



Research Article

**EFFECTIVENESS OF PANCHAVALKALA PRALEPA AND JALAUKAVACHARANA IN REDUCING DURATION FOR REGRESSION OF VRANASHOPHA W.S.R. TO CELLULITIS: A RANDOMIZED CONTROLLED TRIAL**

Jaybhaye.Geeta<sup>1\*</sup>, Badwe. Yogesh<sup>2</sup>

\*<sup>1</sup>PG Scholar, <sup>2</sup>Professor and HOD, Department of Shalyatantra, Shri Ayurved Mahavidyalaya, Nagpur, Maharashtra India.

<p><b>Article info</b></p>	<p><b>ABSTRACT</b></p>
<p><b>Article History:</b> Received: 21-11-2021 Revised: 10-12-2021 Accepted: 29-12-2021</p>	<p><i>Acharya Sushruta</i> was well aware about importance of <i>Vranashopha</i> (stages of abscess formation), <i>Vrana</i> (wound) and their management in surgical practice, along with its unfavourable and untreated complications. The <i>Vranashopha</i> is described as earlier phase of <i>Vrana</i>. <i>Sushruta</i> has mentioned detail description of inflammatory swelling under the heading of <i>Vranashopha</i>. Among the all-available treatment modalities for <i>Vranashopha</i> (Cellulitis), the <i>Jalaukavacharana</i> and <i>Jalaukavacharana</i> with <i>Panchavalkala Pralepa</i> is found to be more effective by considering its feasibility, adoptability, cost-effectiveness and curative results. <i>Sushruta</i> has mentioned <i>Lepa</i> for local application in the treatment of <i>Vranashopha</i>. <b>Methodology:</b> In this present study, <i>Jalaukavacharana</i>, which is one of the proven therapy for treatment of <i>Vranashopha</i> was compared with easily available drug <i>Jalaukavacharana</i> with <i>Panchavalkala Pralepa</i>, by its local application directly on <i>Vranashopha</i>, to find out its effectiveness. A total 70 patients were randomly selected and divided in two groups. <i>Jalaukavacharana</i> and <i>Jalaukavacharana</i> with <i>Panchavalkala Pralepa</i> was done in group A and group B respectively for once for 5 days and observations are noted on 1<sup>st</sup>, 3<sup>rd</sup>, 5<sup>th</sup>, 10<sup>th</sup> and 15<sup>th</sup> day and the result was assessed thoroughly on the basis of observation according to the specially designed proforma. <b>Result:</b> <i>Jalaukavacharana</i> with <i>Panchavalkala Pralepa</i> was found to be more effective in all the four criteria, low cost therapy and easily available throughout the year. <b>Conclusion:</b> it was concluded that <i>Jalaukavacharana</i> with <i>Panchavalkala Pralepa</i> shown significant improvement in reducing pain, swelling, redness, local temperature and healing of wound at affected site without any side effect. Hence, it can be concluded that this <i>Pralepa</i> is useful in the treatment of <i>Vranashopha</i> (Cellulitis).</p>
<p><b>KEYWORDS:</b> <i>Vranashopha</i>, Cellulitis, Inflammation, <i>Jalaukavacharana</i>, Leech.</p>	

**INTRODUCTION**

*Vranashopha* and *Vrana* have been a topic of interest for the surgeons since ancient times. *Vranashopha* is the most encountered condition in *Shalyatantra* which has to be treated as early as possible to avoid further surgical intervention and complications. *Vranashopha* is the preliminary stage of *Nija Vrana* which is one of the most potential and attention seeking clinical condition in daily life.

*Sthanika Shopha* is termed as *Vranashopha* which occupies a significant place in surgical practices<sup>[1]</sup>. *Vranashopha* is characterized by *Ekdeshiya Shotha*, *Twakvivarnata*, *Osha*, *Chosha*, *Paridaha* like *Vedana*<sup>[2]</sup>. There are three stages of any type of *Vranashopha* as *Amavastha*, *Pachyamanavastha* and *Pakwavastha*<sup>[3]</sup>, which has mainly six types. The six types are as *Vataja*, *Pittaja*, *Kaphaja*, *Sannipatika*, *Raktaja* and *Agantuja Vranashopha*<sup>[4]</sup>. Sign and symptoms of *Vranashopha* are more or less similar to cellulitis<sup>[5]</sup>. Cellulitis is spreading type of inflammation of subcutaneous tissue generally associated with bacterial infection. The skin findings in cellulitis follow the classic signs of inflammation: *dolor* (pain), *calor* (heat), *rubor* (erythema) and *tumor* (swelling)<sup>[6]</sup>. The basic principle of *Vranashopha* management is to prevent onset of *Pakwavastha*<sup>[7]</sup>. For early recovery of

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*Vranashopha*, *Sushruta* has mentioned, stage wise treatment (*Upakarma*). In these *Upakramas*, primary eleven are described for *Vranashopha*<sup>[8]</sup>. The *Upakramas* like *Pralepa* and *Vistravana* are used commonly in *Ama* and *Pachyamana Awastha* among these treatment modalities<sup>[9]</sup>.

*Jalaukavacharana* is an ancient method mentioned in *Ayurveda* used for purification of the body by removing deeply seated toxins in the blood and pacifying vitiated *Doshas*<sup>[10]</sup>. It is indicated in acute condition to relieve pain and to prevent *Paka*<sup>[11]</sup>. Leech application i.e., Hirudotherapy bears anti-inflammatory pharmacokinetics due to enzymes like *Bdellins* and *Eglins* in the saliva. So, it can be used in the treatment of *Vranashopha*<sup>[10]</sup>. *Sushruta* has explained *Pralepa* with numerous herbal drugs as *Pradhanatama* treatment of *Vranashopha*<sup>[12]</sup>. One of them is, *Panchavalkala* bear *Kashayarasa* and has *Prakshalana*, *Shothahar*, *Vranaropana* and *Twakprasadana* properties. It also possesses antibacterial property as well as anti-inflammatory effect<sup>[13]</sup>. *Sushruta* praised *Lepa* as it relieves pain as blazing house is readily extinguished by means of showering<sup>[14]</sup>. Above said properties of *Panchavalkala* can subside the *Vranashopha*. *Chakradatta* has also mentioned *Panchavalkala Pralepa* in the management of *Vranashopha*<sup>[15]</sup>.

**Need of Study:** Cellulitis has been treated with antibiotic, analgesics and anti-inflammatory drug along with glycerin and magnesium sulphate dressing due to its hygroscopic property. Although using antibiotics and hygroscopic dressings the oedema and pain takes longer time to resolve cellulitis<sup>[10]</sup>. Application of *Panchavalkala Pralepa* rather than Glycerin-Magsulf dressing will be more beneficial to resolve inflammation in case of cellulitis as per the properties of *Panchavalkala*. *Jalaukavacharana* is an established therapy in treatment of *Vranashopha*. The anti-inflammatory effect of leech therapy was published in various articles same is in the case of *Panchavalkala*. It is observed that *Jalaukavacharana* and different *Pralepa* when used individually, it takes much time to resolve the inflammation. It is hypothetically assumed that by using both therapies

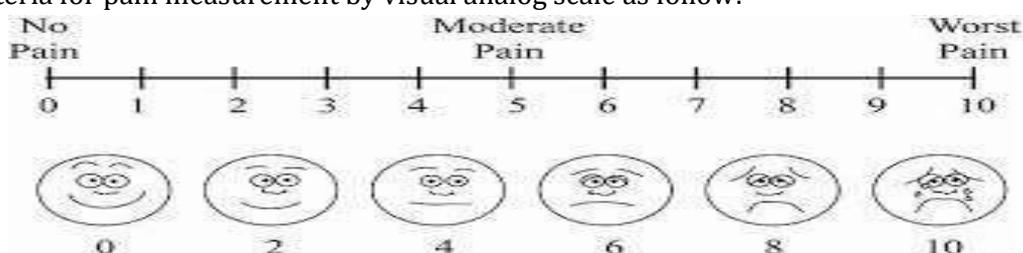
#### Assessment Criteria

##### Subjective Criteria

##### Vedana/Pain

##### Assessment criteria for pain by VAS

Assessment criteria for pain measurement by visual analog scale as follow:



i.e., *Jalaukavacharana* and *Panchavalkala Pralepa*, the time period required for recovery of the patient of cellulitis from the stage of inflammation will be lesser as compared to individual therapies. These results will be much more beneficial to the patient fraternity for early recovery from this grave condition. So, to overcome this disadvantage, comparative effect of *Jalaukavacharana* and *Jalaukavacharana* with *Panchavalkala Pralepa* along with antibiotics coverage for the treatment of *Vranashopha* is selected.

#### MATERIALS AND METHODS

##### Inclusion Criteria

1. Diagnosed case of *Amavastha* and *Pachyamanaavastha* of *Vranashopha*
2. Patient of age group between 18 - 70 years
3. Patient fit for *Raktamokshana*
4. Cellulitis due to varicosity

##### Exclusion Criteria

1. *Pakwavastha* of *Vranashopha*
2. Uncontrolled systemic diseases such as HTN, DM etc.
3. Immuno-compromised patients
4. Severe anemia
5. Septicemia
6. Morbid obesity

**Routine Investigations:** CBC, BSL-F and PP, S. Creatinine, B. Urea, Urine- Routine and Microscopic, BT, CT, HIV, HBsAg.

The study was also registered in Clinical Trial Register of India.

After institutional ethics committee clearance on-15/03/2019. This study was registered in the Clinical Trial Registry-India (CTRI) with CTRI NO. CTRI/2019/06/026421.

For this study 70 patients were selected and randomly divided by simple randomization in Group A- *Jalaukavacharana* with antibiotic Co-amoxycylav, anti-inflammatory drug and dry dressing for 5 days and Group B- *Jalaukavacharana* with *Panchavalkala Pralepa* along with the treatment protocol of Group A after thorough clinical examination. So, 35 patients were allocated in each group. And observations were taken on 1<sup>st</sup>, 3<sup>rd</sup>, 5<sup>th</sup>, 10<sup>th</sup> and 15<sup>th</sup> day upto 15<sup>th</sup> day.

**Table 1: Assessment criteria for Pain**

Sr. No.	Assessment Parameters	Rating Pain Level	Rating	Grade
1	Pain (as per Vas scale)	No Pain	0	0
		Mild Pain	1-3	I
		Moderate Pain	4-6	II
		Severe Pain	7-10	III

**Objective Criteria**

1. *Utsedh*/ Swelling
2. *Sthanik Ushma*/ Local temperature
3. *Twak Vivarnata* / Redness

***Utsedh*/Swelling****Assessment criteria of *Utsedh*/Swelling**

*Utsedh* measured in centimeter by scale or measuring tape before and after treatment.

**Assessment criteria for *Sthanik Ushma*/Local temperature**

Local temperature will be measured by infra-red thermometer

**Assessment Criteria for Redness****Table 2: Assessment criteria for Redness**

Sr.no	Criteria	Reduction in percentage	Grade
1.	Redness	No redness	0
		Redness upto 25 %	1
		Redness upto 26-50 %	2
		Redness upto 51-75%	3
		Redness upto 76-100%	4

**Overall Assessment Criteria:** Criteria of assessment was based on improvement in subjective and objective parameters after the treatment. The results were categorized as,

Complete relief -- 75% and above

Moderate relief -- 50% to 74% improvement

Mild relief -- 25 to 49% improvement

No relief -- Below 24% improvement

**METHODS**

Fresh leeches, storage pot, purification trays, turmeric powder, rice, *Saindhava* salt, sterile needle, dressing materials.

1. *Jalauka* (Leech and Leech lab)
2. *Haridra Churna*
3. Sterilized Gauze pieces, dressing pad, cotton, gloves
4. Kidney tray, distilled water, needle
5. Container of sterile water, for placing leeches after they have been fed. These are the basic requirements for leech therapy

**Methodology of Jalaukavacharana (Leech Therapy)<sup>[16]</sup>: As Described by Sushrut acharya**

**A) Purva karma-** 2-3 *Jalaukas* (according to size of *Vranashopha*) of moderate size was first prepared for *Raktamokshana* by keeping it in *Haridra Jala*. Affected site cleaned by distilled water prior to leech therapy and then by dry gauze.

**B) Pradhana karma** - After wearing the latex gloves prepared active leeches were kept over the *Vranashopha* and its periphery. If needed, *Vranashopha* were punctured with sterilized needle and when blood oozes the leeches were kept on it.<sup>[17]</sup> When leech started to suck blood by itself, then wet cotton pad was placed over it. The process of blood sucking was confirmed by the peristalsis movements on the body of the leeches. When the leech completes blood sucking it detached itself from the bite site.

**C) Paschat karma-** *Haridra Churna* was applied over the bite lesions and pressure dressing done. *Haridra Churna* was sprinkled over the leech's anterior sucker (mouth) for inducing vomiting. After expelling all the blood from its gut, the leech became active again and was stored in fresh water container.

### **Methodology of Panchavalkala Pralepa**

#### **1) Purvakarma: Preparation of Panchavalkala Pralepa**

1. For each patient, the *Pralepa* will be made freshly.
2. Fine powder of *Panchavalkala* will be taken as per the requirement in bowl.
3. Warm *Go-ghrta* and distilled water will be added in *Panchavalkala* as per requirement and mixed well, fine paste for *Pralepa* will be made.

#### **2) Pradhankarma:**

1. The *Panchavalkala pralepa* will be applied locally on the *Vranashopha* once in a day in the morning. After *Jalaukavacharana* by avoiding the site of bite.
2. *Pralepa* of width approximately skinned skin of buffalo was applied against the direction of *Romakupa* i.e., *Pratilomagati*.

#### **3) Pashchatkarma**

1. *Panchavalkala Pralepa* will be removed when it will become dry with the help of cotton ball soaked in Luke warm water.

## **RESULTS**

### **Discussion on Effect of Therapy for Group A**

**Pain:** The initial mean score of pain observed was 5.60, which come down to 0.97 at 5<sup>th</sup> day and 0.20 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 1.22 which comes down to 1.12 at 5<sup>th</sup> day and 0.28 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 64.73% and up to 15<sup>th</sup> day it was 97.58% that means significant relief in pain.

**Redness-** The initial mean score of redness observed was 3.00 which come down to 0.11 at 5<sup>th</sup> day and 0.03 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 0.00 which comes down to 0.32 at 5<sup>th</sup> day and 0.00 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 96.19% and up to 15<sup>th</sup> day it was 99.00% that means significant relief in redness.

**Swelling-** The initial mean score of swelling observed was 28.39 which come down to 27.01 at 5<sup>th</sup> day and 25.60 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 3.90 which comes down to 3.72 at 5<sup>th</sup> day and 5.71 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 4.84% and up to 15<sup>th</sup> day it was 9.81% that means significant relief in swelling.

**Local Temperature-** The initial mean score of local temperature observed was 99.69 which come down to 98.04 at 5<sup>th</sup> day and 97.51 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 0.58 which comes down to 0.22 at 5<sup>th</sup> day and 0.44 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 1.65% and up to 15<sup>th</sup> day it was 2.19% that means significant relief in local temperature.

### **Discussion on Effect of therapy for Group B**

**Pain:** The initial mean score of pain observed was 5.91 which come down to 2.09 at 5<sup>th</sup> day and 0.14 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 0.74 which comes down to 1.12 at 5<sup>th</sup> day and 0.36 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 64.73% and up to 15<sup>th</sup> day it was 97.58% that means significant relief in pain.

**Redness-** The initial mean score of redness observed was 3.00 which come down to 0.46 at 5<sup>th</sup> day and 0.00 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 0.00 which comes down to 0.51 at 5<sup>th</sup> day and 0.00 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 84.76% and up to 15<sup>th</sup> day it was 100% that means significant relief in redness.

**Swelling-** The initial mean score of swelling observed was 27.74 which come down to 26.37 at 5<sup>th</sup> day and 24.93 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 5.71 which comes down to 5.72 at 5<sup>th</sup> day and 5.73 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 4.94% and up to 15<sup>th</sup> day it was 4.94% that means significant relief in swelling.

**Local Temperature-** The initial mean score of local temperature observed was 99.83 which come down to 98.21 at 5<sup>th</sup> day and 97.52 mean at 15<sup>th</sup> day of treatment. At initial standard deviation was 0.50 which comes down to 0.27 at 5<sup>th</sup> day and 0.37 at 15<sup>th</sup> day. Change in effect from baseline up to 5<sup>th</sup> day was 1.63% and up to 15<sup>th</sup> day it was 2.32% that means significant relief in local temperature.

**Table 3: Comparison of change in all parameter of two groups**

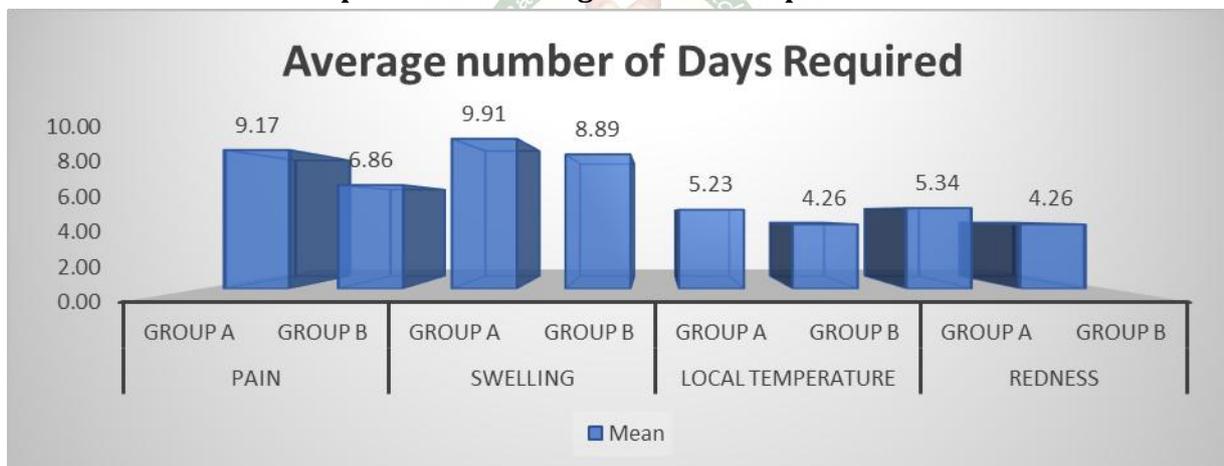
Days Required	Group	N	Mean	SD	SE	Z- Value	P-Value
Pain	Group A	35	9.17	2.86	0.48	- 3.163	0.002338
	Group B	35	6.86	3.25	0.55		
Swelling	Group A	35	11.89	2.52	0.43	- 2.440	0.017278
	Group B	35	7.50	2.51	0.42		
Local Temperature	Group A	35	7.80	0.94	0.16	- 4.227	0.000072
	Group B	35	4.26	0.98	0.17		
Redness	Group A	35	7.20	0.97	0.16	- 4.661	0.000015
	Group B	35	4.26	0.98	0.17		

We have used Z-test for comparison between Group A and Group B. From above table we can observe that P-Value is less than 0.05. Hence we can conclude that, there is significant difference between Group A and Group B. Further we can observe that, mean value of number of days required for Group B is less than Group A. Hence we can conclude that, effect observed in Group B is better than Group A.

**Table 4: Average number of days required in both group**

Group	Average No of Days Required
Group A	9.02
Group B	5.72

**Graph no.1: Percentage of relief in 4 parameters.**



**Images of Patients**

**1) Control group (group A): Jalaukavacharana**



**Before**

**During**

**After**

**2) Trial group (Group B): Jalaukavacharana with Panchavalkala Pralepa**



**Discussion on Comparison of Result in Both Groups**

In this study *Jalaukavacharana* was compared with *Jalaukavacharana with Panchavalkala Pralepa* as it is abundantly and easily available treatment for *Vranashopha*. There is no need to state that modern medical treatment has its own limitation in managing this type of disease. This suggests special need of an Ayurvedic management for this type of conditions. As the number of patients suffering from this disease are increasing day by day. Ayurvedic physician should also make effort continuously to find out effective remedy for the patients of *Vranashopha* from Ayurvedic classics. To achieve good results and early reduction in signs and symptoms of *Vranashopha*, *Acharya Sushruta* has explained *Shashti Upakramas* (sixty types of treatment procedures) in *Dwivraniya Adhyaya* of *Chikitsasthana* for comprehensive management of *Vrana* out of them first eleven (*Apatarpana* to *Virechana*) is described for treatment of *Vranashopha*. *Acharya Sushruta* also mentioned *Shodhana* by *Raktamokshana* (bloodletting) in acute inflammatory conditions, indurate, cyanosed, painful swellings and many inflammatory conditions like *Vidhradhi*, *Granthi*, *Arbuda* etc. It contains various bioactive constituent which possesses anti-inflammatory, analgesic, thrombolytic, antioxidant, vasodilator, anti-coagulant and blood circulation enhancing properties and advised *Jalaukavacharana* (Leech therapy) in *Vranashopha* (Cellulitis)<sup>[18]</sup>.

*Sushruta* has explained *Pralepa* with numerous herbal drugs as *Pradhantama* treatment of *Vranashopha*<sup>[19]</sup>. *Panchavalkala* have bark of 5 *dravyas* i.e., *Ashwattha*, *Vat*, *Udumbar*, *Plaksha* and *Parisha* has *Kashayarasa* and *Prakshalana*, *Shothahara*, *Vranaropana* and *Twakprasadana* properties. It also possesses antibacterial property as well as anti-inflammatory effect. *Pralepa* itself bears *Rakta-*

*prasadana* and *Shothahara* properties<sup>[13]</sup>. *Chakradatta* explained *Panchavalkala Pralepa* for treatment of *Vranashopha*. it reduces all the inflammatory sign and symptoms of *Vranashopha*.<sup>[20]</sup>

**Average Number of Days Required for Both Group**

For Group A it was about 9 days and for group B it was about 5 to 6 days for regression of overall symptoms of *Vranashopha*.

**Overall Result of Therapy-** Among 70 patients, overall effect of therapy as, Group A: 20 (57.14%) patients were markedly improved while 15 (42.86%) patients moderately improved.

**Group B:** 33 (94.29%) patients were markedly improved while 2 (5.71%) patients moderately improved.

No cases noticed mild improved and unchanged in both groups. By the observations and more effect of group B (trial group), we can say that this add on effect is due to *Panchavalkala Pralepa*.

**CONCLUSION**

1. Time required for the regression of overall symptoms of *Vranashopha* in *Jalaukavacharana* with *Panchavalkala Pralepa* was about 5 to 6 days and only *Jalaukavacharana* was about 9 days was found statistically significant.
2. *Panchavalkala Pralepa* with *Jalaukavacharana* in the patients of *Vranashopha* w. s. r. to Cellulitis was found early effective.
3. Remission of symptoms like pain, redness, swelling and local temperature was found in the treatment of *Jalaukavacharana* with *Panchavalkala Pralepa* than *Jalaukavacharana* only.
4. During the whole study, we found that there was no adverse reaction of *Jalaukavacharana* and *Panchavalkala Pralepa*. Hence the therapy is safe.

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**\*Address for correspondence**

**Dr. Geeta Baban Jaybhaye**

PG Scholar,

Department of Shalyatantra,

Shri Ayurved Mahavidyalaya,

Nagpur, Maharashtra India.

Email: [jaybhayegeet093@gmail.com](mailto:jaybhayegeet093@gmail.com)

Mob: 9765436371

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