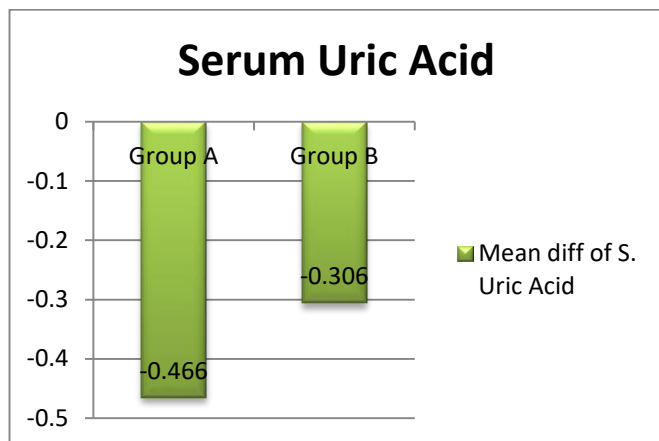
**Figure 1** Between the Group A and Group B effect of therapy on ESR by showing their mean score values

➤ Between the group A and group B analysis of ESR, showed significant difference in Group A then Goup B

➤ Statistical analysis the Group A and Group B effect of therapy on Serum Uric Acid Before treatment and After treatment by showing their mean score values Table 5 and Figure 2.

**Table 5** Between the Group A and Group B effect of therapy on Serum Uric Acid Before treatment and After treatment by showing their mean score values

Serum Uric Acid	N	Mean	SD	SE	df	't' Value	P Value
<b>Group A</b>	12	-.4667	0.17753	.05125	25	-2.070	.049
<b>Group B</b>	15	-.3067	0.21536	.05561	25	-2.116	.045



**Figure 2** Between the Group A and Group B effect of therapy on Serum Uric Acid Before treatment and after treatment by showing their mean score values

- Between the group A and group B analysis of ESR, showed no significant difference in Group A then Group
- Statistical analysis of the subjective Criteria by Wilcoxon Signed Rank Test within the Group A and Group B shown in Table 6

**Table 6** Statistical analysis of the subjective Criteria by Wilcoxon Signed Rank Test within the Group A and Group B

Parameter	Group	Negative Rank			Positive Rank			Ties	Total	Z value	p value	Inference
		N	MR	SR	N	MR	SR					
Sandhi graha	Group A BT-AT	12	6.50	78. 00	0	0.0	0.0	0	12	-3.134	0.002	H.S
	Group B BT-AT	14	7.50	105 .00	0	0.0	0.0	1	15	-3.372	0.001	H.S
Sandhi Shoola	Group A BT-AT	12	6.5	78. 00	0	0.0	0.0	0	12	-3.217	0.001	H.S
	Group B BT-AT	15	8.0	120 .0	0	0.0	0.0	0	15	-3.535	0.000	H.S
Sandhi Sphurana	Group A BT-AT	8	4.50	36. 00	0	0.0	0.0	4	4	-2.714	0.007	H.S
	Group B BT-AT	9	5.00	45. 00	0	0.0	0.0	6	15	-2.810	0.005	H.S
Sandhi Shotha	Group A BT-AT	12	6.50	78. 00	0	0.0	0.0	0	12	-3.134	0.002	H.S
	Group B BT-AT	14	7.50	105 .00	0	0.0	0.0	1	15	-3.372	0.001	H.S
Daha	Group A BT-AT	11	6.0	66. 00	0	0.0	0.0	1	12	-3.125	0.002	H.S
	Group B BT-AT	13	7.00	9.0 0	0	0.0	0.0	2	15	-3.236	0.001	H.S
Sparsha Asahishnuta	Group A BT-AT	11	6.0	66. 00	0	0.0	0.0	1	12	-3.017	0.003	H.S
	Group B BT-AT	11	6.0	66. 00	0	0.0	0.0	4	15	-2.994	0.003	H.S
Twak vaivarnya	Group A BT-AT	6	3.50	21. 00	0	0.00	0.00	6	12	-2.333	0.020	S
	Group B BT-AT	11	6.00	66. 00	0	0.0	0.0	4	15	-3.207	0.001	H.S

- Statistical analysis of the subjective Criteria by Mann Whitney Test between the Group A and Group B Table 7.

## DISCUSSION

### Effect on therapy

- Objective criteria

- As per statistical analysis made in Table 4 and Table 5

- Between the group A and group B analysis of ESR, showed significant difference in Group A then Group B, vardhamana pippali Rasayana found to have better result.



➤ Between the group A and group B analysis of then Goup B. vardhamana pippali Rasayana found ESR, showed no significant difference in Group A to have better result.

**Table 7** Statistical analysis of the subjective Criteria by Mann Whitney Test between the Group A and Group B

Parameter	N	Group		Mean rank		Sum of rank		U Value	Z Value	p value	Remarks	
		A	B	A	B	A	B					
Sandhi shoola	AT- BT	27	12	15	13.08	14.73	157.00	221.00	79.00	- 0.740	0.459	NS
Sandhi graha	AT- BT	27	12	15	11.25	16.20	135.00	243.00	57.00	- 1.826	0.068	NS
Sandhi Sphurana	AT- BT	27	12	15	13.88	14.10	166.50	211.50	88.500	-0.81	0.935	NS
Sandhi shotha	AT- BT	27	12	15	14.13	13.90	169.50	208.50	88.500	-0.80	0.936	NS
Daha	AT- BT	27	12	15	12.38	15.30	148.50	229.50	70.500	- 1.053	0.292	NS
Sparsha asahishnuta	AT- BT	27	12	15	13.04	14.77	156.50	221.50	78.500	- 0.598	0.550	
Twak vaivarnya	AT- BT	27	12	15	15.54	12.77	186.50	191.50	71.50	- 1.023	0.306	

➤ Between the group A and group B analysis of Serum Uric Acid, showed significant difference in Group A then Goup B, vardhamana pippali Rasayana found to have better result.

➤ Between the group A and group B analysis of Serum Uric Acid, showed no significant difference in Group A then Goup B. vardhamana pippali Rasayana found to have better result.

➤ **Subjective criteria**

As per statistical analysis made in Table 6 and Table 7

**1. Sandhi graha**

- When the results were obtained between the group analysis (at the mean rank of subordinate level of significance) of effect on Sandhi Graha, it showed no statistical significant difference in both the group. Group A showed better result (MR=13.08)

- This could be because of presence of anti-inflammatory and anti-oxidative action of both pippali and guduchi.

**2. Sandhi Shoola**

- When the results were obtained between the group analysis (at the mean rank of subordinate level of significance) of effect on Sandhi Shoola, it showed no statistical significant difference in both the group. Group A showed better result (MR=11.25)

- Studies show that pippali and guduchi acts as analgesics and has steroidal effects due to presence of its chemical constituents. This may have reduced the sandhi shoola.

**3. Sandhi Sphurana**

- When the results were obtained between the group analysis (at the mean rank of subordinate level of significance) of effect on Sandhi Sphurana, it showed no statistical significant



difference in both the group. Group A showed better result (MR=13.88)

#### 4. Sandhi Shotha

- When the results were obtained between the group analysis (at the mean rank of subordinate level of significance) of effect on Sandhi Shotha, it showed no statistical significant difference in both the group. Group B showed better result (MR=13.90)

- Both pippali and guduchi are proved to have anti-inflammatory actions. This might have resulted in the tremendous reduction of shotha in the subjects.

#### 5. Daha

- When the results were obtained between the group analysis (at the mean rank of subordinate level of significance) of effect on Daha, it showed no statistical significant difference in both the group. Group A showed better result (MR=13.38)
- Due to anti-inflammatory action of the drugs, the inflammation reduced thus reducing the burning sensation.

#### 6. Sparsha Asahishnuta

- When the results were obtained between the group analysis (at the mean rank of subordinate level of significance) of effect on Sparsha Asahishnuta, it showed no statistical significant difference in both the group. Group A showed better result (MR=13.04)
- Due to anti-inflammatory action of the drugs, the inflammation reduced thus reducing the tenderness in the joints

#### 7. Twak vaivarnya

- When the results were obtained between the group analysis (at the mean rank of subordinate level of significance) of effect on Twak Vaivarnya, it showed no statistical significant difference in both the group. Group B showed better result (MR=12.7)

- After srotoshodhana, circulation around the joints was improved resulting in reduction in the discoloration of the skin.

#### Probable mode of action of drug

The basic pathology in Vatarakta is Vata and Rakta being aggravated independently due to its etiological factors and mutually gets aggravated and obstructed. This aggravated vata along with Rakta dushti moves throughout the body and takes sthanasamsraya at the padangushta sandhi due to its vyadhi prabhava. This is told as anyonya avarana by chakrapani. So Vatarakta is considered as anyonya avaranajanya Vatavyadhi. Due to its properties like sukshmatva and saratva of vayu, dravatva and ushnatva of Rakta, they spread all over the body. The spread is ashukari i.e. acute manifestation, and it is facilitated by vyana vata. Due to sushma sira and convoluted marga in sandhi pradesha the aggravated dosha and dushya gets lodged in smaller sandhies. This is why the main and first site of manifestation is seen in padamula, hasta mula and later spreads to other sandhies in upward direction. The process of spreading can be understood similar to that of rat poison.

Pippali having snigdha, ushna and teekshna quality helps in subsiding the aggravated vata, and due to its madhura vipaka and it do not aggravate





the Rakta dosha, perhaps due to its *deepana*, *pachana* action it does *sroto shodhana* and relieves the obstruction caused due to *vata* and *Rakta*. *Rasayana* action of *pippali* improves the metabolic function, strength and immunity of the individual. The proteins of *Piper longum* are good antioxidants as compared to standard antioxidants and also having anti-inflammatory studies. The study was conducted to find and evaluate antioxidant activities of proteins isolated from boiling water extract of *Pippali* showed that the obtained results of proteins of Long pepper are very promising and had anti-oxidant properties, and it also showed that the *pippali* is non-toxic for cells<sup>13</sup>. This action of *pippali* helps in the reduction of inflammation in the disease *Vatarakta*. Once the inflammation reduces other symptoms like pain, swelling and redness also gets reduced. Along with anti-inflammatory action the immunomodulatory action of *pippali* plays an important role in regaining the affected immunity and strength of the individual. This can be a probable mode of action of *vardhamana pippali Rasayana*. *Guduchi* is having *snigdha guna* that helps to subside *ruksha guna* of *vata*. Usually *tikta rasa* converts into *katu vipaka* which cause *vibanda*, but *Guduchi* exceptionally having *madhura vipaka* expels *pureesha* etc. *Tikta rasa* subsides *rakta* and *madhura vipaka* subsides *vata*. *Guduchi* as a *Rasayana dravya* has *balya* (increases strength), *tridoshashamaka*, *deepaniya* (appetiser), *shothahara* (relieves oedma), *vata-shonithara* (subsides *gouty arthritis*) properties<sup>14</sup>. It ultimately increases the functioning of immune system of the

body. A study conducted showed the potential antioxidant activities of *guduchi* leaf as well as stem and it can be used as a source of antioxidant for health benefits through dietary supplementations<sup>15</sup>. This property helps in reduction of pain and swelling in *Vatarakta*, and augments the healing of the damaged tissue. This can be the probable mode of action of *Guduchi Rasayana*.

## CONCLUSION

*Vatarakta* can manifest into two different ways depending upon the *nidana*, predominance of *dosha*, *dushya* and *samprapti vighatana*. It is one among the unique disorders of *Vatavyadhi*. When *vata* and *rakta* aggravates by its own etiological factors and gets morbid with each other causing the disease *vatarakta* is the one form of *samprapti*. Other is the one when the *kapha* and *medas* get involved in the pathology of *vatarakta* causes the *margavarana* of the morbid *dosha*. Both are said to have the severe impact on the formation of the disease. As it is a disease caused by the metabolic impairment, in the conventional system of medicine it can be co-related to the multiple forms of the disease having different forms of signs and symptoms including *Gouty Arthritis*, *peripheral artery diseases*, and *periphery venous disease*. Even though various *chikitsa* are mentioned in the classics, the selection of the treatment is solely depends upon the *rogi bala* and *vyadhi bala*. As per statistical evaluation of the present study, both *vardhamana pippali Rasayana* and *Guduchi* are found to be effective in the treatment of *Vatarakta*.



No severe complications were observed during the study.



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