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A CLINICAL TRIAL TO EVALUVATE THE EFFICACY OF SHUNTI-TAGARA LEPA & DASANGAM GULIKA IN VRISCHIKA VISHA DAMSA

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ABSTRACT

Background: Scorpionism is a particularly devastating & an endemic public health problem in some part of the India such as Rathnagiri in Maharashtra, Bellary in Karnataka, *Parassinikkadavu* in Kerala. 50 species out of 700, in India, can cause serious illness. They cause simple cytotoxic effect to severe cardio or neurotoxic effect. Those illness managed by sophisticated management measures. Ayurveda has explained numerous medicinal preparations in the management of *Vrishchika Damsha*, but so far very little statistical data is available regarding the efficacy of these medicines. The main objective of the present study was to evaluate combined effect of *Shunti-Tagara Lepa* along with *Dasangam Gulika Sevana* in reducing the five cardinal signs and symptoms due to Scorpion sting viz. Pain, Swelling, Burning sensation, Itching and Erythema. Methods: A randomized clinical study was conducted in Pappinissery Visha Chikitsa Kendra, Kannur. Total 30 subjects suffering from Scorpion sting satisfying inclusion criteria were selected and included in a single group. Group received *Shunti-tagara lepa* and *Dasangam gulika* for 4 days and follow up was recorded on 7th day. Results: Results were observed on 7th day after completion of the treatment. Both the drugs when combined showed highly significant results in reducing the three cardinal symptoms by paired t test. (P<0.001). Interpretation & Conclusion: Both the drugs when combined were highly significant, on account of percentage of relief obtained, particularly in *Kaphavaataja* predominant condition.

Keywords: Scorpion, Vrischika damsha, Shunti-Tagara Lepa, Dasangam Gulika

INTRODUCTION

Ayurveda, term vrischika¹ is derived from a root word means cedane-to cut. Based on vishadamsa lakshana² (signs of sting envenomation) classified

Manda(mild), Madhya(moderate) and Teekshna(strong). Avabhasini to Rohini (layers of skin) is affected except mamsadhara(innermost layer

of skin) of twacha³ (skin) and leads to vitiation of doshas presenting pradhaanasthaanikalakshanas (cardinal symptoms) viz, Vedana(pain), Damsa-(swelling), Daha(burning sensation). sopha *Kandu(itching)*and Rakthavarnyatha(erythema). Sarvadaihikalakshanas (physiological symptoms) include jvara(fever), jihwasthambha (stiffness of tongue), kampa(tremor), gatrasthambha(stiffness of body) and murccha⁴ (shock). Ashtanga Hrudaya⁵, Keetalootadivishapratishedha Uttarasthana. (chapter in ashtanga hridaya that deals with the treatment of spider and other insect poisoning) mentions Dasanga Agada Paana in the context of vrischikavishadamsa (scorpion sting envenomation). Acara Kanda which comes under Poorvakanda of Garudapurana⁶ discuss about sarpa(snake), keeta(insects and scorpions) and other type of visha with lakshana and chikitsa. There explains Shuntitagaralepa in vrischikavishadamsha and Garuda purana poorvakanda presents Dhanwantharisamhitha, medicine. treatise on *Upasaya(treatment)* and Samprapti(prognosis) related chapters of Garudapurana are similar to Nidanasthana of AshtangaHridaya. Garuda purana⁶ being one of the 18thMahapurana deals with highly diverse collection of topics like Utpatti of Loka(origin of universe), Mithya, relationship between Devas and Asuras, Yama and Niyama, Satkarma and Paapakarma, Samkhya, Nyaaya, Vaisheshika, Purvamimamsa, Vedanta, Yoga, theory of Swarga and Naraka with respect to Karma and Punarjanma, Shraddha, Nirvaana, Prakriti, types of Dhatus(minerals and metals) and Ratnas(gem stones), various Rogas and their Lakshanas, various Oushadhayogas (medicinal recipes), Rasayana (rejuvenatives) and Vajeekarana aushadhis Jvotishastra (astrology), (aphrodisiacs). Vaasthushastra (architecture) etc. The chikitsa of vrischikavishadamsa in areas where population of the species is high lacks emergency care as pradhaanalakshana swiftly manifests, an awareness of easily available yogas need to be done. Before the medical theories are established as practicable, they

should be substantiated by practical experience. Simple theoretical argumentation based on inference signifies zero. Clinical studies are considered as one of the best tools to reach to a certain wrapping up in the medical field. Dasangamgulika is helpful in pacifying vedana, daha, kandu and Shuntitagaralepa for damsa-shopha and raktavarnyatha due to sthaanika vrischika vishadamsa(locally manifested cardinal symptoms). Dasangamgulika and Shunti-tagara lepa the trial drugs are cost effective, easily prepared, and easily administrable.

Materials and Methods:

- a. **Literary source:** Garuda Mahapuranam Acara kanda 1st Volume, Chapter no 191, Prayoga Samucchayam 7th Chapter on Vrischika samanya chikitsa, Ashtanga Hrudaya uttaratantra 37th chapter on Keetaloothadi visha pratishedham.
- b. **Drug source:** The drug is selected from local areas and market after proper identification. Authentication and preparation of *Shuntitagaralepa* and *Dasangam gulika* done from Alva's pharmacy, Mijar
- b. Sample source: Patients of Scorpion Sting cases are from Papinissery Visha Chikitsa Kendram, Parassinikkadavu, Kannur, Kerala & Other referral cases of scorpion sting poisoning that comes under inclusion criteria
- c. **Research Design:** 30 Patients of *Vrishchika Damsha* were selected as per the inclusion criteria, from the Visha Chikitsa Kendra, Pappinisseri, and other sources. They were included in a single group. Group received *Shunti-tagaralepa* and *Dasangamgulika Pana* was given for 4 days and followed up to 7th day [Total study duration was 7 days]. Thorough clinical assessment was done before and after the treatment. The result was analyzed statistically.

Selection of Subjects: Patients were selected as per the selection criteria for the study and were assigned to a single group.

- d. Inclusion criteria: Patients irrespective of sex, religion, socio-economic status having age between 16-65 years. Patients with history of Scorpion sting with duration not more than 48 hours. Patients with essential symptoms like Pain, Swelling, Burning sensation, Itching & Erythema due to Scorpion sting.
- e. Exclusion criteria: Patients below 16 years and above 65 years of age. Patients suffering from other systemic diseases that interfere with the prognosis and management of scorpion sting. Patient with serious condition such as convulsion, unconscious, coma and other sign of neuropathy. Patient of red scorpion sting and any post sting systemic involvement. Patient who

- have undergone any other treatment for same complaint.
- Research Techniques and Tools: A proforma was designed to collect and record the information verbally reported by the subjects and physically examined by the researcher. Proper grading was done to calculate the exact intensity of the cardinal symptoms like Pain, Burning sensation, sweating, Numbness. Swelling, Referral pain (localized lymph node involvement) etc as per Sushrutha samhitha-Vrischikadamshalakshana. Haemogram was done to subject who shows the systemic involvement. Photos of the affected site have been taken with prior informed consent of the

Table 1: Clinical Study Plan

Sl No.	Details	Trial Group			
1	Sample size	30 patients			
2	Drug (Externally)	Suficient quantity of Shunti-tagaralepa With Madhu ⁷			
3	Temperature	Room temperature			
4	Thickness	1/3 Angula ⁸ (0.587 cms)			
5	Site	Over the affected area of sting			
6	Duration of lepa	From application to just before complete drying			
7	Frequency of lepa	4 times a day with an interval of 4 hours			
8	Drug (orally)	Dasangamgutika			
9	Dose	2 tablet (500mg) BID			
10	Anupana	Ushnajala			
11	Duration	7 days			

Assessment & Statistical Analysis: -

Assessment was done before treatment, on 4th day & on 7th after the treatment and the score for the cardinal symptoms was obtained. Pre-treatment and post treatment (7th day) data was subjected to statistical analysis and the comparison was done within the group by using student's paired t- test.

Total Effect of Therapy: -

Total effect of therapy on 30 subjects of VrishchikaDamsha was given in percentage by calculating the mean difference of the scores, before and after the treatment.

1. 100 % relief --- Cured.

research participants.

2. >75 % to 99 % --- Marked improvement.

3. >50 % to 75% --- Moderate improvement.

4. >25 % to 50 % --- Mild improvement.

5. 0 % to 25 % --- Unchanged.

RESULTS

EFFECT OF TREATMENT ON INDIVIDUAL SYMPTOM IN TRIAL GROUP

Table 2: Effect of the Therapy on Pain (Paired t - test)

Sl. No	Symptoms	Mean			Mean difference	%	Paired 't' test			
							SD	SE	t	P
1	Pain	BT			1.0	39.47				
		2.5	AT	1.5			0.681	0.124	3.595	< 0.001
			AF	0.6			0.490	0.0895	34.106	< 0.001

As seen in table no. 40 Which compares the effectiveness of the treatment on pain, the mean score was reduced from 2.5 to 1.5 after the treatment i.e. on 4th day and 0.6 at follow up i.e. on 7th day, mean difference was 1.0 with SD

+ 0.681 after the treatment & 0.490 at follow up. Percentage of relief obtained was 39.47%. t value was found to be 3.595 after the treatment & 34.106 at follow up which was statistically highly significant (P< 0.001).

Table 3: Effect of the Therapy on Swelling (Paired t - test)

Sl. No	Symptoms	1	Mean		Mean difference	%	Paired 't' test			
							SD	SE	t	P
1	Swelling	BT			1.0	90.91				
		1	AT	0			0.403	0.0735	5.955	< 0.001
			AF	0			0.254	0.0463	31.000	< 0.001

As seen in table no. 41 Which compares the effectiveness of the treatment on swelling, the mean score was reduced from 1 to 0 after the treatment i.e. on 4th day and 0 at follow up i.e. on 7th day, mean difference was 1.0 with SD

+ 0.403 after the treatment & 0.254 at follow up. Percentage of relief obtained was 90.91%. t value was found to be 5.955 after the treatment & 31.000 at follow up which was statistically highly significant (P< 0.001).

Table 4: Effect of the therapy on Burning sensation (Paired t - test)

Sl. No	Symptoms	Mean		Mean	%	Paired 't' test				
					difference		SD	SE	t	P
1	Burning	BT			1.0	93.75				
	Sensation	1.1	AT	0.1			0.254	0.0463	5.595	<0.001
Ĭ			AF	0.33			0.183	0.033	31.000	< 0.001

As seen in table no. 42 Which compares the effectiveness of the treatment on burning sensation, the mean score was reduced from 1.1 to 0.1 after the treatment i.e. on 4th day and 0.33 at follow up i.e. on 7th day, mean difference was

1.0 with SD + 0.254 after the treatment & 0.183 at follow up. Percentage of relief obtained was 93.75%. t value was found to be 5.595 after the treatment & 31.000 at follow up which was statistically highly significant (P< 0.001).

Table 5: Effect of the therapy on Itching (Paired t - test)

Sl.	Symptoms	Mean		Mean	%	Paired 't' test				
No					difference		SD	SE	t	P
1	Itching	BT			0.367	100				
		0	AT	0			0.000	0.0910	6.595	< 0.001
			AF	0			0.000	0.000	4.097	< 0.001

As seen in table no. 43 Which compares the effectiveness of the treatment on itching, the mean score was reduced from 0 to 0 after the treatment i.e. on 4th day and 0 at follow up i.e. on 7th day, mean difference was 0.367 with

SD + 0.000 after the treatment & 0.000 at follow up. Percentage of relief obtained was 100%. t value was found to be 6.595 after the treatment & 4.097 at follow up which was statistically highly significant (P< 0.001).

Table 6: Effect of the therapy on Erythema (Paired t - test)

Sl.	Symptoms	l	Mean		Mean	%	Pai	ired 't' test		
No					difference		SD	SE	t	P
1	Erythema	BT			0.6	60			<u>-</u>	
		1	AT	0.4			0.498	0.0910	6.595	< 0.001
			AF	0			0.000	0.000	4.697	< 0.001

As seen in table no. 44 Which compares the effectiveness of the treatment on erythema, the mean score was reduced from 1 to 0.4 after the treatment i.e. on 4th day and 0 at follow up i.e. on 7th day, mean difference was 0.6 with SD

+ 0.498 after the treatment & 0.000 at follow up. Percentage of relief obtained was 60%. t value was found to be 6.595 after the treatment & 4.697 at follow up which was statistically highly significant (P< 0.001).

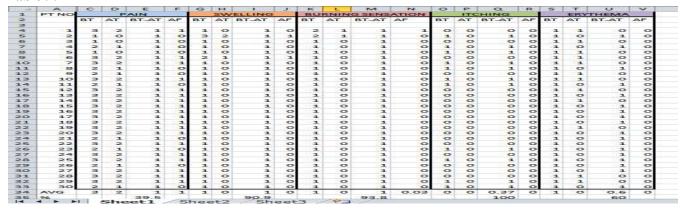
Table 7: Percentage of Relief obtained in each sign & symptom

Symptom	Percentage of relief obtained
Pain	39.47%
Swelling	90.91%
Burning Sensation	93.75%
Itching	100%
Erythema	60%

Table 8: Percentage of effect of therapy in the group

Effect of therapy	Group	Percentage (%)
100% relief - Cured	0	0
>75% <100% - Marked improvement	19	63.33
>50% to 75% - Moderate improvement	9	30
>25% to 50% - Mild improvement	2	6.66
>0% to 25% - Unchanged	0	0

Table 9: Master Chart



DISCUSSION

Effect on the Individual symptom: -

Effect of therapy on Pain (Ruja): - (Table No.2)

❖ The result on Ruja showing statistically highly significant results in combination, which

indicates that *ShuntitagaraLepa* along with *Dasangamgulika* gives an effective action on *Ruja* in *Vrischikavisha*. If we see the % of relief, it is 39.47% relief in the trial group. This may be due to the *Tridoshahara*, *Ushnaveerya*,

Vedanasthapana and Vishaghna properties of the drugs of the both the yogas which subsides Vathadosha and reduces Ruja in VrischikaVisha. So the combined effect of Shunti-tagaralepa along with Dasangamgulika gives significant efficacy in pain

Effect of therapy in Swelling (*Damsasopha*) (Table No 3)

❖ The result on damsasopha showing statistically highly significant results in combination, which indicates that ShuntitagaraLepa along with Dasangamgulika gives an effective action on damsasopha in Vrischikavisha. If we see the percentage of relief, it is 90.91% relief in the trial group. This may be due to the thiktha and kashaya rasa, vishaghna and sopha-sothahara properties of the drugs of the both the yogas which subsides Kapha Vatha & VrischikaVisha. So the combined effect of Shunti-tagaralepa along with Dasangamgulika gives significant efficacy in damsasopha.

Effect of the therapy on Burning sensation (Daha) (Table No 4)

❖ The result on daha showing statistically highly significant results in combination, which indicates that ShuntitagaraLepa along with Dasangamgulika gives an effective action on Ruja in Vrischikavisha. If we see the % of relief, it is 93.75% relief in the trial group. This may be due to the thikthakashaya rasa pradhana, Sheethaveerya, and dahaprashamana properties of drugs of the both the yogas which subsides Pitta dosha and does raktashodhana in VrischikaVisha. So the combined effect of Shunti-tagaralepa along with Dasangamgulika gives significant efficacy in daha

Effect of the therapy on Itching (Kandu) (Table No 5)

The result on kandu showing statistically highly significant results in combination, which indicates that ShuntitagaraLepa along with Dasangamgulika gives an effective action on kandu in Vrischikavisha. If we see the % of relief, it is 100% relief in the trial group. This may be due to the thikthakashaya rasa pradhana, lekhaneeya, kandughna and vishaghna properties of some of the drugs which subsides Kaphadosha and gives a better result in Kandu

Effect of the therapy on Erythema (Raktavarnyatha) (Table No 6)

The result on raktavarnyatha showing statistically highly significant results which indicates individually, that ShuntitagaraLepa along with Dasangamgulika gives an effective action on raktavarnyatha in Vrischikavisha. If we see the % of relief, it is 60% relief in the trial group. This may be due to sheethaveerva. thikthakashava rasa. vishaghna, and rakthashodhana properties of some of the drugs which subsides Pitta dosha and does Rakthashodhana and gives a better result in Kandu.

DISCUSSION REGARDING OVERALL EFFECT: - (Table no 7 & 8)

Overall effect shows that the drugs when combined were highly significant in the management of *Vrishchikadamsha cases*. (P<0.001) (Paired t test). On assessing overall effect of therapy, it is found that 63.33% of patients had marked improvement, 30% had moderate improvement and 6.66% had mild improvement from symptoms.

Highly significant results were found as the combined efficacy has provided more significant results, which shows that for complete cure of the symptoms of Vrischikavisha both the internal and external medication are necessary.

It suggests that shuntitagaralepa along with dasangamgulikasevana in vrischikavisha is a quite stable and suitable therapy.

PROBABLE MODE OF DRUG ACTION: - > Probable mode of action of *Lepa*:-

The concept of per cutaneous absorption envisaged in the modern physiology can be summed up as follows: There are three possible routes of absorption. The pilo sebaceous follicles play some part in absorption of many compounds. The transfollicular absorption, the route of penetration is through the follicular pores to the follicles and then to the dermis via the sebaceous gland. The permeability of the cells of the sebaceous gland is greater than that of granular layer of the epidermis. In this way the substances, which are used in *Lepa*, may absorbed and enter in the blood and removes the pathology. The modern physiology and biochemistry says that it is possible to produce a certain amount of absorption by the application of substances conveyed in fatty vehicles (Lovatt Evan's Physiology, 11th edition).

- Lesser the particle size more the surface area.
- Lesser the particle size lesser will be the drying time.
- Lesser the particle size more the rate of absorption.

Discussion on Madhu:-

Madhu, A naturally occurring, thick, syrupy, translucent yellow to yellowish brown fluid, sweet to taste with a pleasant odour and flavor produced by honey bees by enzymatic transformation of floral nectar ingested by them and deposited in the cells of hives or combs which is administered due to disorders due to poison. When poured on to a tray as a thin layer, no impurities like mould, dirt, bee wax, insect fragments, plant ebris or any other objectionable foreign matter should be visible to the naked eye in daylight. Alepa can be applied only with a suitable medium. The yogavahi property of honey enhances the action of other drugs in this lepa, thus resulting in quick relief in symptoms like pain, itching, edema, erythema and burning sensation. Vishahara and tridoshahara property of honey further add to the visha and sophasamanatva of the lepa. When an edema occurs, the inflammatory response results in transudation of fluids. progressive vasodilation, and increased blood flow. So, topical medicines if applied externally can penetrate the dermal layer easily. Further the medication is also absorbed through hair follicles

and sweat glands. The active principles, thus reached in to the deeper layers of skin undergo cutaneous biotransformation and help to pacify symptoms .Thus

Proportionate distribution of all the properties in Shuntitagaralepa shows that drugs are having UshnaVeerya, among them and are Vataghna and kaphaghna. The yogavahi property of Madhu enhances the action of the drugs in the lepa. Vishahara and tridoshahara property of honey further add to the visha and sophashamanatva of the lepa. The inflammatory response results in the transudation of fluids, progressive vasodilatation and increased blood flow. So, topical medicines if applied externally can penetrate the dermal layer easily. The active principles reach the deeper layers and go cutaneous biotransformation and pacify symptoms. By these properties the Shuntitagaralepa may give relief in Pain, Swelling and Burning sensation.

Probable Mode of action of Dasangam Gutika: -

In the present study, over all result obtained can be partially attributed to the composition Dasangamgulikasevana. It was practiced as per treatment protocol in Kerala for VrischikaDamsha and also to avoid anubandhaupadravas. Proportionate distribution of all the properties in DasangamGulika shows that 85.71% drugs are having *UshnaVeerva*, among them 78.57% are *Vata*-Kaphaghna. By these properties the Drug Dasangamgulika may give relief in Pain, Swelling & Itching. It contains *Pippali* which is also having the properties like anti-allergic (Dahanukar S.A et al 1984), Anti pyretic (Singh et al 1973), Analgesic (Singh et al 1973), and Anti-inflammatory (Singh et al 1973). Dasangamgulika contents 7.14% Sheeta and Anushnasheeta Veeryadravya, which may act as pittaghna. 21.42% are with Madhura rasa and 28.57% are *Tridosh'aghna*. All these properties may help to reduce the Erythema as well as burning sensation due the Scorpion sting.

Discussion on Overall Study:-Scorpions found in the western coastal belts can be compared with Mandavishavrischika. Extend of toxicity depends on toxicity of the venom, quantity of venom, size of the victim and general medical condition of the victim. Severe envenomation symptoms as explained by textual references were never found in any of the patient during the trial. Antivenom must only be administered in the case of severe systemic envenomation.33.33% subjects were having Tachycardia, Hypertension was present in 30%. 30% subjects were having local rise in the temp and reduced after 4 days of treatment and this would probably due to systemic action of dasangamgulika. Working class of labours, homemaking women, people whose employment is mediocre as per educational qualifications, people who work on wood and stone, agriculture related workers and farmers and also people who depend on firewood as fuel for cooking purpose are more prone to suffer from vrischikavishadamsa. People who moves back to their home from their work place, who have addictions like alcohol and also of vaata-pitta prakriti is more prone to suffer from vrischikavishadamsa. Due to madhyamarogabala and rogibala, and madhyamasatwa more significant results were obtained. Due to the Tridoshahara, Ushnaveerya, Vedanasthapana and Vishaghna, properties of the drugs of the both the yogas which Ruja subsides Vatadosha and reduces VrischikaVisha. Due to the thiktha and kashaya rasa, vishaghna and sopha-sothahara properties of the drugs of the both the yogas which subsides Kapha & Vata in VrischikaVisha. Due to the thikthakashaya rasa pradhana, Sheethaveerya, and dahaprashamana properties of drugs of the both the yogas which subsides Pitta dosha and does raktashodhana in VrischikaVisha. Due to the thikthakashaya rasa pradhana, lekhaneeya, kandughna and vishaghna properties of some of the drugs which subsides Kaphadosha and gives a better result in Kandu. Due the thikthakashaya rasa. sheethaveerva. vishaghna, and rakthashodhana properties of some of the drugs which subsides Pitta dosha and does Rakthashodhana and gives a better result in Kandu.63.33% of patients had marked improvement, 30% had moderate improvement and 6.66% had mild improvement from symptoms. It that shuntitagaralepa along dasangamgulikasevana in vrischikavisha is a quite stable and suitable therapy. Shuntitagaralepa have UshnaVeerya drugs and are Vataghna kaphaghna. Yogavahi property of Madhu enhances the action of the drugs in the lepa. Vishahara and tridoshahara property of honey further add to the visha and sophashamanatva of the lepamay give relief in Pain, Swelling and burning sensation. In 85.71% Dasangamgulika drugs are having UshnaVeerya, among them 78.57% are Vata-Kaphaghna and reduce Pain, Swelling & Itching. 7.14% Sheeta and Anushnasheeta Veeryadravya, which may act as pittaghna. 21.42% are with Madhura rasa and 28.57% are Tridoshaghna. All these properties may help to reduce the Erythema as well as burning sensation due the Scorpion sting. In Vrischikavishadamsa, people usually medications once the cardinal symptoms subside for them. These later result in the formation of Garavisha due to incomplete expulsion of Vrischikavisha. As per classical references, Vrischikavisha takes 21 days for the complete recovery of symptoms, so a medication of 21 days duration is recommended

CONCLUSION

The rate of drug absorption depends mainly on the dosage form, route of administration and particle size. Increase surface area of drugs helps in quick absorption of active principles by facilitating easy penetration of drug mixture in to the skin tissue. Honey acts as an ideal base to transport the active principles of the drug in to the deeper stratum of skin and also helps in resolving the symptoms of Majority the Vishajasopham. of drug in Dasangamgulika have properties of Vedanasthapana, So, this Drug is beneficial in VrischikaDamshaa. Half of ingredients are having property of Shothahara. So this drug

recommended to *VrischikaDamsha*. In present study by analysing all these factors we found that *Shuntitagaralepa* along with *Dasangamgulikasevana* in *Vrischikavisha* is a quite stable and suitable therapy and is highly significant (P<0.001) in reducing the cardinal symptoms selected for the study viz. Pain, Burning sensation, Swelling, Itching and Erythema.

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Treatment Profile



Before treatment

During treatment



After treatment

At Follow up

Source of Support: Nil

Conflict Of Interest: None Declared

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