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A Comparative Clinical Trial To Evaluate Efficacy Of *Shaliparni Thaila Dhara* (Pseudarthria Viscid Linn) Against *Gritha Saindava Dhara* In The Management Of Vrischika Damsha. (Scorpion Sting).

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Abstract

Background: Scorpion sting being a major public health problem is an acute life threatening, time limiting medical emergency especially in rural parts of India. Ayurveda recommend several medicinal preparations for the management of scorpion sting but so far very little statistical data is available regarding the efficacy of these medicines. The prevailing situation is in need of revalidation of *ayurvedic* formulation. Hence two varieties of *dhara* yoga such as *saliparni thaila dhara* and *gritha saindava dhara* have been selected to compare effectiveness in the management of *vrischika damsha* along with *dasanga agada*. **Aims**: To evaluate comparative effect of *saliparni thaila dhara* against *gritha saindava dhara* along with *dasanga agada* in the management of *vrischika damsha*.

Methods: A comparative clinical trial was conducted at a tertiary Ayurveda centerwith 100 subjects satisfying inclusion and diagnostic criteria. They were selected by simple random lottery method and divided in to two groups. In group 1 diagnosed case of *vrischika damsha* received *saliparni thaila dhara* externally, group 2 was given *gritha saindava dhara* externally for two days and dasanga gulika (2gm) TDS was administered orally in both groups for two days. Ordinal numerical rating scale was utilized to record intensity of cardinal symptoms pain, erythema, swelling and burning sensation. Statistical analysis was done in single group by Friedman test within the group by wilcoxon signed ranks test and in between the group by Mann- Whitney U Test

Results: - The study showed significant improvement within the group in reducing the 4 four cardinal symptoms with $P<0.001$.A significant result was obtained between the group with $P<0.05$.

Conclusion: *Saliparni thaila dhara* is more or equal effective when compared to *gritha saindava dhara* along with *dasanga agada* in the management of *vrischika damsha*.

Keywords: Dasanga agad, Dhara,Saliparni thaila, , Gritha saindava, agad tantra,scorpion sting.

INTRODUCTION:

Scorpion stings are a life –threatening emergency, and are considered one of the most important health challenges in tropical and sub tropical regions.[1,2,3] Tremendous local as well as radiating pain with erythema and swelling are the most common signs symptoms found in case of scorpion sting which may be persisting for more than 72 hours.[4] It may also influence mood, functional status, and quality of life.[5,6] In case of scorpion sting ,it has been stated that severe the pain, less venomous the scorpion and better the prognosis and vice versa.[7] Scorpions are nocturnal predators. When disturbed in their hiding places, they sting promptly and several times. India is most affected with a incidence of 0.6%.[8]. Commonest species found in India are Mesobuthus tamulus(Indian red scorpion.),Heterometrus swammerdami(Indian black scorpion and buthus landersoni on coconut and palm trees in southern part of india.[9,10] The species of scorpions such as *Heterometrus kanarensis*, *Heterometrus keralensis*, *Heterometrus swammerdami*, and *Palamneus gravimanus* are big in size, produce no systemic manifestation, and are seen in these regions with no reported fatality till date. These varieties of scorpions can be compared with *Mandavisha vrischika* (mild poisonous scorpion bite) in Ayurveda, as the envenomation is rather mild and with no known human fatalities. Within the first hour after their sting, there is the formation of maculae or papules at the sting site causing localized pain. The lesion later becomes a purpuric plaque that will necrotize and ulcerate. The amount of venom injected determines the size of the lesion. Swelling is also seen in most cases. Lymphangitis results from the transfer of venom through the lymphatic vessels. Inflammation, edema, and redness of the skin may last for hours to a few days.[11] Ayurveda elucidates treatment protocol under the broad heading of *Vrishchika damsha chikitsa* aiming at *vedanasthapana* (analgesic), *Vishaghna* (anti poisonous), and *Shophahara* (antiinflammation) [12]. According to the degree of poison, multitude of treatment strategies have been enumerated [13]. In this context variety of herbo mineral preparation have been incorporated internally as well as externally based on the symptoms.[14] Ayurveda proposes a range of medicinal prepration (internal & external) in the management of vrischika damsha(scorpion sting) but so far very little statistical data is available regarding the efficacy of these medicines. Few studies suggest the anti-venom effect of certain medicinal plants in the conditions of envenomation.[15] Present study was an effort to find out the efficacy of one of such preparations. Among them saliparni thaila dhara[16,17] and gritha saindava dhara[18] are tropical anti-inflamatory medication,and dasanga agada[19] is a potent vishahara medicine(Alexeterics).

METHODOLOGY:

STUDY DESIGN: A comparative clinical trial done at tertiary ayurveda center. A clinical study with 100 subjects satisfying inclusion criteria were selected and divided randomly in to two groups by simple random lottery method. Group 1 administered *saliparni thaila dhara* externally. Group 2 administered *gritha saindav dhara* externally for two days and *dasang agada* 2gm tds was administered orally in both groups for two days. Third day patient was on rest without internal and external treatment and fourth day the follow up was done. The ethical clearance was obtained from institutional ethics Committee. Parul University – No PU/PIA/IE/02/2021/034, MVR Ayurveda Medical College, Parassinikadavu – IEC/Agada-phd/01/2021/14. CTRI registration no: -CTRI/2022/10/046109.

RESEARCH POPULATION: 100 consenting subjects, diagnosed as per the clinical features of scorpion sting, aged between 18 to 60 years of either gender, irrespective of socio economic and religious background. Patients with history of black scorpion sting with duration not more than 48hours presenting with essential symptoms like pain, swelling, erythema and burning sensation due to scorpion sting were included. Subjects with severe systemic manifestation due to scorpion sting, patient who have already undergone treatment for pain and patients who are not in position to give consent were excluded. Ordinal numerical rating scale was utilized to record intensity of the cardinal symptoms pain, erythema, selling and burning sensation.

Intervention: Selected subjects were treated in two groups with *saliparni thaila dhara* and *gritha saindava dhara* and *dasanga agada* 2gm TDS for both the group. Trial drug tabulated in Table 1, Table 2 and Table 3

Table 1: INGREDIENTS OF TRIAL DRUGS

		1.DASHANGA AGAD		
Sl. no	Sanskrit name	Scientific name	Part used	Quantity
1.	Vacha	Acorus calamus Linn	Rhizome	Equal parts
2.	Hingu	Ferula narthex Boiss	Resin	Equal parts
3.	Vidanga	Embelia ribes Burm	Fruit	Equal parts
4.	Saindava	Rock salt	Salt	Equal parts
5.	Gajapippali	Piper chaba Hunter	Root	Equal parts
6.	Patha	Cyclea peltata	Root	Equal parts
7.	Prativisha	Aconitum heterophylum wall.	Tuberous root	Equal parts
8.	Sunti	Zingiber officinale Rose	Rizome	Equal parts
9.	Maricha	Piper nigrum Linn	Friut	Equal parts
10.	Pippali	Piper longum Linn	Fruit	Equal parts

Table 2: SHALIPARNI THAILA :

Sl.no	Sanskrit name	Scientific name
1.	Shaliparni	Pseudarthria Vscid Linn
2.	Tila Tailam	Sesamum indicum Linn

Table 3: GRITHA SAINDHAVA

Sl no	Sanskrit name	Scientific Name
1.	Gritha	Butyrum deparatu
2.	Saindava	Rock salt

In *gritha saindava dhara* a luke warm mixture of 100gm gritha (ghee) and 5gm *saindava* (potassium chloride)was used for *dhara*. These drugs are collected from institution pharmacy and were authenticated in the institution research center.trial drug prepared as per clinical method.[20,21]Packing and labeling was done in pharmacy as per the standard procedure.[22] The intervention details are tabulated in Table 4

Table 4:- INTERVENTION

DETAILS	GROUP 1(TRIAL)	GROUP 2 (CONTROLL)
SAMPLE SIZE	100	100
DRUG INTERNAL	DASANGA AGADA	DASANGA AGADA
DOSE	2GM TDS with hot WATER	2GM TDS with hot WATER
STUDY DURATION	6 dose (4 days)	6 dose (4 days)
Drug external	200 ml of saliparni thaila dhara	200 ml of gritha saindava dhara
DISTANCE FROM SITE	12 A" above from bite site	12 A" above from bite site
Duration of dhara	One hour	One hour
Temperature of dhara	40^0 c	40^0 c

Statistical Test Used:

The collected data were analysed using a SPSS in stat software. The parameters assessed were pain, swelling, erythema and burning sensation. Demographic data and other relevant information were analysed with descriptive statistics. Statistical analysis done by Friedman test within the group by using Wilcoxon signed-rank test and in between the group by Mann Whitney U test. Results are tabulated Table 5-Table 10.

Results:

Total 107 patients were screened for the study details Fig 1

Fig 1 –Consort chart

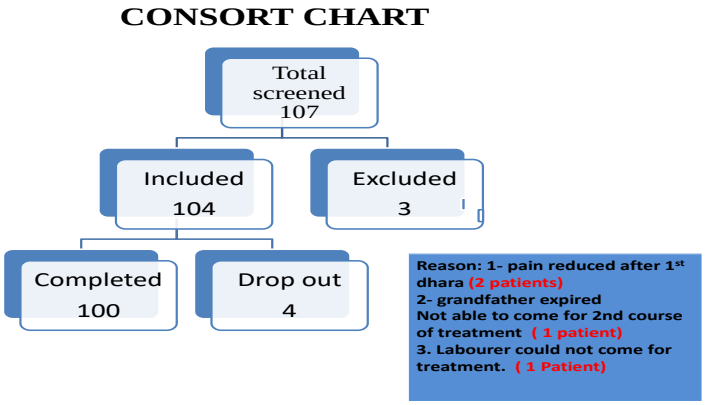

Table 5 :-WILCOXON SIGN RANK TEST GROUP A (Shaliparni thaila dhara)

	pain_ day1 - pain_bt	pain_ day2 - pain_bt	pain_ day4 - pain_bt	ery_ day1 - ery_bt	ery_ day2 - ery_bt	ery_ day4 - ery_bt	swe_da y1- swe_bt	swe_day 2 - swe_bt	swe_da y4 - swe_bt	bur_day 1 - bur bt	bur_da y2 - bur BT	bur_da y4 - bur BT
Z	-6.737[b]	-6.887[b]	-7.071[b]	000[c]	-6.928[b]	-6.928[b]	-1.000[b]	-4.574[b]	-4.815[b]	-4.840[b]	-6.928[b]	-6.928[b]
Asymp. Sig. (2-tailed)	.000	.000	.000	1.000	.000	.000	.317	.000	.000	.000	.000	.000

Table 6 :-WILCOXON SIGN RANK TEST GROUP B (Gritha saindava dhara)

	pain_ day1 - pain_bt	pain_ day2 - pain_bt	pain_ day4 - pain_bt	ery_ day1 - ery_bt	ery_ day2 - ery_bt	ery_ day4 - ery_bt	swe_day 1-swe_bt	swe_da y2 - swe_bt	swe_da y4 - swe_bt	bur_da y1 - bur bt	bur_da y2 - bur BT	bur_da y4 - bur BT
Z	-6.467[b]	-6.360[b]	-6.693[b]	-1.633[b]	-3.819[b]	-6.186[b]	.000[c]	-1.244[b]	-3.151[b]	-4.093[b]	-6.934[b]	-6.621[b]
Asymp. Sig. (2-tailed)	.000	.000	.000	.102	.000	.000	1.000	.213	.002	.000	.000	.000

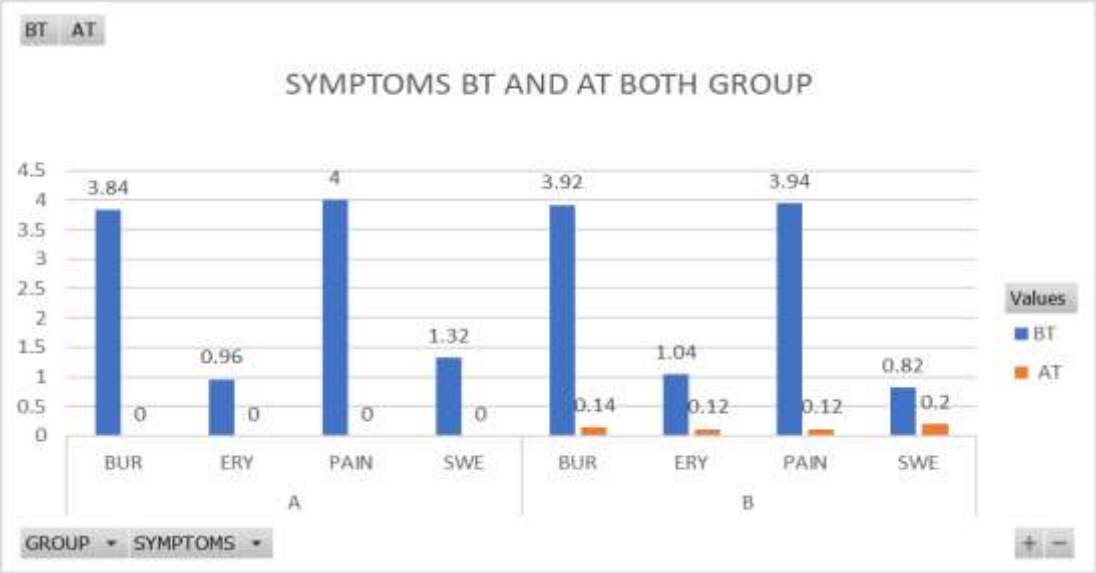

Table 7:-Mann-Whitney U Test:

	pain_bt	pain_day1	pain_day2	pain_day4
Mann-Whitney U	1200.000	1132.000	550.000	1100.000
Wilcoxon W	2475.000	2407.000	1825.000	2375.000
Z	-1.421	-1.276	-5.881	-2.514
Asymp. Sig. (2-tailed)	.155	.202	.000	.012

Table:8

	ery_bt	ery_day1	ery_day2	ery_day4
Mann-Whitney U	1248.000	1175.000	475.000	1100.000
Wilcoxon W	2523.000	2450.000	1750.000	2375.000
Z	-.029	-1.170	-6.669	-2.514
Asymp. Sig. (2-tailed)	.977	.242	.000	.012

Table 9 :-

	swe_bt	swe_day1	swe_day2	swe_day4
Mann-Whitney U	963.500	967.500	1005.000	1000.000
Wilcoxon W	2238.500	2242.500	2280.000	2275.000
Z	-2.174	-2.144	-1.986	-3.317
Asymp. Sig. (2-tailed)	.030	.032	.047	.001

Here above table p value is less than alpha value so we reject null hypothesis and also we can see that mean rank value is A is less than B so group A is different from group B. Group A is moderately better than group B in swelling based on effect size0.3.

Table 10:-
Test Statistics

	Bur _Bt	BUR_day1	BUR day2	BUR_day4
Mann-Whitney U	1225.000	928.500	1225.000	1075.000
Wilcoxon W	2500.000	2203.500	2500.000	2350.000
Z	-583	-2.461	-1.000	-2.730
Asymp. Sig. (2-tailed)	.560	.014	.317	.006

BEFEORE AFTER treatment of group A (Shaliparni thaila dhara) (Fig 2)

BEFEORE AFTER treatment of group A (Gritha saindava dhara) (Fig 3)

DISCUSSION

The study was designed to investigate the effect of saliparni thaila dhara against gritha saindava dhara along with dasanga agada in the management of vrischika damsha. Gritha is considered as one of the best vata pittaghna dravya;it also acts as pittaghna by virtue of its properties like rasa,virya vipaka and doshaghna.[23,24] Saindava acts as tridoshaghna by its veerya and vipaka properties.[24] It is also used to reduce pain, inflammation and irritation from insect bites.[25] Salparni is tridoshaghna among karma and is vishaghna.[26,27,28] Angamardaprashamanahara, jantughna, shophahara and kanduhara.[29] Researchers have proved antioxidant and anti-inflammatory property of shaliparni.[30] Dasanga agada contains Vacha (Acorus calamus Linn) and Saindhava, which are considered as a Mootrajanana (diuretics) drugs. Again this may be helpful in inflammatory condition. Drug like Patha (Cyclea peltata) is a Vishaghan (Anti-poisonous) drug. Vacha (Acorus calamus Linn) Hingu (Ferula narthex Boiss) and Pippali (Piper longum) also act as a Sagyasthapana dravya. As mentioned earlier, Pippali (Piper longum) is also having the properties like anti-allergic[31] Anti pyretic[32], Analgesic[32] and Anti-inflammatory[32]. It is shown to enhance the bioavailability of various structurally and therapeutically diverse drugs. Previous studies show that Piperine is absorbed very fast across the intestinal barrier. It may act as a polar molecule and form a polar complex with drugs and solutes. It may modulate membrane dynamics due to its easy partitioning thus helping in efficient permeability across the barriers. Embelin present in Embelia ribes has non-narcotic analgesic property which acts centrally.[33] A heterophyllum is potential enough to inhibit sub-acute inflammation by interruption of the arachidonic acid metabolism.[34] Zingiber officinale is known anti-inflammatory herb.[35,36] So these therapeutic combinations are beneficial in scorpion sting.

Probable mode of action of *dhara* – constant temperature was maintained throughout the procedure of dhara as it is beneficial for relieving pain.[37] Sushruta samhita describes the mode of absorption of tropical application like oils used in abhyanga.[38] similar concept of percutaneous absorption is envisaged in the modern physiology also.[39.] There are three possible routes of absorption. The pilo sebaceous follicles play some part of absorption of many compounds. The trans-follicular absorption, the route of penetration, is through the follicular pores to the follicles and then to the dermis via the sebaceous glands is greater than that of granular layer of the epidermis.

CONCLUSION:

In the present study, within the groups, *saliparni thaila dhara* and *gritha saindhava dhara* along with dasanga agada area highly significant.($p<0.001$) in reducing cardinal symptoms *viz* pain, burning sensation, erythema and swelling. When the results were compared by Mann withney U Test statistically not significant both group are equally effective. Clinically group A is moderately better than group B in swelling. No adverse drug reaction reported during the study. So saliparni thaila dhara can be effectively used for the scorpion bite management.

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CONFLICTS OF INTEREST:

The authors confirm that there is no conflict of interest.

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