



# A COMPARATIVE CLINICAL TRIAL TO EVALUATE THE EFFECTIVENESS OF *AADAREE-HARIDRA LEPA* AGAINST *SHIGRUPUNARNAVADI LEPA* IN *KEETA VISHA* WITH SPECIAL REFERENCE TO WASP STING

Anagha Madhusoodhanan<sup>1</sup>, T.S. Krishna Kumar<sup>2</sup>, Jayadeep.K<sup>3</sup>

PG scholar<sup>1</sup>, Professor<sup>2</sup>, Associate Professor<sup>3</sup>

Department Of Agada Tantra, MVR Ayurveda Medical College, Kannur, Kerala, India

## ABSTRACT

Wasps makes up an enormously diverse array of insects, wasps are identified from bees by their pointed lower abdomens and the narrow waist called petiole that separates the abdomen from thorax. Wasp sting are very common among the poisonous stings and it requires medical care. Most of the times, wasp sting causes only minor problems but it may also become fatal due to anaphylactic reaction. In order to pacify the harmful poisonous effect some *vishahara yogas* along with *agada pana* are found beneficial and the references are found in many *Keraleeya visha chikitsa granthas*. In this study, the effectiveness of *Aadaree-Haridra lepa* mentioned in *Prayoga samuchaya Navama paricheda*, *Kriyakaumudi-Keeta visha prakarana* for wasp sting has been studied along with *Dasanga agada* in comparison with *Shigrupunarnavadi lepa* which has already been proved and practiced.

**Key words:** *Aadaree-Haridra lepa*, wasp sting, *Shigrupunarnavadi lepa*, *kanabha visha*.

## INTRODUCTION

Wasp are predatory insects that falls under the order Hymenoptera, suborder Apocrita. This insect abounds many parts of India and other tropical and temperate region. About 20,000 species of wasp have been described and vast majority are solitary in habitat. Social wasps are confined to about 1000 species with in the family Vespidae and includes hornet and yellow jackets. Insect bites and stings are un-noticed until an itchy bump form on skin. Wasps are subdivided into two groups- solitary wasps, which lives alone and social wasp that have been described<sup>[1]</sup>. Wasp usually injects venom by stinging. Most of the times, wasp sting causes only minor problems but it may also become fatal due to anaphylactic reaction<sup>[2]</sup>. Local reaction which includes redness, pain, swelling and systemic toxic reaction occur due to multiple stings.<sup>[3]</sup>

Wasp may be correlated to *Kanabha*. *Kanabha visha* is a *keeta visha* which is categorized under *jangama visha*. There are mainly 4 kinds of *kanabha*- *Trikantaka*, *Karini*, *Hasthikaksha*, *Aparajitha*. Several regional and classical literature have narrated about this visha., these produces symptoms like *theevra vedana* (severe pain), *shwayadhu*(swelling), *Angamardha* (body ache), *guru gaatratha* (heaviness of body)<sup>[4]</sup>. *Aadaree-Haridra lepa*<sup>[5]</sup> mentioned in *Kriyakaumudi* and *prayoga samuchaya* is a simpler lepa preparation for *kanabha visha*.

## BACKGROUND AND RATIONALE

A wasp is an insect of narrow waisted and usually inject venom by its sting. Sometimes the stinger may leave in the skin. Not all wasp sting human only females have stingers, and wasp don't lose their stings easily and it's possible to sting multiple times by the same wasp. They are most common during summer<sup>[6]</sup>. 20 years Australian data found wasp sting fatality rate of 0.02% per million population per year, death occurs due to anaphylaxis.<sup>[7]</sup> Wasp venom composed of (a)biogenic amines-histamines, acetylcholine,5-hydroxy tryptamine (b)enzymes-phospholipase A&B, hyaluronidase (c)toxic peptides-kinin (d)others-antigens, phosphates, serotonin<sup>[8]</sup>. Wasp venom can cause significant pain and irritation and the result of wasp sting may vary from a localized inflammation to a general urticarial rash.

Most of the cases include one or more stings where there is no much complications. In order to pacify the harmful poisonous effect some vishahara yogas along with agada pana are found beneficial. Most commonly used medicines in case of kanabha visha are *Dasanga agada*<sup>[9]</sup> and *shigrupunarnavadi lepa*<sup>[10]</sup>. As the number of ingredients are more in *shigrupunarnavadi yoga*, there is a need of a simpler formulation. *Aadaree-Haridra lepa* mentioned in various literatures which includes *prayoga samuchaya-navama paricheda*<sup>1</sup>, *kriyakaumudi-keeta visha prakarana*<sup>[11]</sup> is a better and simpler formulation which is not explored till date. Hence, this study is meant to find out the effectiveness of *Aadaree- Haridra lepa* in kanabha visha which is an easily available.

## AIMS AND OBJECTIVES

### AIM

To evaluate the effectiveness of *Aadaree-Haridra lepa* against *Shigrupunarnavadi lepa* along with *Dasanga agada* for better management of kanabha visha.

### OBJECTIVES

- To analyze the effectiveness of *Aadaree-Haridra lepa* along with *Dasanga agada* in the management of kanabha visha
- To analyze the effectiveness of *Shigrupunarnavadi lepa* along with *Dasanga agada* in the management of kanabha visha.
- To compare the effectiveness of *Aadaree-Haridra lepa* against *Shigrupunarnavadi lepa* along with *Dasanga agada* in the management of kanabha visha.

Table no 1: MATERIALS AND METHODS

MATERIALS	METHODS
Available Literature	Systemic Arrangement
Drugs	<ul style="list-style-type: none"> <li>• <i>Dasanga agada</i></li> <li>• <i>Aadaree-Haridra lepa</i> (trial group)</li> <li>• <i>Shigrupunarnavadi lepa</i> (standard group)</li> </ul>

Case Record Format	Prepared and data entry will be made
Consent Form	Prepared
Research Participants	Participants satisfying diagnostic and inclusion criteria
Area of Study	Clinical

## STUDY DESIGN

Randomized comparative clinical trial

## STUDY SETTING

Pappinisery Visha Chikitsa Kendra, Post Graduate Department of Agada Tantra, MVR Ayurveda College, Kannur.

## STUDY POPULATION

Participants satisfying the diagnostic and inclusion criteria will be selected from Pappinisery Visha Chikitsa Kendra, postgraduate department of Agadatantra, MVR Ayurveda medical college, Parassinikadavu, Kannur)

## SELECTION CRITERIA

### DIAGNOSTIC CRITERIA

The participants satisfying any three or more of the following criteria will be included for the study

- History of acute wasp sting.
- Pain at the site of sting
- Swelling at the site of sting.
- Redness at the site of sting.
- Itching at the site of sting.
- Burning sensation at the site of sting.

### INCLUSION CRITERIA

- Participants with the history of wasp sting with in 48hours.
- Age group of 16-60 years.
- Participants with symptoms like pain, swelling, redness and burning sensation.
- participants irrespective of gender, caste, religion, economy.

## EXCLUSION CRITERIA

- All sting cases apart from wasp sting.
- Participants presenting various complications of sting like anaphylactic reaction.
- Pregnant and lactating women.
- Participants with systemic diseases.
- Participants who have undergone any other treatment for wasp sting.
- Participants having multiple stings.

## SAMPLE SIZE CALCULATION

2 groups each of 20 participants

$$n = \frac{2SD^2 \left(P + \frac{C}{2}\right)^2}{d^2}$$

P (power) = 2.58

C (confidence interval), C/2 = 1.96

D (Mean difference) =1.2

SD (standard deviation) =1.18

n =39.86

## SAMPLING PROCEDURE

Simple Random Lottery Sampling Method

Group 1 (trial group) :20cases

Group 2(standard) :20 cases

## INTERVENTION

DRUG SOURCE:

- The drugs for the preparation of *Dasanga agada and Shigrupunarnavadi lepa churna* purchased from the market and authenticated from department of dravyaguna, MVR College of Ayurveda, Parassinikadavu, Kannur.
- The drugs for *Aadaree-Haridra lepa, Aadaree and Haridra* -cultivated in home garden for the study purpose.
- Preparation -carried out from the pharmacy of MVRAMC under GMP guidelines.

## PREPARATION OF MEDICINES:

❖ Table no 2: DASANGA AGADA [A.H.U.37/27-28]<sup>[9]</sup>

INGREDIENTS	BOTANICAL NAME	FAMILY	MALAYALAM NAME	PART USED	PROPORTION
VACHA	<i>Acorus calamus</i>	Araceae	Vayambu	Rhizome	Equal parts
HINGU	<i>Ferula asafoetida</i>	Apiaceae	Kaayam	Resin	Equal parts
VIDANGA	<i>Embilias ribes</i>	Myrsinaceae	Vizhal ari	Fruit	Equal parts
SAINDAVAM	Rock salt		Indhupp	Salt	Equal parts
GAJAPIPPALI	<i>Scindapsus officinalis</i>	Araceae	Ati thippali	Fruit	Equal parts
PATHA	<i>Cyclea peltate</i>	Menispermaceae	Paatakizhang u	Root	Equal parts
PRATIVISHA	<i>Aconitum heterophyllum</i>	Ranunculaceae	Athividayam	Tuberous root	Equal parts
SHUNDI	<i>Zingiber officinale</i>	Zingiberaceae	Chukku	Rhizome	Equal parts
MARICHA	<i>Piper nigrum</i>	Piperaceae	Kurumulaku	Fruit	Equal parts
PIPPALI	<i>Piper longum</i>	Piperaceae	Thippali	Fruit	Equal parts

All the above drugs are taken in equal quantity by weight and made handmade pill of 2g each according to *vatikalpana vidhi*.

❖ Table no 3: SHIGRUPUNARNAVADI LEPA CHOORNA<sup>[10]</sup> (Prayoga samuchaya, thritheeya paricheda)

DRUG	BOTANICAL NAME	FAMILY	PART USED	PROPORTION
SHIGRU	<i>Moringa oleifera</i>	Moringaceae	Bark	Equal parts
PUNARNAVA	<i>Boerhavia diffusa</i>	Nyctaginaceae	Root	Equal parts
HARIDRA	<i>Curcuma longa</i>	Zingiberaceae	Rhizome	Equal parts
VACHA	<i>Acorus calamus</i>	Araceae	Rhizome	Equal parts
RAKTACHANDANA	<i>Pterocarpus santalinus</i>	Fabaceae	Heartwood	Equal parts

<i>PATA</i>	<i>Cyclea peltate</i>	Menispermaceae	Root	Equal parts
<i>ESWARI</i>	<i>Aristolochia indica</i>	Aristolochiaceae	Root	Equal parts
<i>YASTIMADHU</i>	<i>Glycyrrhiza glabra</i>	Fabaceae	Stem	Equal parts
<i>SIRISHA</i>	<i>Albizia lebbek</i>	Fabaceae	Bark	Equal parts
<i>GOKSHURA</i>	<i>Tribulus terrestris</i>	Zygophyllaceae	Seed	Equal parts

All the above drugs are taken in equal quantity by weight, dried and made into very fine powder. And lepa is prepared by adding sufficient quantity of water at the time of application.

❖ **Table no 4: AADAREE HARIDRA LEPA** <sup>[9]</sup>

DRUG	BOTANICAL NAME	FAMILY	PART USED	MALAYALAM NAME
<i>AADAREE</i>	<i>Caesalpinia mimosoides</i>	Caesalpiniaceae (Gulmohar family)	Tender leaves	<i>Kumullu</i>
<i>HARIDRA</i>	<i>Curcuma longa</i>	Zingiberaceae	Rhizome	<i>Pacha manjal</i>

*Aadaree* (tender leaves) and *Haridra* (rhizome) are taken in equal quantity. Both the ingredients are washed well and then grinded well in *khalwa yantra* and *lepa* is prepared as per the need at the time of administration.

#### WITHDRAWAL CRITERIA AND STOPPAGE RULES

- Patient if not co-operative to the procedure
- If symptoms get worsens.
- Patient if experiences any complications.
- Patient will be diagnosed according to the conditions and necessary management will be given.

#### OUTCOME MEASUREMENT

The following subjective and objective variables will be assessed using different grading methods before and after treatment.

##### SUBJECTIVE VARIABLE:

- Pain
- Burning sensation

##### OBJECTIVE VARIABLE:

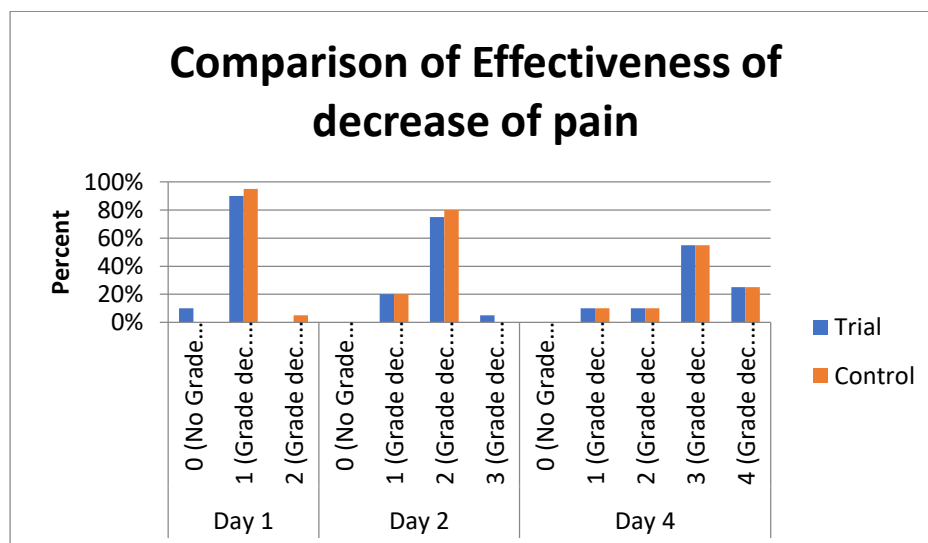
- Swelling
- Erythema

### PLAN OF ANALYSIS

- The main symptoms like pain, burning sensation, swelling and redness are analyzed. The changes in above said parameters are noted at specific intervals and assessment were done accordingly. Overall relief obtained are assessed based on the result obtained by statistical analysis.
- 100% relief-cured
- 76%-99% relief-marked improvement
- 51%-75% relief-moderate improvement
- 26%-50% relief-mild improvement
- 0%-25% -unchanged

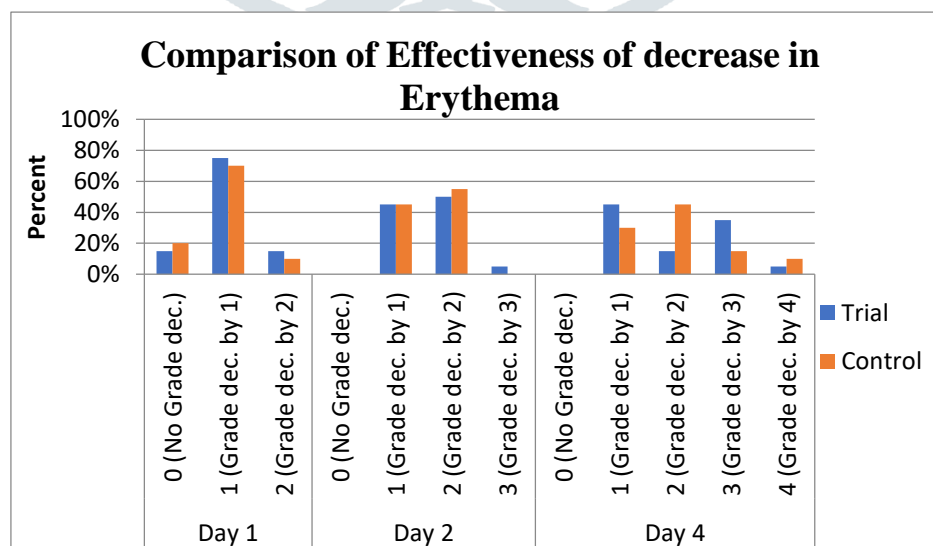
### RESULT

Fig 1: Comparison of Effectiveness of decrease of pain



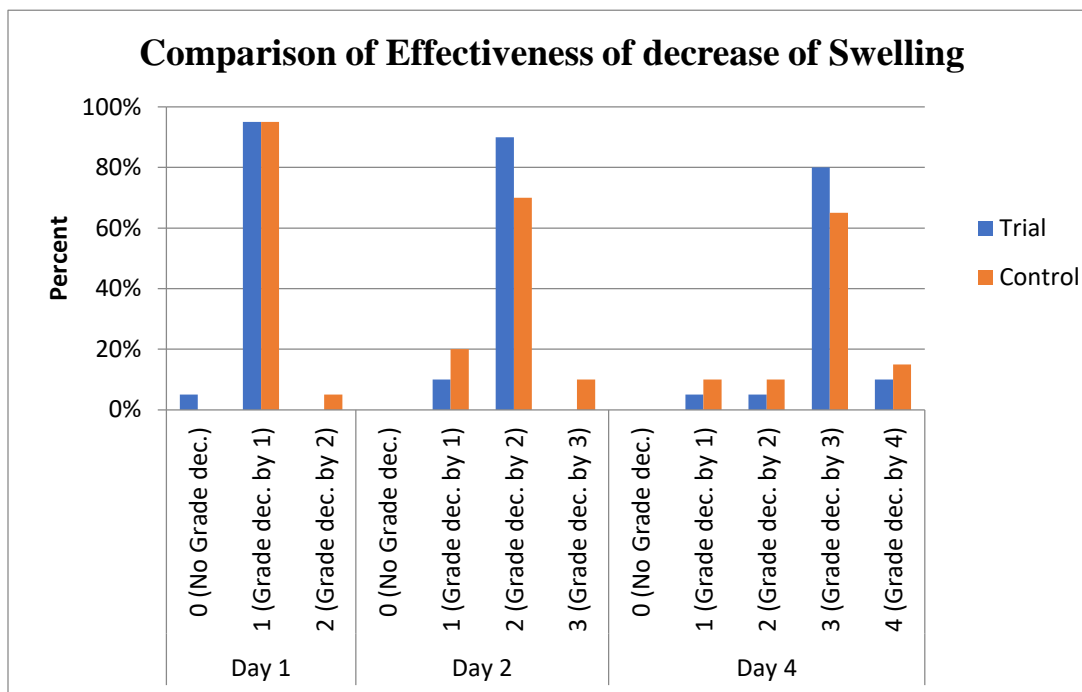
Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of Pain between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

Fig 2: Comparison of Effectiveness of decrease in Erythema



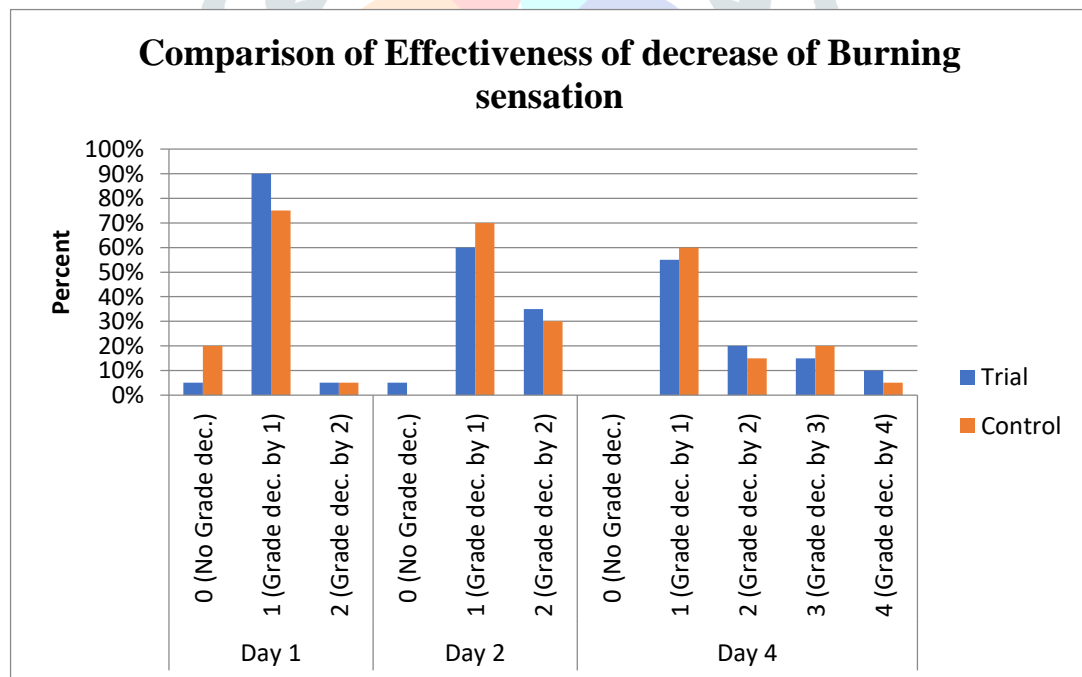
Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of Erythema between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

**Fig 3: Comparison of Effectiveness of decrease of Swelling**



Here Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of Swelling between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

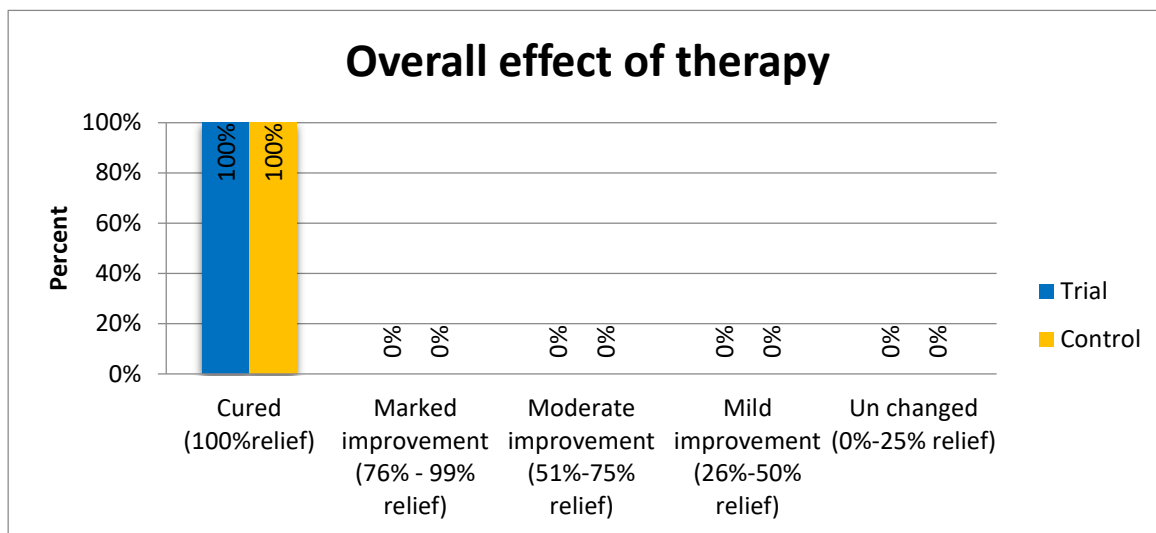
**Fig 4: Comparison of Effectiveness of decrease of Burning sensation**





Here Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of burning sensation between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

Fig 5: Overall effect of therapy



There is no significant difference in overall relief between group1 and group 2. Thus, statistically it is derived that *Aadaree-Haridra lepa* is equally effective when compared with *Shigrupunarnavadi lepa* in the management of pain, erythema, swelling and burning sensation caused by Wasp sting.

## DISCUSSION

The ingredients of *Dasanga agada* possess *vedanahara, sophahara, Vishagna* action. *Shigrupunarnavadi yoga* - While analyzing the *Doshagna* property of the ingredients of the yoga, the drugs are having *vata kaphaghna* and *vatapithaghna* property. *Aadaree* - is *vatapithaghna* and having *kashaya thiktha rasa, laghu ushna guna, ushna veerya* and *katu vipaka*. It acts as *kushtahara* and *malamootra soshaka* and having *vrana ropana* and *srotho sodhana* property. *Haridra* is *lekhaniya, kushtaghna, vishagna* and *sleshma prasamana*. *Aadaree – Haridra lepa* - a synergistic action of this yoga is *vishaharatva* and is effective in the management of *Kanabha visha*.

The symptoms – pain, swelling, erythema, burning sensation were computed by using appropriate grading scale. Erythema and swelling are objective signs – easier to measure. Pain and burning sensation were subjective parameters. Here patients' personality, attitude and belief strongly affected in the presentation of symptoms. Statistically there was no significant difference in the overall effect between two groups and clinically it was noticed that both the drugs are equally effective. No complication or adverse drug reaction were noted during the treatment period.

## CONCLUSION

Mann-Whitney U test and Wilcoxon Signed rank test were used to draw the conclusion after analysis. The research design was developed such that all the participants satisfying the inclusion and exclusion criteria were selected for the study by simple random lottery method as sampling technique. Both the treatment groups were found to be statistically and clinically equal effective in the management of wasp sting. Hence alternate hypothesis was proved. Clinical application and acceptability were more in *Aadaree – Haridra lepa* because of the easy availability and cost effectiveness as compared to *Shigrupunarnavadi lepa*.

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