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EVALUATION OF THE EFFICACY OF KUSHMANDABEEJADI LEPA AGAINST SIGRUPUNARNAVADI LEPA IN WASP STING - A COMPARATIVE CLINICAL TRIAL

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ABSTRACT

Wasp stings are common especially during the warmer months when people are outside for longer periods of time. They are equipped with a stinger for self-defence. A wasp's stinger contains venom that is transmitted to humans during a sting. Local manifestations following stings are common and usually life-threatening anaphylaxis may occur. Most of the cases involve one or a few stings where only local symptoms without any serious allergic reactions. In such cases *Vishaghna lepas* (antitoxic topical applications) can be used as it nullifies the harmful or poisonous effects along with medicinal intake. Here, in this study, the efficacy of *Kushmandabeejadi lepa churna,* mentioned in *Kriyakoumudi* (traditional book on toxicology) for wasp sting is studied by administering it along with another widely practiced classical preparation. **Aim and Objectives**- The study was conducted to study the efficacy of *Kushmandabeejadi lepa* against *Sigrupunarnavadi lepa* along with *Dasanga agada* in the management of Wasp sting **Methods-** A clinical study with 20 participants fulfilling the diagnostic and inclusion criteria was selected alternately and assigned in to two groups. Group 1(trial group) received *Kushmanadabeejadi lepa churna* and Group 2(control group) received *Sigrupunarnavadi lepa churna* five times daily for a period of three days, both as external application. Fourth day was observatory period and assessment was done on fifth day. In both groups, *Dasanga agada* was used as common internal medicine. **Results-**The outcome variables – pain, itching, erythema and swelling were assessed for the change in mean score values. Data were analysed statistically using Mann-Whitney U Test and Wilcoxon Signed Rank Test. The result obtained was significant in relieving the cardinal symptoms of wasp sting **Conclusion-** The overall effect shows that both the treatments individually

were significant in the management of wasp sting and *Kushmandabeejadi lepa* is equally effective in managing the signs and symptoms produced by wasp sting when compared with *Sigrupunarnavadi lepa*.

Keywords: *Kushmandabeejadi Lepa*; wasp sting; *Sigrupunarnavadi Lepa*; *Vishaghna Lepa, Dasanga agada*

INTRODUCTION

Although different types of insects are able to inflict poisonous bites or stings, the insects most likely to cause medical problems are bees and wasps. Wasp stings are a real hazard and worth some research. Most times it may cause only minor medical problems. But it may also become fatal due to anaphylactic reactions. This insect abounds in many parts of India and other tropical and temperate regions, especially during flowering season. Wasp stings are very common especially in population living in proximity of forest areas all over the world.

Most of the cases involve one or a few stings where only local symptoms are developed without any serious allergic reactions. In such cases, *Vishaghna lepas* can be used as it nullifies the harmful or poisonous effects along with medicinal intake. In *Vishachikitsa* (toxicology), *lepas* (topical applications) are considered as first and prime treatment aspect[1]. Commonly used internal medicine in Wasp sting is *Dasanga agada*[2] as it is indicated in all types of *keetavisha* (insect poisoning). *Sigrupunarnavadi lepa*[3] is scientifically proven in *keetavisha* and is traditionally used by *vishavaidyas* (traditional toxicologists) in Kerala to treat Wasp sting. But the number of ingredients in *Sigrupunarnavadi lepa* makes it a costly one which invites for the need for simpler preparation.

Kushmandabeejadi lepa[4] *yoga* mentioned in *Kriyakoumudi* chapter *Keetadi vishaprakarana* is indicated for wasp sting. *Kushmanda* (Benincasa hispida) being *Vata-pitha shamana*[5,6] where *Keetavishas* are generally having the same *Dosha* predominance[7] along with *Haridra* (Curcuma longa) possessing *Vishahara* (antitoxic) property can be effective in wasp sting. Here in this study, an attempt is made to find out the efficacy of *Kushmandabeejadi lepa* which is cost effective and easily available.

Materials and Methods

A treatment modality based on the principles set in classical text and *Keraleeya Vishagranthas* (ancient toxicology books of Kerala) was developed incorporating procedures and medicines described in the treatment of wasp sting and is applied in this clinical trial. The whole plan of study was approved by Institutional Ethics Committee (IEC) prior to starting of work IEC No:-IEC/2017/11; Dated- 29/03/2017. Consent form was prepared and prior consent of all the participants were obtained on the consent form. A pamphlet containing the details of the research was given to the participants.

A clinical study with 20 participants fulfilling the diagnostic and inclusion criteria was selected alternately and assigned in to two groups, age group between 16 to 60 years, attending OPD within 48 hours following wasp sting. Group 1 (trial group) received *Kushmandabeejadi lepa churna* and Group 2 (control group) received *Sigrupunarnavadi lepa churna* five times daily for a period of three days. Fourth day was observatory period and assessment were done on fifth day. In both groups, *Dasanga agada* was used as common internal medicine.

	Group 1 (trial group)	Group 2 (control group)
Drug internal	*Dasanga gutika*	*Dasanga gutika*
Dose	2 grams twice daily	2 grams twice daily
Drug external	*Kushmanda beejadi lepa*	*Sigrupunarnavadi lepa*
Medium of application	Water	Water
Area of application	In and around the bite site where swelling and redness are seen	In and around the bite site where swelling and redness are seen

Diagnostic Criteria

- 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

Inclusion Criteria

- Age group between 16 to 60 years
- Diagnosed cases of wasp sting within 48 hours.
- Participants with any of the essential symptoms like pain, swelling, redness and itching.
- Participants irrespective of gender, caste, religion and economic status.

Exclusion Criteria

- All sting cases apart from Wasp sting.
- Stings over fatal areas like eyes, lips etc.
- Cases having more than one sting
- Participants presenting with complications of sting like dyspnoea and anaphylactic reactions
- Pregnant and lactating women.
- Participants with systemic diseases like DM, HTN and other systemic disorders

Preparation of Drugs

Dasanga Gulika[2]

Table 1: Ingredients of *Dasanga gulika*

Ingredients	Botanical name	Family	Part used
Vacha	Acorus calamus	Araceae	Rhizome
Hingu	Ferula narthex	Umbelliferae	Resin
Vidanga	Embelia ribes	Myrsinaceae	Fruit
Saindavam	Rock Salt		Salt
Gajapipali	Scindapsus officinalis	Piperaceae	Fruit
Patha	Cissampelos pareira	Menispermaceae	Root
Prativisha	Aconitum heterophyllum	Ranunculaceae	Tuberous Root
Sundi	Zingiber officinale	Zingiberaceae	Rhizome
Maricha	Piper nigrum	Piperaceae	Fruit
Pippali	Piper longum	Piperaceae	Fruit

All the above drugs are taken in equal quantity by weight and made in to a hand-made pill of 2gm.

Kushmandabeejadi lepa churna[4]

Table 2: Ingredients of *Kushmandabeejadi lepa churna*

Drug	Botanical name	Family	Part used
Kushmanda	Benincasa hispida	Cucurbitaceae	Seed
Haridra	Curcuma longa	Zingiberaceae	Rhizome

Kushmanda Beeja and *Haridra* are dried and made into a very fine powder

Table 3: Ingredients of *Sigrupnarnavadi lepa churna*

Drug	Botanical name	Family	Part used
Sigru	Moringa olifera	Moringaceaea	Bark
Punarnava	Boerhavia diffusa	Nyctanginaceae	Root
Haridra	Curcuma longa	Zingiberaceae	Rhizome
Vaca	Acorus calamus	Araceae	Rhizome
Rakta chandana	Pterocarpus santalinus	Fabaceae	Heartwood
Pata	Cyclea peltata	Menispermaceae	Root
Iswari	Aristolochia indica	Aristolochiaceae	Root
Yashtimadhu	Glycyrrhiza glabra	Fabaceae	Stem
Sireesha	Albizia lebbeck	Fabaceae	Bark
Gokshura	Tribulus terrestris	Fabaceae	Seed

All the above drugs are taken in equal quantity by weight, dried and made into a very fine powder.

Proportion of *Lepa churna* with water

Depending up on the condition and site of the sting, the amount of *lepa churna* needed may vary. Adequate amount of water is added to *churna* and made into a fine paste.

Assessment Criteria

The following Subjective and Objective parameters will be assessed using different grading and scoring methods before and after treatment.

Subjective Parameters: Local pain., Local itching

Objective Parameters: Swelling**.,** Redness/ erythema

Assessment

Assessment criteria includes the 4 main cardinal symptoms, namely, pain, oedema, itching and erythema. The changes in the above said parameters will be noted at specific intervals and assessment will be done accordingly. It was recorded in the concerned CRF and evaluated systematically to draw a conclusion on the effect at individual & comparative level for the groups by means of Mann – Whitney U test and Wilcoxon Signed Rank test. The overall relief obtained will be assessed as follows:

100% Relief- cured, 76% - 99%- marked improvement, 51%-75%-moderate improvement, 26%-50% - mild. 0 –25% - unchanged

Table 4: Variables of Pain

0	No pain
1	Pain on pressure
2	Dull continuous, not disturbing movement or functioning of the part.
3	Sharp continuous, not disturbing movement or functioning of the part.
4	Sharp continuous, Patient is unable to move the part, normal routine including sleep is disturbed

Table 5: Variables of Erythema

0	No redness
1	Diffused, only at the point of sting
2	Diffused, involving the surrounding area up to 5cm
3	Marked, involving the surrounding area up to 5cm
4	Marked, involving area more than 5cm

Table 6: Variables of swelling

0	No Swelling
1	Below 0.5cm increase in circumference
2	Up to 0.5 cm – 1cm increase in circumference
3	1cm – 1.5cm increase in circumference
4	more than 1.5cm increase in circumference

Table 7: Variables of Itching

0	no itching
1	occasional itching
2	continuous itching
3	continuous itching disturbing daily work
4	continuous itching disturbing sleep

Statistical Analysis - Pain, erythema, swelling and itching changes were assessed on comparing their values after applying Mann–Whitney U test and Wilcoxon signed-rank test.

Results: Table no. 8 shows that, according to age, out of 40 participants 45% were in the age group of 16 – 30 years, 25% were in the age group of 31– 45 years.30% were in the age group of 46 – 60 years. (n=40).

Table no. 9 shows that according to the time of the sting, out of 40 participants, 2.5% had a sting in between 12 am and 6 am 72.5 % had a sting in between 6.01am and 6 pm and 25% had a sting in between 6.01pm- 11.59 pm. Table no: 10 shows distribution of 40 participants according to their domicile, 32.5% of participants are from rural area and 67.5% are from urban area.

Table 8: Distribution of 40 participants according to age

Age	Group I (n=20)		Group II (n=20)		Total (n=40)	
	No	%	No	%	No	%
16-30	9	45	9	45	18	45
31-45	3	15	7	35	10	25
46-60	8	40	4	20	12	30

Table 9: Distribution of 40 participants according to the time of sting

Time of sting	Group I (n=20)		Group II (n=20)		Total(n=40)	
	No	%	No	%	No	%
12am-6am	1	5	0	0	1	2.5
6.01am-6pm	15	75	14	70	29	72.5
6.01pm-11.59pm	4	20	6	30	10	25

Table 10: Distribution of 40 participants according to domicile

Domicile	Group I (n=20)		Group II (n=20)		Total(n=40)	
	No	%	No	%	No	%
Rural	9	45	4	20	13	32.5
Urban	11	55	16	80	27	67.5

Table 11: Comparison of Effectiveness of decrease in pain

Decrease in Pain (in Grade)		Trail		Control		Z$	p
		Count	Percent	Count	Percent		
3rd day	1	5	25.0	7	35.0	0.28	0.777
	2	12	60.0	9	45.0		
	3	3	15.0	4	20.0		
5th day	1	1	5.0	0	0.0	0.8	0.425
	2	10	50.0	9	45.0		
	3	7	35.0	8	40.0		
	4	2	10.0	3	15.0		

Table 12: Comparison of Effectiveness of Erythema

Erythema		Trail		Control		Z$	P
		Count	Percent	Count	Percent		
3rd day	No redness	12	60.0	16	80.0	1.28	0.199
	Diffused, only at the point of sting	7	35.0	3	15.0		
	Diffused, involving the surrounding area up to 5 cm	1	5.0	1	5.0		
5th day	No redness	20	100.0	20	100.0	0	1.000
	Diffused, only at the point of sting	0	0.0	0	0.0		
	Diffused, involving the surrounding area up to 5 cm	0	0.0	0	0.0		

Table 13: Comparison of Effectiveness of Swelling

Swelling		Trail		Control		Z$	p
		Count	Percent	Count	Percent		
3rd day	No swelling	7	35.0	8	40.0	0.09	0.926
	Below 0.5cm increase in circumference	13	65.0	10	50.0		
	Up to 0.5cm - 1cm increase in circumference	0	0.0	2	10.0		
5th day	No swelling	20	100.0	20	100.0	0	1.000
	Below 0.5cm increase in circumference	0	0.0	0	0.0		
	Up to 0.5cm - 1cm increase in circumference	0	0.0	0	0.0		

Table 14: Comparison of Effectiveness of Itching

Itching		Trail		Control		Z$	p
		Count	Percent	Count	Percent		
3rd day	No itching	17	85.0	13	65.0	1.44	0.149
	Occasional itching	3	15.0	7	35.0		
5th day	No itching	20	100.0	20	100.0	0	1.000
	Occasional itching	0	0.0	0	0.0		

Mann-Whitney U test was used to compare the efficacy in relieving pain, erythema, swelling and itching between groups. On day 3, 25 percent patients experienced a decrease of one grade pain and 60 percent experienced a reduction of 2 grade pain in trial group. The decrease of 1 grade pain and 2 grade pain in control group was 35 percent and 45 percent. Mann-Whitney U test showed that ($p>0.05$) the decrease in pain between groups is not significant at 0.05 level. In short, the intervention in trial and control group is effective in relieving pain, but when compare the efficacy of treatment, the intervention in trial group and control group is equally effective in reducing pain (Table no.11). On fifth day, in trial group percentage of relief obtained was 100% and in control group percentage of relief obtained is 100%. P value obtained is 1.000($p >0.05$) which shows result is statistically insignificant. We can conclude the group are equally effective in relieving erythema (Table no.12). On fifth day, in trial group percentage of relief obtained was 100% and in control group percentage of relief obtained is 100%. P value obtained is 1.000($p >0.05$) which shows result is statistically insignificant. We can conclude the group are equally effective in relieving swelling (Table no. 13). On fifth day, in trial group percentage of relief obtained was 100% and in control group percentage of relief obtained is 100%. P value obtained is 1.000($p >0.05$) which shows result is statistically insignificant. We can conclude both the group are equally effective in relieving itching. (Table no.14).

DISCUSSION

Probable mode of action of *Kushmanda Beejadi Lepa Yoga*

Kushmandabeejadi lepa choorna is a *lepa yoga* mentioned in *Kriyakoumudi* under *Keetadi visha prakarana* for treatment of wasp sting. This yoga consists of only two ingredients- *Kushmanda beeja* and *Haridra*. *Kushmanda* has got *Madhura rasa, Laghu guna, Ushna virya* and *Tridoshahara* property. *Madhura rasa* is *Vata-pithahara, Vishahara* and *Varnya. Laghu guna* possess *Srothoshodhana* and *Ropana* properties. *Ushna guna* being *Vata-kaphahara* helps in reducing the pain, swelling and itching produced by wasp sting. By virtue of these properties such as *Vishahara, Srothoshodhana* and *Ropana,* the external signs and symptoms produced by poisonous bites can be pacified. *Haridra* is *Katu Tikta rasa, Ruksha guna, Ushna virya* and *Kapha-pithahara. Katu rasa* acts *as Kanduhara, Krimihara* and *Sophahara.* It pacifies *Kapha* and helps in *Srotovivarana. Tikta* rasa possess *Krimihara, Vishahara* and *Pitha-kaphahara* properties. *Ruksha guna* helps in reducing *Sopha. Ushnaguna* being *Vata-kaphahara* helps in reducing the pain, swelling and itching. It is an excellent *Vishahara dravya* which has been proven since years. In *Kushmandabeejadi lepa choorna,* these two ingredients are

mixed in equal proportion which gives a synergetic action in the treatment of poisonous symptoms produced by wasp sting.

CONCLUSION

Sigrupnarnavadi lepa has been practically found to be effective in all types of *Keetavisha.* But the number of ingredients in *Sigrupunarnavadi lepa* makes it a costly preparation which invites for the need for simpler preparation. *Kushmandabeejadi lepa yoga* mentioned in *Kriyakoumudi* chapter *Keetadi vishaprakarana* is indicated for wasp sting. *Kushmandabeejadi lepa* is a simpler preparation which contains only two ingredients i.e., *Kushmandabeeja* and *Haridra*. In this study both the treatments were found to be effective. Both the *lepa yogas* were equally effective in managing the four parameters i.e., pain, swelling, erythema and itching. No complications or adverse drug reactions were noted during the treatment period.

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