



## Research Article

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### EVALUATION OF THE CLINICAL EFFICACY OF *ZANTHOXYLUM RHETSA* (ROXB.) DC. IN SIRAJA GRANTHI (VARICOSE VEIN)

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#### ABSTRACT

Ayurveda is a science describes about many diseases condition with appropriate manifold therapeutic conditions. Siraja granthi (Varicose vein) is a disease, where due to exertion, vata increases and cause pain, squeezing, dilatation of veins mostly seen in the lower limbs. The folklore practitioners of Dakshina Kannada district are successfully using the *Zanthoxylum rhetsa* (Roxb.) DC. bark powder mixed with lemon juice as external application in case of varicose veins. Objectives- To evaluate the clinical efficacy of *Zanthoxylum rhetsa* (Roxb.) DC. in Siraja granthi. Methodology- Single blind clinical study with 2 Groups, 100 patients in each group, Group A is with *Zanthoxylum rhetsa* (Roxb.) DC bark kwatha internally and external application of *Zanthoxylum rhetsa* (Roxb.) DC with lemon juice, where as in Group B only *Zanthoxylum rhetsa* (Roxb.) DC external application with lemon juice, was given, intervention period was for 14 days and follow up on 28<sup>th</sup> day and 42<sup>nd</sup> day. Observation- Subjective and objective parameters were assessed using grading criteria on the 7<sup>th</sup>, 14<sup>th</sup>, 28<sup>th</sup>, and 42<sup>nd</sup> days. The collected data was then analysed statistically. Results- It has been proved with good effect. Conclusion- The subjective parameters, Shoola (pain), Kandu (itching), and Daha (burning sensation) showed significant reduction. The objective parameters, including Shotha (swelling), tortuosity, and skin changes, exhibited moderate improvement.

**Keywords:** *Zanthoxylum rhetsa* (ROXB.) DC. Siraja granthi, Varicose vein, clinical study.

#### INTRODUCTION

In today's fast-paced lifestyle, many people experience health issues due to prolonged standing and sedentary work. One such condition is varicose veins, which are permanently dilated and tortuous veins resulting from pathological circulation. This occurs due to faulty valves, leading to a reversal of blood flow, most commonly affecting the legs<sup>1</sup>. In some individuals, varicose veins are asymptomatic or cause only mild discomfort, while in others, they can lead to pain, itching, and a significant impact on quality of life. If left untreated, the condition may worsen over time, resulting in complications such as skin pigmentation changes, eczema, superficial thrombophlebitis (inflammation of veins), bleeding, and venous ulceration<sup>2</sup>. Several medical and surgical interventions<sup>3</sup> are available for varicose veins. Foam sclerotherapy is a minimally invasive procedure where a special foam is injected into the veins to close them. Radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) use heat energy radiofrequency and laser, respectively, to collapse the affected veins. In more severe cases, surgical stripping, a traditional method of removing the damaged vein, may be required. Early diagnosis and appropriate treatment can help manage symptoms and prevent complications, improving both health and quality of life.

In Ayurvedic text it is correlated to Siraja granthi, according to Vagbhat<sup>4</sup>, due to exertion vata increases, which invades in siras causes, sampeedan, sankochya, vishoshana, and vakrikarana of siras, whereas Sushruta<sup>5</sup> describes in person who are weak indulging in more of physical exercise vata gets aggravated invades in the network of veins and squeezes constricts and dries

up and give rise to an elevated quick developing and round swelling of vein (siraja granthi). Its Chikitsa, in initial stage saharataila should be administer internally, along with that basti karma can be adopted. Abhyang and compression treatment can be advised, estimates of the prevalence of varicose veins vary widely from 2-56% in men and from 1-60% in women<sup>6</sup>. Visible varicose veins in the lower limbs are estimated to affect at least one-third of the population. While the exact risk factors remain unclear, their prevalence increases with age and they commonly develop during pregnancy. With reported prevalence ranging between 10% and 30% worldwide<sup>7</sup>. Many medicinal plants had been described in this condition. As ethnomedicine, *Zanthoxylum rhetsa* (Roxb.) DC bark powder is used for external application over Sirajgranthi. This plant belongs to Rutaceae family locally known as Gaamatemara. It is a small or moderate sized tree with pale corky bark covered with conical prickles on stem as depicted in image 1, leaves clustered towards the end of the stout branchlets, pinnate, opposite, ovate to elliptic, base very oblique, acuminate at apex, Flowers in large terminal paniculate cymes, 4-merous petals yellowish. Fruits 6mm in diameter, globose, rugose. Seeds globose, bluish-black, smooth.<sup>8</sup> In our Samhitas it has been described obscurely, it can be considered as a variety of tumburu<sup>9</sup>. It is also called by name Tejasvini (tejbala)<sup>10</sup> Tejashwini tejovati tejovha tejbala its Rasa is tikta katu, Guna is deepan pachan, it is ushna aruchikara and tikshna, its Virya is ushna, Vipak is katu and Kaphavatahara.

**Objectives:** To evaluate the clinical efficacy of *Zanthoxylum rhetsa* (Roxb.) DC. in Siraja granthi (varicose vein).

## MATERIALS AND METHODS

**Source of data:** A comprehensive review of available literature in Ayurveda and contemporary sciences, including internet sources, was conducted to gather information on the drug and disease. The patients diagnosed with Siragranthi attending the OPD of Government Ayurvedic Medical College, Mysore, Karnataka, India, were selected for the study.

The study was carried out only after approval by Institutional clinical ethics committee having clearance number ICEC/AAMC/Date: 11/10/2019. The study was carried out as per ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

### Method of collection of data *Zanthoxylum rhetsa* (Roxb.) DC in Sirajagranthi. (Varicose vein)

This is a single-blind clinical study involving 200 randomly selected patients, divided into two groups: Group A and Group B, each consisting of 100 patients. "Participants were selected based on inclusion and exclusion criteria (Table 1) from the outpatient and inpatient departments of Government Ayurveda Medical College, Mysore, irrespective of sex, religion, or occupation. Interventions were assigned: "as per Table 2. Clinical assessments included BP, systemic examination, pulse rate, and leg examination for varicosity.

Subjective and objective parameters were recorded on days 0, 7, 14, 28, and 42 (Table 3). Pratyahara (Dietary Recommendations): Included Amalaki, fibrous vegetables, grains, black and blue berries, cherries, carrots, lemons, onions, Brahmi, garlic, ginger, pineapple, eggs, milk, and meat (excluding red meat). Vihara (Lifestyle Recommendations): Included healthy activities such as walking, swimming, and cycling. Alcohol, strong coffee, and daytime sleep were contraindicated. Assessment was conducted based on subjective and objective parameter grading (Table 4).

## OBSERVATION

### Demographic and Clinical Observations

**Sex-wise Distribution:** Female patients were more affected than males, with 54% females and 46% males.

**Age-wise Distribution:** The study observed that all age groups were affected:

**30-40 years:** 35%

**41-50 years:** 33%

**51-65 years:** 31%

**Occupation-wise Distribution:** Individuals engaged in occupations requiring prolonged standing were more affected:

**Business:** 25%

**Labourers:** 22%

**Housemakers:** 21%

**Teachers:** 18%

**Others:** 14%

**Urban vs. Rural Distribution:** Patients were primarily from urban areas:

**Urban:** 56%

**Rural:** 44%

**Digestive Fire (Agni) Pattern:** Most patients had Samagni and Vishamagni types:

**Samagni:** 40%

**Mandagni:** 29%

**Vishamagni:** 31%

**Leg Involvement:** Most patients had bilateral involvement:

**Unilateral:** 55%

**Bilateral:** 45%

### Incidence of Lakshanas (Symptoms) in Groups A and B

**Group A:** Shoola (pain), Shotha (swelling), Kandu (itching), and Tortuosity were observed.

**Group B:** Shotha (swelling), Shoola (pain), Kandu (itching), and Tortuosity were noted.

The subjective and objective parameters are assessed as in Table 5.

## RESULTS

The effect of the drug in Group A showed a significant reduction in severe Shoola (pain), Kandu (itching), and Shotha (swelling), while Tortuosity was moderately reduced. In Group B, Shotha (swelling) and Shoola (pain) were remarkably reduced, whereas Tortuosity showed only mild improvement as depicted in Table 6. The detailed statistical inference of subjective and objective parameters recorded on different days is presented in Table 7 and in image 3 and 4.

## DISCUSSION

Siraja Granthi is a disease associated with Siravaha Srotas, which are responsible for carrying Rakta (blood). Due to excessive exertion or exposure to Vata-prakopaka factors, Vata Dosha increases and invades the Siras (veins), leading to their Vakrikarana (tortuosity). The imbalance of Doshas, Dhatus, and Malas results in pathological conditions, necessitating the use of drugs with specific inherent properties such as Rasa (taste), Guna (qualities), Virya (potency), Vipaka (post-digestive effect), and Prabhava (specific action), collectively known as Panchapadarthas.

The drug action can be explained through Dravya Prabhava (substance effect), Guna Prabhava (property effect), and Dravyaguna Prabhava (combined effect of substance and property). As per Charaka, the pharmacological action of any Dravya (medicinal substance) depends on these properties, influencing its absorption and effects inside the body<sup>11</sup>. The therapeutic constituents within the Dravya interact in a hierarchical manner, with some properties superseding others<sup>12</sup>.

These pharmacodynamic properties help in pacifying Tridosha, maintaining Dhatu and Mala balance, purifying Srotas (Srotoshuddhi), and enhancing Agni (Agnivruddhi), thereby alleviating the pathological condition of Siraja Granthi. The management of Siraja Granthi involves Ushna Virya (hot potency) drugs to subside Vata, while Katu-Tikta Rasa (pungent-bitter taste) and Katu Vipaka (pungent post-digestive effect) reduce localized Kapha and Medas (fat) and purify Rakta.

From a modern pharmacological perspective, the bark of *Zanthoxylum rhetsa* (Roxb.) DC contains alkaloids, terpenes, mineral contents, and secondary metabolites, exhibiting antioxidant and anti-inflammatory properties. These pharmacological effects align with the Samprapti (pathogenesis) and Chikitsa (treatment) flowcharts (Images 2), further supporting its therapeutic potential in Siraja Granthi management.

**Table 1: Inclusion and Exclusion criteria**

<b>Inclusion Criteria</b> 1. Patient age between 30-65yrs 2. Patient suffering from Sirajagranthi (Varicose veins) in lower limbs only selected. 3. Grade 0 to 4 are selected	<b>Exclusion criteria</b> 1. Patients with other systemic disorders, bleeding disorders. 2. Patient indicated for surgery. 3. Pregnant women. 4. Doppler study will be carried out to rule out DVT
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**Table 2: Intervention details**

Group	No. of Patients	Duration	Procedure
Group A	100	14 days	Kashaya of the Bark powder of <i>Zanthoxylum rhetsa</i> (Roxb). DC is given internally in the dose of 25ml BD and fine powder of the of <i>Zanthoxylum rhetsa</i> (Roxb). DC mixed with lemon juice, applied externally and washed with water after two hours
Group B	100	14 days	Bark powder of <i>Zanthoxylum rhetsa</i> (Roxb.) DC mixed with lemon juice, applied externally and washed with water after two hours.

**Table 3: Subjective and Objective parameters**

Subjective parameters	0 day	07 <sup>th</sup> day	14 <sup>th</sup> day	28 <sup>th</sup> day	42 <sup>nd</sup> day
Shoola					
Kandu					
Daha					
Objective parameters					
Shotha					
Tortuosity					
Skin changes					

**Table 4: Grading Criteria for Subjective and Objective Parameters**

Grade		Shoola	Kandu	Daha	Shotha	Tortuosity	Skin changes
0	Absent	no pain	no itch	no burning sensation	no inflammation	no dilated veins	no discoloration
1	Mild	occasional pain after long exertion	occasional itch	occasional burning sensation	occasional inflammation	few veins dilated after exertion	blacking patchy hyper pigmentation
2	Moderate	frequent pain	frequent itch	frequently burning sensation	frequently inflammation	multiple veins confined to calf or thigh	hyper pigmentation with eczema
3	Severe	pain throughout the day	itching throughout the day	throughout the day burning sensation	Permanently inflamed	extensive involving both calf and thighs	hyper pigmentation with eczema and itching sensation

**Table 5: Observation of Subjective and Objective Parameters**

Subjective parameters			Objective parameters		
Shoola	Group A (100)	Group B (102)	Shotha	Group A (100)	Group B (102)
Absent	4%	2%	Absent	5%	1%
Mild	21%	10.8%	Mild	20%	14.7%
Moderate	33%	50%	Moderate	37%	50%
Severe	42%	37.3%	Severe	38%	34.3%
Kandu	Group A (100)	Group B (102)	Tortuosity	Group A (100)	Group B (102)
Absent	38%	42%	Absent	31%	22.5%
Mild	38%	41.2%	Mild	32%	28.4%
Moderate	26%	14.7%	Moderate	31%	42.2%
Severe	1%	2%	Severe	6%	6.9%
Daha	Group A (100)	Group B (102)	Skin changes	Group A (100)	Group B (102)
Absent	53%	47.1%	Absent	48%	38%
Mild	40%	48.0%	Mild	34%	40.02%
Moderate	7%	3.9%	Moderate	15%	13.7%
Severe	0%	1%	Severe	3%	8.8%

**Table 6: Results Summary – Improvement in Clinical Symptoms**

Shoola	Marked improvement
Kandu	Marked improvement
Daha	Marked improvement
Shotha	Moderately improvement
Tortuosity	Mild improvement
Skin changes	Mild improvement

Table 7: Statistical Analysis of Subjective and Objective Parameters

<table border="1"> <thead> <tr> <th>Duration</th> <th>Mean Rank for Group A</th> <th>Mean Rank for Group B</th> </tr> </thead> <tbody> <tr> <td>Shoola day 0</td> <td>4.89</td> <td>4.89</td> </tr> <tr> <td>Shoola day 7</td> <td>3.34</td> <td>3.72</td> </tr> <tr> <td>Shoola day 14</td> <td>2.44</td> <td>2.48</td> </tr> <tr> <td>Shoola day 28</td> <td>2.17</td> <td>1.98</td> </tr> <tr> <td>Shoola day 42</td> <td>2.17</td> <td>1.94</td> </tr> <tr> <td colspan="3">Test statistics</td> </tr> <tr> <td>N</td> <td>100</td> <td>102</td> </tr> <tr> <td>Chi-Square</td> <td>324.904</td> <td>348.475</td> </tr> <tr> <td>Df</td> <td>4</td> <td>4</td> </tr> <tr> <td>P value</td> <td>.001</td> <td>.001</td> </tr> </tbody> </table>	Duration	Mean Rank for Group A	Mean Rank for Group B	Shoola day 0	4.89	4.89	Shoola day 7	3.34	3.72	Shoola day 14	2.44	2.48	Shoola day 28	2.17	1.98	Shoola day 42	2.17	1.94	Test statistics			N	100	102	Chi-Square	324.904	348.475	Df	4	4	P value	.001	.001	
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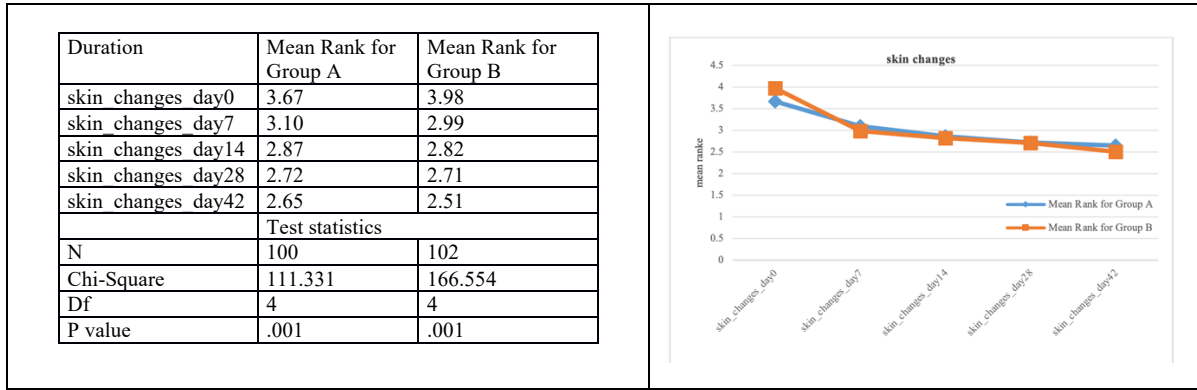


Image 1: *Zanthoxylum rhetsa* (Roxb.) DC bark

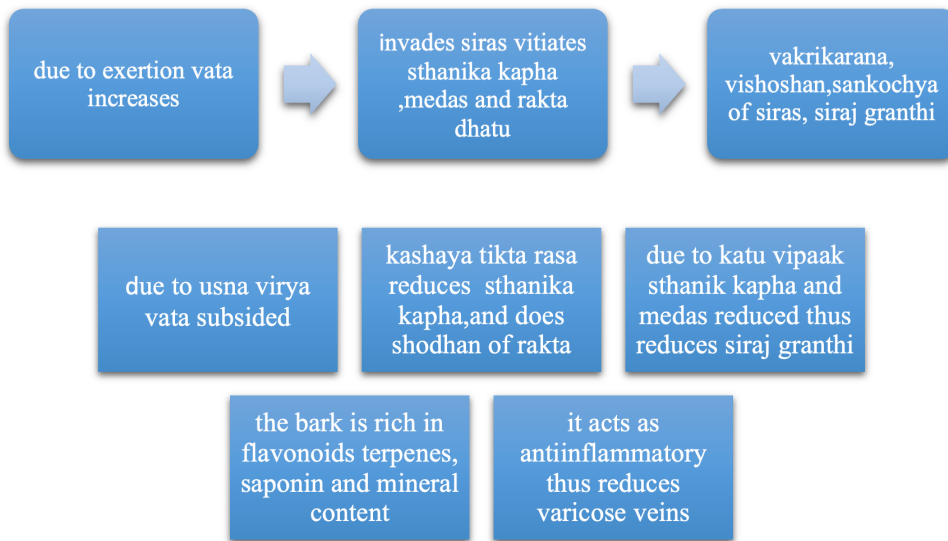


Image 2: Samprapti and Chikitsa



Image 3: Before and After Treatment



Image 4: Before and After Treatment

## CONCLUSION

A total of 202 patients were recruited for the study, with 100 in Group A and 102 in Group B. The assessment of subjective and objective parameters from Day 0 to Day 42 demonstrated a linear decrease in mean ranks, indicating a progressive reduction in symptoms. Shoola (pain), Shotha (swelling), Kandu (itching), and Daha (burning sensation) showed remarkable improvement, while Shotha reduced moderately, and Tortuosity and skin changes exhibited mild improvement. The clinical efficacy of the treatment demonstrated an overall positive impact on Siraja Granthi. The study was assessed using grading methods for subjective and objective parameters, and the results were statistically calculated and analyzed to validate the findings.

## ACKNOWLEDGMENT

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