



### Comparative clinical study of efficacy of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni Ointment* in the management of *Agantuja Vranashotha* with special reference to superficial thrombophlebitis

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#### Abstract:

Superficial thrombophlebitis is inflammation of the vein which is common complication of intravenous administration of drugs as by IV Cannulation. This inflammatory condition arises due to local injury and microbial contamination. Local treatment seems better than systemic drugs and if not treated timely can cause cellulitis and even suppuration. Hence immediate treatment needed which includes topical ointment, Hand Elevation, Use of Antibiotics etc.

*Acharya Sushruta* has mentioned a detail description of inflammatory swelling under the heading of *Vranashotha*. IV Cannulation induced Superficial Thrombophlebitis can be correlated with *Agantuja Vranashotha*. There are many modalities for treating this condition

amongst which *Lepa* is one of the important measures. For this purpose, we had hypothesized a drug, which could reduce local signs and symptoms of *Vranashotha* as mentioned in various *Ayurvedic text*.

In this study we had prepared *Rohni iSiddha Taila* with 3 *Kalka dravya* like *Rohitak*, *Haridra* & *Nirgundi* which was further divided into *Rohni Sikhta Taila* by mixing *Sikhta* (i.e. beewax), *Rohni Sarjarasa Malahara* by mixing *Sarjarasa* (i.e. *Shala Niryasa* resin extract) & *Rohni Ointment* (i.e. with Alcohol extract + Petroleum Jelly). Considering the Initials of the Contents the Name *Rohni* is derived as By *Rohitak+Haridra+Nirgundi*. 15 patients of *Agantuja Vranashotha* i.e. superficial thrombophlebitis for each group were selected and treated with local application of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment*

respectively. It was found that all 3 i.e *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment* are effective in reducing the signs and symptoms of *Vranashotha* with less or more varying degree.

So, it would be concluded that *Rohni ointment* is most suitable to be used in large scale for treatment of *Vranashotha* with special reference to superficial thrombophlebitis.

**Keywords:** *Acharya Sushrut*, *Aagantuja Vranashotha*, superficial thrombophlebitis Inflammation, *Lepa*, *kalkadravya*, *Siddha taila*, *Malahara*.

### Introduction:

Thrombophlebitis ranges from mild local erythema to life threatening cellulitis. Also, Thrombophlebitis is an prominent reason of pyrexia in post-op period so to stop spreading the inflammation in primary condition becomes essential. Though there are several systemic anti-microbial drugs available for management of the problem but these are not sufficient to eradicate and have their own limitations.

In inflammatory swellings, many systemic and local drugs are effective but not much safer due to complications, similarly the local drug also causes unwanted incidences like contact dermatitis, staining, hypersensitivity etc. In *Ayurveda*, inflammatory swellings are well managed medically along with surgical interventions.

*Shalyatrantra* is one of the important eight branches of *Ayurveda* in which surgical and para-surgical Techniques are described for management of various diseases.

*Vranashotha* is the preliminary stage of *Nija vrana*. *Acharya Sushruta* has mentioned detailed description of

inflammatory swelling under heading of *Vranashotha*

*Acharya Sushruta*, father of Indian surgery (*Shalya tantra*) was aware of importance of *Vranashotha* (inflammatory swelling) and *Vrana* (Wound) and their management in surgical practice. The *Vranashotha* was described as earlier phase of *Vrana*.

*Acharya Sushruta* has described seven *upkramas* for the management of *Vranashotha*. In this *Upakrama*, first is *Vimlapan* (softening by kneading with fingers), second *Avasechan* (Bloodletting), third *Upanaha* (warm poultices) fourth *Patana* (Cutting/incision), fifth *Shodhana* (Cleaning), sixth *Ropana* (Healing) and seventh *Vaikrutapaham* (Removing/Warding) off the abnormalities. S.S.Su 17/22-23.

So, keeping these things in mind the drug with the Prefix *Rohni* has been formulated due to presence of its contents namely *Rohitak*, *Haridra* and *Nirgundi*. *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni Ointment* is selected for study which can be effective and combination of common indigenous drugs for local application in *Vranashotha* and as described in various *ayurvedic* texts they possess the properties of *Shophaghana*, *Shothahara* and *Vishaghana* vividly.

### Aim:

Evaluation of efficacy of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni Ointment* in *Agantuja Vranashotha* with special reference to Thrombophlebitis

### Objectives:

1. To evaluate effect of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment* respectively topically in *Vranashotha* with respect to superficial

thrombophlebitis of vein as used twice a day under 5 days treatment.

2. To find and develop a new drug formulation for a common condition arising in patients due to treatment by Intravenous route.
3. To study the management of swelling by application of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni Ointment* respectively in superficial thrombophlebitis .

### Material and Method:

*Ayurveda* provides an effective solution to the problem of curing *Vranashotha* with the use of herbs, use of herbal powder massage and local Application of herbal drugs like *Lepa*

The *Ayurvedic* Manoeuvre suggests that *lepa* is the topical formulation and should be gently rubbed in an upward or reverse direction of the hair over the skin.

The main indication for the use of *Lepa* is mentioned in shashti vrana upkrama (60 steps to treat wound)

The use of this prepared *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment* was done in various swellings like cellulitis, lymphatic swelling, fracture induced swelling etc apart from IV Cannulation induced thrombophlebitis which yielded significant results.

So, it was decided to do comparative clinical study of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment* Classifying into 3 Different groups used in the management of *Agantuja Vranashotha* with special reference to superficial thrombophlebitis.

### Selection of the drug:

The prepared Drug is divided into 3 Different Groups as Group 1- *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment* is the medicine formulated by the Rasashashtra Department of Ayurvedic College and Arogyashala Rugnalaya which is then distributed for the use by Shalyatantra Department

*Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment* is a herbal preparation made by using *Rohni Siddha Taila*. In this study we had prepared *Rohni Siddha Taila* with 3 *Kalka dravya* like *Rohitak*, *Haridra* & *Nirgundi* which was further divided into Group1- *Rohni Sikhta Taila* by mixing *Sikhta* (i.e beewax), Group 2- *Rohni Sarjarasa Malahara* by mixing *Sarjarasa*(i.e *Shala niryasa* i.e resin extract) & Group 3 - *Rohni Ointment* (i.e with Alcohol extract + Petroleum Jelly)

These drugs and their properties with useful part are given in Table no. 1

**Table: 1 Contents of *Rohni Sikhta Taila* and their Properties**

<i>Plant</i>	<i>Rasa (Taste)</i>	<i>Guna (Physical properties)</i>	<i>Virya (Potency)</i>	<i>Dosh karma (Effect on doshas)</i>	<i>Useful part</i>
<b>1. Rohitak</b> ( <i>Tecoma undulata</i> )	<i>Katu Tikta Kashaya</i>	<i>Laghu Ruksha</i>	<i>Sheeta</i>	Vranaropaka Raktashodhaka Vishaghna	Twaka ( <i>Tecomin</i> )
<b>2. Haridra</b>	<i>Katu</i>	Laghu	<i>Ushna</i>	<i>Kapha-</i>	Rhizome

( <i>Curcuma longa</i> .)	<i>Tikta</i>	Ruksha		<i>Vatashamak, Pittarechak, shothahara, Varnya.</i>	
<b>3. Nirgundi</b> ( <i>Vitex Negundo</i> )	<i>Katu Tikta</i>	Laghu Ruksha	<i>Ushna</i>	<i>shothahara, vrana Shodhana, vrana Ropan, vedana sthapana, Kusthaghana, Kandughna</i>	Leaves, roots, seeds
<b>4. Til taila:</b>	which is <i>sushkma, vyavayi</i> and <i>Tikshna</i>				
<b>5. Sikhta</b>	i.e. Honeybee wax				

*Rohni siddha taila* is made with the help of 3 *kalkadravya* namely *Rohitak Haridra* & *Nirgundi* 50 gms. each. By the *Taila Kalpana* procedure adding 75 gms of *Sikhta* to it.

**Table: 2 Contents of Rohni Sarjarasa Malahara and their Properties**

(Content of this table remains same as of table 1)

*Rohni Siddha Taila* 300 ml, *Sarjarasa* i.e. Resin extract of 75gms *Shaal* and *dravdravya* i.e. *Jala/Nirgundi Kwatha*.

**Table: 3 Contents of Rohni ointment and their Properties**

Above 3 each 50 gms processed with Alcohol Extraction method in Soxhlet apparatus mixed with petroleum jelly.

**Method of Study**

**1. Selection of the patient**

All patients of *Vranashotha* with special reference to superficial thrombophlebitis were registered from OPD/IPD of the Department of *Shalya Tantra*.

**Criteria for selection of patient:**

**1. Inclusive criteria –**

- Patients diagnosed with superficial thrombophlebitis as soon as occurred at upper and lower limb. With sign and symptoms as pain, tenderness, oedema, erythema, local temperature.
- Patient's subject willing to participate in the project.
- Patients of age group 20-60 years of both sexes.

**2. Exclusive criteria-**

- HBsAg, HIV positive patients.
- Pregnancy
- Patients with uncontrolled Diabetes mellitus, CKD and Malignancy

**Assessment criteria:**

**A. Subjective criteria -**

- Criteria as erythema, oedema, temperature, indurations, and tenderness were assessed by different grading system in the patients *Vranashotha*.
- Mild, moderate, and severe grading were

done according to standard protocol.

#### B. Generalised criteria –

- As general condition pulse rate, Blood pressure, Respiratory rate, Pain and fever were assessed. For all these symptoms following grades were applied.

#### C. Objective Criteria

##### 1. Oedema

Clinical observation	Score	Grads
Absence of clinical oedema	0	0
Slight pitting	1	+
Deeper pitting	2	++
Deeper pitting with visible dependent swelling taking seconds to vanish	3	+++

##### 2. Pain VAS (Visual Analogue Scale) is applied.

Clinical observation	Score	Grads
No pain	0	0
Mild pain aggravates with movement	1	+
Moderate Pain	2	++
Severe Pain	3	+++
Severe pain with Radiation and Sleep disturbances	4	+++ +

##### 3. Erythema

Clinical observation	Score	Grades
No evidence of erythema present	0	0
Slight pinkish	1	+

colouration		
Definite redness locally	2	++
Gross Discoloration with Intense itching	3	+++

#### 4. Tenderness

Clinical observation	Score	Grades
Absent	0	0
Mild pain (tolerable)	1	+
Moderate pain but patient is in visible agony	2	++
Severe pain with crying and wincing when the arm is drawn	3	+++
Touch at the site unbearable	4	+++ +

#### Method of application of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment*:

##### 1) *Purvakarma*-

- Written informed consent of patient was taken.
- Procedure site clean with a Tap-water.

##### 2) *Pradhan Karma*-

- Patient was asked to lie in comfortable position and disease area was properly exposed.
- A pre photograph was taken after permitting the patient in different view.
- Required amount of prepared *lepa* was taken
- *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni ointment*

respectively applied to whole affected area in the opposite direction of hairs.

- Wound of Venepuncture (If present) was spared from paste application.

### 3) *Paschat karma*-

- The time depends upon drying of *lepa*

### Study Design:

Comparative clinical trial with simple random sampling. Also, with Nonbiased open label blinding.

### Duration of Study:

5 Days (To be applied twice a day) from the occurrence of Superficial thrombophlebitis.

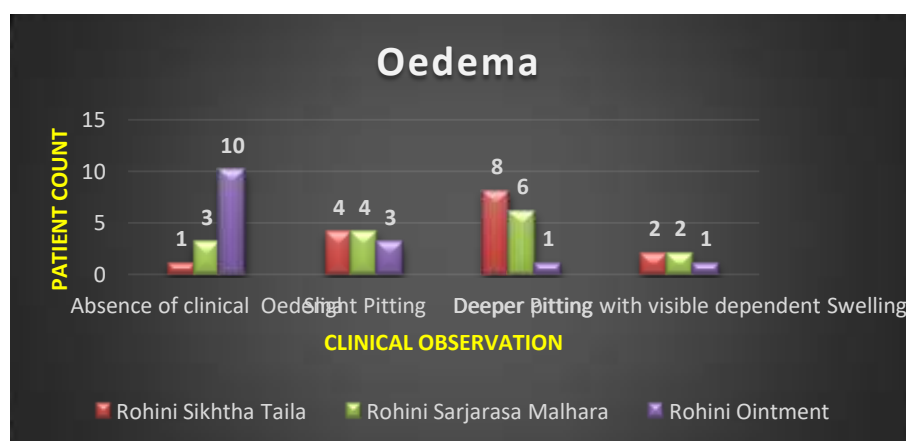
### Observation and result:

This study was done on 15 patients of each group from *Shalya Tantra* department and the observation are as follows.

## 1. Oedema

Clinical observation		Score	Grade
Absence of clinical		0	0
Oedema		0	0
Slight Pitting		1	+
Deeper Pitting		2	++
Deeper pitting with visible dependent Swelling taking few seconds to vanish		3	+++
Oedema	Group 1 <i>Rohini Sikhtha Taila</i>	Group 2 <i>Rohini Sarjarasa Malahara</i>	Group 3 <i>Rohini Ointment</i>
0	1	3	10
1	4	4	3
2	8	6	1
3	2	2	1
TOTAL	15	15	15

The Chi Square statistics is 15.35. The p-value is 0.01768. The result is significant at  $P < 0.05$ . Hence Group 3 i.e. *Rohini ointment* was effective in reducing oedema as compared to Group 1 and Group 2.

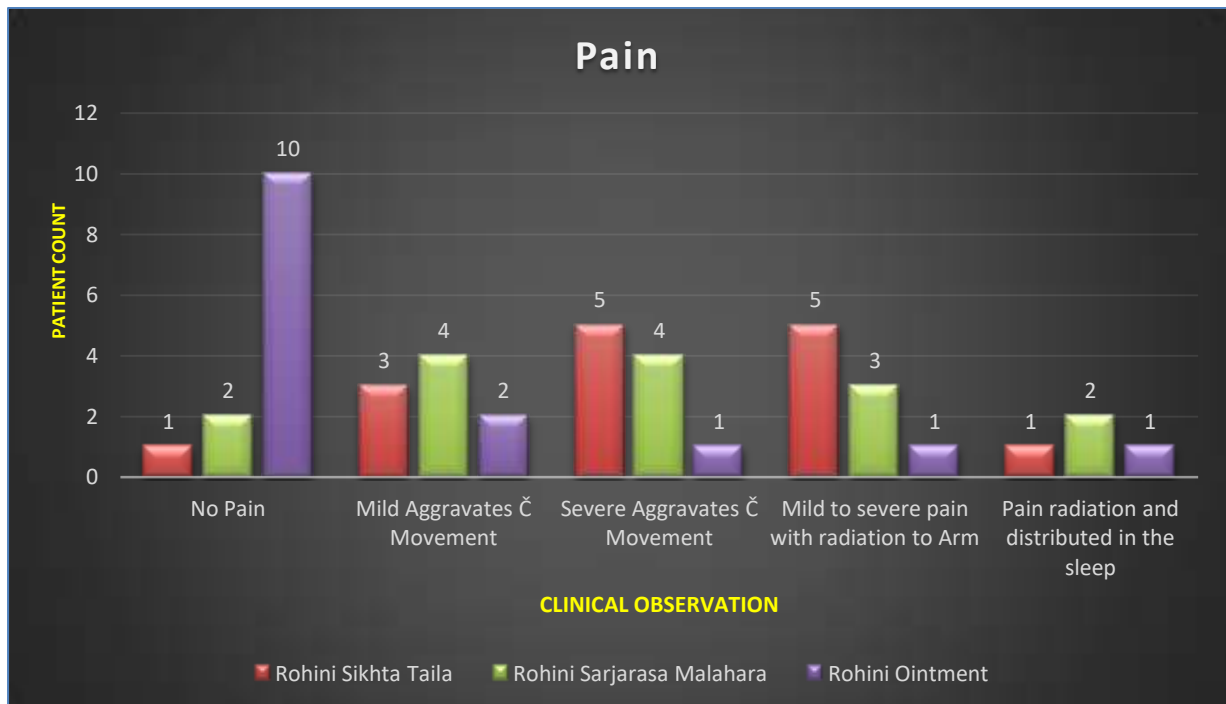


## 2. Pain- Vas Scale is applied

Clinical observation	Score	Grade
No Pain	0	0
Mild Pain	1	+
Moderate Pain	2	++
Severe pain	3	+++
Severe Pain with radiation and sleep disturbances	4	++++

Pain	Group 1	Group 2	Group 3
	<i>Rohini Sikhta Taila</i>	<i>Rohini Sarjarasa Malahara</i>	<i>Rohini Ointment</i>
0	1	2	10
1	3	4	2
2	5	4	1
3	5	3	1
4	1	2	1
TOTAL	15	15	15

qThe Chi Square statistics is 17.66. The p-value is 0.0238. The result is significant at  $P < 0.05$ . Hence Group 3 i.e *Rohini ointment* was effective in reducing pain as compared to Group 1 and Group 2.



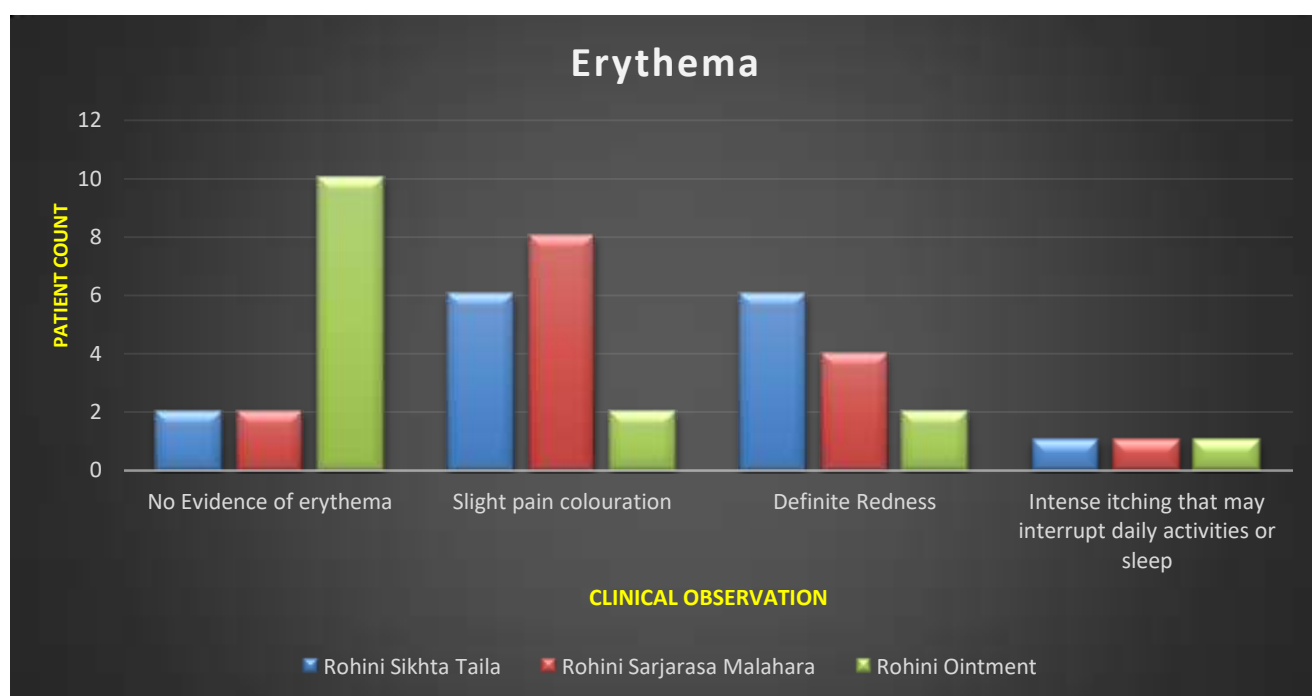


### 3. Erythema

Clinical observation	Score	Grade
No Evidence of erythema	0	0
Slight pinkish colouration	1	+
Definite Redness locally	2	++
Gross discoloration with Intense itching	3	+++

Erythema	Group 1	Group 2	Group 3
	<i>Rohini Sikhta Taila</i>	<i>Rohini Sarjarasa Malahara</i>	<i>Rohini Ointment</i>
0	2	2	10
1	6	8	2
2	6	4	2
3	1	1	1
TOTAL	15	15	15

The Chi Square statistics is 14.64. The p-value is 0.023. The result is significant at  $P < 0.05$ . Hence Group 3 i.e *Rohini ointment* was effective in reducing Erythema as compared to Group 1 and Group 2.



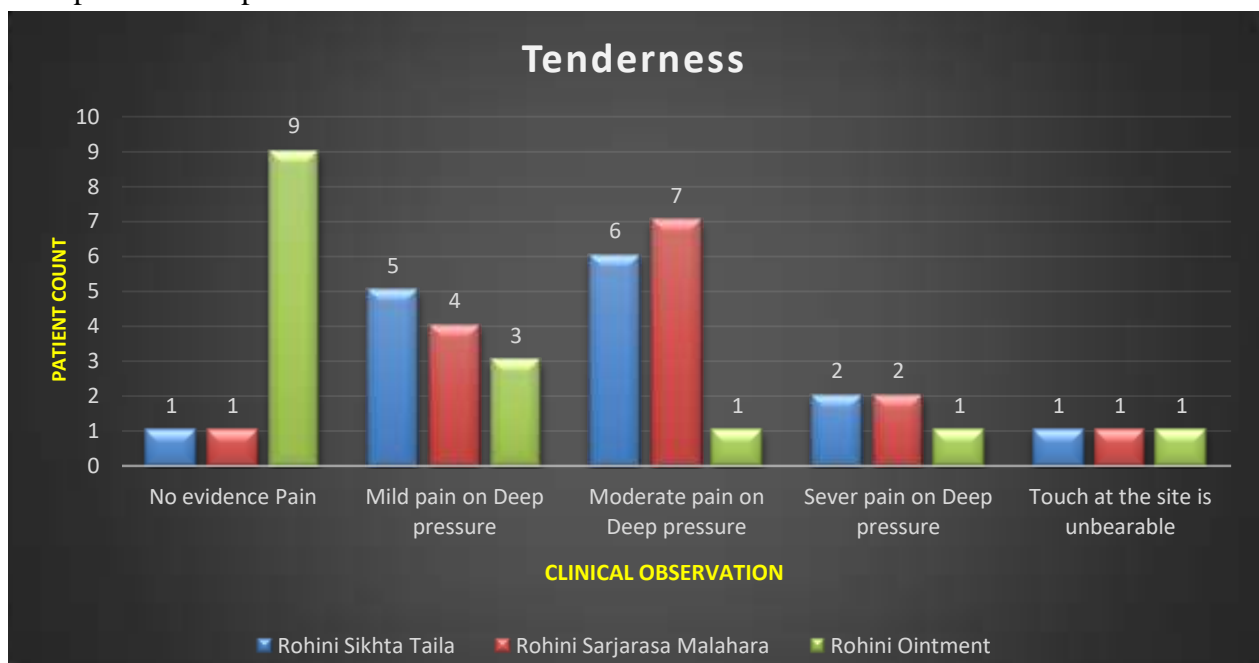


#### 4. Tenderness

Clinical observation	Score	Grade
Absent	0	0
Mild pain (tolerable)	1	+
Moderate tolerable pain but patient is in agony	2	++
Sever pain with crying and wincing when arm is drawn	3	+++
Touch at the site is unbearable	4	++++

Tenderness	Group 1	Group 2	Group 3
	<i>Rohini Sikhta Taila</i>	<i>Rohini Sarjarasa Malahara</i>	<i>Rohini Ointment</i>
0	1	1	9
1	5	4	3
2	6	7	1
3	2	2	1
4	1	1	1
TOTAL	15	15	15



The Chi Square statistics is 16.96. The p-value is 0.0304. The result is significant at  $P < 0.05$ . Hence Group 3 i.e *Rohini ointment* was effective in reducing Tenderness as compared to Group 1 and Group 2.



- From the table no.1 to table no: 4 there is significant improvement is observed in all the parameters like Oedema, Pain, Erythema and Tenderness in all the patients. The prominent relief on symptoms has been observed

**Fig: 1 Total relief in sign and symptoms of *Vranashotha* during treatment.**

	
<p><i>Preparation of Rohni Sarjarasa Malahara.</i></p>	<p><i>Preparation of Rohni Sikhta Taila</i></p>
	
<p><i>Preparation of Rohni Ointment</i></p>	<p><i>Final product i.e. Rohni Sikhta Taila, Rohni Sarjarasa Malahara &amp; Rohni ointment respectively</i></p>
	
<p><i>Before Treatment (prior to procedure)</i></p>	

	
<p><i>Intra procedure</i></p>	<p><i>After procedure (End Procedure)</i></p>

## Discussion:

### 1. PAIN AND TENDERNESS-

The present study revealed that the *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni* Ointment is effective and highly significant in terms of pain. It might be due to decrease in prostaglandin levels. This clearly shows this drug contain analgesic properties functioning as *Vednasthapaka* due to presence of *Vatashamaka* *Nirgundi* posses this Property as *Hanti Shula* *Shotha* *Aama* *Marutan* (*Bhavprakash*)

*Haridra* contains turmerons, curcumin and curcuminoids. *Shunthi* chemical constituents like ginerols, shogoals and zingerons. Hence both these drugs and their chemical constituents are potent anti- inflammatory and antioxidant.

### 2. OEDEMA-

The Inflammatory oedema is reduced which is probably due to *dhatushoshak* (Absorptive) effect of *kashaya* and *tikta rasa* and also *Kledashoshaka* (astringent) effect of *Haridra*. The *laghu Ruksha Guna* of *Haridra* also helps for the same. Other content in the drug especially

*Nirgungi* alleviates vitiated kapha to reduce the oedema working as *Shothahara* (*sindhu shotham varyati Iti Sindhuvara- bhavprakash*)

### 3. ERYTHEMA-

Erythema in inflammatory process due to increase blood supply over injured area due to vasodilatation. The prepared drug formulation is found to reduce erythema (redness) also does the work of *Raktaprasadana* especially by *Haridra* and *Rohitak* (*Bhavprakash* and *Dhanvantari Nighantu*)

In present study prepared 3 groups of drugs has been effective in terms of reduction in erythema (Redness). This might *pittashamaka* & *Pittarechaka* effect of the *Haridra* acting as cooling agent and astringent.

The *kashaya*, *Tikta rasa* and *sheeta virya* of the contents in this drug formulation have capability to constrict blood vessels, hence it reduces erythema.

### 4. OTHER BENEFITS-

It has remarkable action on skin acting as *Varnya* (skin illuminator) and also *Vranashodhak* & *Vranaropaka*. *Nirgundi* has prominent effect on all kinds of

*Vrana* so called as *Sarvavraneshujita* (*ChakraDutta*) *Haridra* called as *Twakdosahara* Healing all the ailments of skin *Taila* used for *Rohni Siddha taila* having *shukshma guna* makes the deep penetration into tissues possible giving high efficacy. Also, the *Shala nirayasa* used for *Rohni Sarjarasa Malahara* gives a base to the preparation by enhancing binding effect making it patient use friendly and handy for application. Most of the patient showed significant relief and found to be free from toxic effect of disease within 5 days of the application of the prepared drug formulation.

#### Conclusion:

This formulation of 3 different groups reduces all cardinal features of *vrnashotha* with special reference to superficial thrombophlebitis. Thus, it can be proven as potent anti-inflammatory medicine. No adverse reaction was found after topical application

In This case series total 45 patients, each group 15 were enrolled and all the selected patients showed significant improvement in thrombophlebitis within 5 days like in Oedema, Erythema, Pain and Tenderness but to be concluding amongst the 3 groups namely *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni* Ointment the group 3 i.e the *Rohni* Ointment is most effective as compared to other 2 groups. The same contents when processed with alcohol extraction method and mixed with petroleum jelly resulted in Ointment having highest significance

The constituents of *Rohni Sikhta Taila*, *Rohni Sarjarasa Malahara* & *Rohni* Ointment are easily available without much efforts, relatively cheap and with no obvious adverse effects making it certainly

more desirable than the conventional ointments in use.

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