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EFFICACY OF TWO AYURVEDA REGIMEN IN MILD SCORPION STING: AN OPEN-LABEL, TWO-ARM, CLINICAL TRIAL

T. Kumar Sanath^{*1}, Shrilata², Acharya Niranjana³ and A. K. Muraleedhran⁴

Department of Agad Tantra¹, Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi - 221005, Uttar Pradesh, India.

Department of Kayachikitsa², KVS Institute of Ayurvedic & Medical Science and Research Centre, Ghazipur - 275204, Uttar Pradesh, India.

Department of Agada Tantra evumVyavahara Ayurveda³, Alvas Ayurveda Medical College, Moodbidre - 574227, Karnataka, India.

Department of Rasashastra and Bhaishajya Kalpana⁴, Parassinikkadavu Ayurveda Medical College, Parassinikkadavu, Kannur - 670563, Kerala, India.

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Correspondence to Author:

Dr. T. Sanath Kumar

Assistant Professor,
Department of Agad Tantra,
Faculty of Ayurveda, Institute of
Medical Sciences, Banaras Hindu
University, Varanasi - 221005,
Uttar Pradesh.

E-mail: sanathkm@bhu.ac.in

ABSTRACT: Background: Scorpionism is an endemic and highly prevalent public health predicament causing severe cardio or neurotoxic effect. Ayurveda proposes a range of medicinal preparations (internal & external) in the management of *Vrishchika Damsha* (Scorpion sting). Among them, Hingwadi and *Jeerakadi lepa* are topical anti-inflammatory medications, and Bilwadi Gutika is a potent vishahara medicine (Alexeterics). **Aims:** To evaluate the comparative effect of *Hingwadi Lepa* against *Jeerakadi Lepa* with Bilwadi Gutika *pana* in the management of manda *vrishchika damsha* (mild scorpion sting). **Methods:** The present study adopted an open labelled two armed clinical trial of before and after the pilot study. It was conducted at a tertiary Ayurveda center with 30 subjects satisfying inclusion and diagnostic criteria. They were selected by convenience sampling method and divided randomly into two groups. Group I received *Hingwadi lepa*, and Group II was given *Jeerakadi Lepa* twice daily & *Bilwadi Gutika pana* (1gm) t.i.d. was administered orally in both groups for 7 days. Standard scoring of cardinal symptoms was used to measure the efficacy of treatment before and after treatment. Statistical analysis was done within the group by using student's paired t-test and in between the groups by using an unpaired t-test. **Results:** The study showed highly significant improvement within the group in reducing the three cardinal symptoms with $P < 0.001$. A significant result was obtained between the group with $P < 0.05$. **Conclusion:** *Hingwadi lepa* is more effective when compared to *Jeerakadi Lepa* along with *Bilwadi Gutika pana* in mild scorpion sting.

INTRODUCTION: The scorpion envenomation is hazardous, remains a significant public health predicament¹.

Around 1.5 million scorpions envenoming with 3,250 deaths are reported worldwide annually². The scorpion sting is more prevalent and severe in the underdeveloped tropical countries¹. Among 86 species in India, *Buthus tamalus*, *Palamneus gravimanus*, and *Mesobuthus tamulus* (Indian red scorpion) are lethal to humans³. In coastal Karnataka and Kerala, the lethal red scorpion is rarely found, but mild poisonous *Heterometrus swammerdami* is copious⁴.

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Though it is not fatal but this scorpion sting can be severe enough to cause local pain, inflammation, oedema, and redness of skin⁵. The current treatment strategies for scorpion envenomation comprise anti-venom, and supportive therapies like pain relief, steroid and a postsynaptic alpha-adrenergic blocker⁶. But according to the Meta analysis published recently, the use of anti-venom is debatable⁷. As the scorpion is heterogeneous, the treatment strategies cannot be generalized. Hence according to the species, its habitat, and range of envenomation, the treatment protocol has to be designed. Owing to this, Agada tantra (the branch of Ayurveda dealing with Toxicology) explains a variety of Vrishchika based on its origin, structure, its sting effect and treatment. Based on the signs of sting envenomation, *Vrishchika damsha* is classified into *Manda*, *Madhyama* and *Teekshna* i.e. mild, moderate, and severe, respectively⁸. *Manda Vrishchika* is predominantly black in colour and produces the similar effect of genus *Heterometrus* scorpion⁹. Pain, Burning sensation, and Oedema are its cardinal symptoms.

Ayurveda elucidates treatment protocol under the broad heading of *Vrishchika damsha chikitsa* aiming at *vedanasthapana* (analgesic), *Vishaghna* (anti poisonous), and *Shophahara* (anti inflammation)¹⁰. According to the degree of poison, multitude of treatment strategies have been enumerated¹¹. Variety of herbo mineral preparations have been incorporated internally as well as externally based on the symptoms¹². *Hingu*, *Jeeraka*, *Matulunga* and *Ghrita* are among them. *Bilwadi Gutika* is one of the *Vishahara Agada* indicated for scorpion sting¹³. Line of management proposes *Lepa* (topical application) as one of the prime modes, which alleviates the inflammation of local envenomation¹⁴. The prevailing situation is in need of revalidation of the Ayurvedic formulations. Hence two varieties of *Lepa* yoga, such as *Hingwadi Lepa* and *Jeerakadi Lepa* have been selected to compare its effectiveness in the management of *Manda Vrishchika Damsha* (mild scorpion sting) along with *Bilwadi Gutika Pana*.

Methodology: Study design: A randomized, open labelled, two-armed clinical trial of before and after pilot study at tertiary Ayurveda center between 2012 and 2014. Total of 30 subjects satisfying

inclusion criteria were selected and divided randomly into two groups by convenience sampling method. Group I received *Hingwadi Lepa*, and Group II was given *Jeerakadi Lepa* twice daily & *Bilwadi gutika pana* (1gm) t.i.d. was administered orally in both the groups for 7 days **Fig. 1**. The ethical clearance was obtained from Institutional Ethics Committee. (IEC No: PAMC/IECC/CT 2012/SY02).

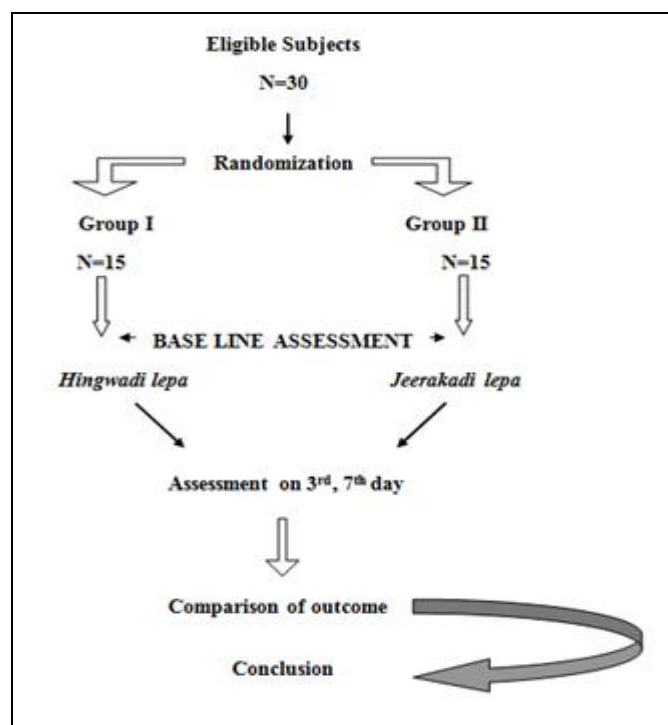


FIG. 1: RESEARCH DESIGN

Research Population: 30 consenting (in written form) subjects, diagnosed as per the Clinical features of Scorpion stings, aged between 16 and 65 years of either gender, irrespective of socio-economic and religious background, were included.

Patients with a history of black scorpion sting with duration not more than 48 h presenting with essential symptoms like Pain, Swelling, and burning sensation due to Scorpion sting were included as well. Subjects of red scorpion sting and any post sting systemic involvement with treatment history were excluded.

Subjects having diabetes mellitus, hypertension, and other systemic diseases that interfere with the prognosis and management of scorpion sting were also excluded. In addition, subjects with major systemic, neurocognitive and psychiatric illnesses were excluded.

Clinical Evaluation: Subjects were clinically screened using a pre-defined symptom scale exclusively designed for the study. A case pro forma was prepared with diagnostic criteria justifying *Manda Vrishchika damsha* such as *Vedana* (pain), *Vepathu* (tremor), *daha* (burning sensation), *sweda* (perspiration), *damshashopha* (swelling), *rakthagama* (bleeding), *Gatrahsthambha*

(local stiffness) as per *Sushruta manda visha Vrishchika lakshana*. Pain, Burning sensation and oedema were reported among classical symptoms, which were assessed according to severity on day one, and seven (after the treatment) **Table 1**. Objective Parameters (blood haemogram) were also investigated to measure the difference.

TABLE 1: SUBJECTIVE PARAMETER GRADING

Grading	Pain	Burning sensation	Oedema observational
0	No pain	No burning sensation	No oedema
1	Pain on pressure	Burning sensation, not continuous	Slight oedema
2	Continuous mild pain not disturbing	Continuous burning sensation, not disturbing	Slight, involving surrounding area
3	Moderate pain disturbing	Continuous, disturbing	Moderate, involving surrounding area.
4	Severe, continuous, disturbing	Severe, continuous, disturbing	Severe oedema involving area

According to percentage of relief, improvements were defined.

100 % relief	Cured
>75 % to 99 %	Marked improvement
>50 % to 75%	Moderate improvement
>25 % to 50 %	Mild improvement
0 % to 25 %	Unchanged

Intervention: Selected subjects were treated in two groups with *Hingwadi lepa*¹⁵, *Jeerakadi lepa*¹⁶, and *Bilwadi gutika*¹³ pana 1 t.i.d. for both the

group. Ingredients of trial drugs are tabulated in **Table 2**.

These drugs were collected from institution Pharmacy and were authenticated in the institution Research center. Trial drugs were prepared as per classical method^{5, 17}.

Packing and labelling was done in Teaching Pharmacy as per the standard procedure¹⁸. Then it was administered in both groups. Details are tabulated in **Table 3**.

TABLE 2: INGREDIENTS OF TRIAL DRUGS

1. <i>Hingwadi Lepa</i>				
S. No.	Sanskrit name	Scientific name	Part used	Quantity
1	<i>Hingu</i>	<i>Ferula foetida</i> , Linn	Resin	1 Part
2	<i>Haratala</i>	As ₂ S ₃ Arsenic trisulphide	<i>Pinda tala</i>	1 Part
3	<i>Matulunga swaras</i>	<i>Citrus medica</i> Linn	Fruit juice	Quantity Sufficient
2. <i>Jeerakadi Lepa</i>				
1	<i>Jeeraka</i>	<i>Carum carvi</i> Linn.	Fruit	1 Part
2	<i>Saindhava</i>	Potassium chloride, KCl	Salt	1 Part
3	<i>Ghrita</i>	<i>Butyrum deparatu.</i>	Ghee	Quantity Sufficient
3. <i>Bilwadi gutika</i>				
1	<i>Bilwa</i>	<i>Aegle marmelos</i> Corr	Root	1 Part
2	<i>Surasa</i>	<i>Ocimum sanctum</i> linn.	Flower	1 Part
3	<i>Karanja</i>	<i>Pongamia pinnata</i> Perri.	Fruit	1 Part
4	<i>Natam</i>	<i>Valeriana wallichii</i> De	Root	1 Part
5	<i>Devadaru</i>	<i>Cedrus deodara</i> Roxb	Tuber	1 Part
6	<i>Vibheetaki</i>	<i>Terminalia bellirica</i> Roxb	Fruit	1 Part
7	<i>Hareetaki</i>	<i>Terminalia chebula</i> Retz	Fruit	1 Part
8	<i>Amalaki</i>	<i>Emblica officinalis</i> Gaertn	Fruit	1 Part
9	<i>Shunti</i>	<i>Zingiber officinale</i> Roscoe	Tuber	1 Part
10	<i>Maricha</i>	<i>Piper nigrum</i> L.	Fruit	1 Part
11	<i>Pippali</i>	<i>Piper longum</i> L.	Fruit	1 Part
12	<i>Haridra</i>	<i>Curcuma longa</i> L.	Tuber	1 Part
13	<i>Daruharidra</i>	<i>Berberis aristata</i> DC.	Tuber	1 Part
14	<i>Aja mootra</i>	Goat Urine	Urine	Quantity Sufficient

TABLE 3: INTERVENTION

S. no.	Details	Group I	Group II
1	Sample size	15	15
2	Drug (Externally)	<i>Hingwadilepa</i>	<i>Jeerakdi lepa</i>
3	Thickness	1gm/cm ² bd	1gm/cm ² bd.
4	Drug (orally)	<i>Bilwadigutika</i>	<i>Bilwadi gutika</i>
5	Dose	1 gm tid	1 gm tid
6	Anupana	Warm water	Warm water
7	Duration	7 days	7 days

Statistical Tests Used: The collected data were analyzed using a graph pad in stat software. Demographic data and other relevant information were analyzed with descriptive statistics. Continuous data was expressed in mean +/- standard deviation, and nominal and ordinal data was expressed in percentage. Statistical analysis

was done within the group by using student's paired t-test and in between the groups by using an unpaired t-test. The changes with P value<0.05 were considered as statistically significant.

Results: Total 30 subjects completed the study without any dropout. A majority of the subjects were males aged between 36 to 45 years (63.33%) belonging to lower economic status working as a manual labourer (60%) **Table 4.**

Eighty percent of subjects were presented with oedema at the site of the sting, while 73.33% of subjects reported moderate, disturbing pain and 50% continuous burning sensation **Table 5.**

TABLE 4: DISTRIBUTION OF DEMOGRAPHIC DATA

Distribution	Observation	Group 1 (n=15)		Group 2 (n=15)		Total (n=30)	
		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Gender	Male	8	53.33%	11	73.33%	19	63.33%
Age	36-45	4	26.66%	4	26.66%	8	26.66%
Occupation	Manual labourer	8	53.33%	10	66.66%	18	60%
Economic status	Lower status	14	93.33%	14	93.33%	28	93.33%

TABLE 5: DISTRIBUTION ON SYMPTOMS

Distribution	Observation	Group 1 (n=15)		Group 2 (n=15)		Total (n=30)	
		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Pain	Moderate pain, disturbing	10	66.66%	12	80%	22	73.33%
Burning sensation	Continuous disturbing	8	53.33%	7	46.66%	15	50%
Oedema	Moderate	13	86.67%	11	73.33%	24	80%

TABLE 6: EFFECT OF THE THERAPY (PAIRED T - TEST) (BETWEEN 1ST&7TH DAY)

Group	Parameters	Mean Score		M. diff.	% Relief	SD	SE	t - value	P value	Remarks
		BT	AT							
Group I	Pain	2.99	0.267	2.667	91.07%	0.617	0.159	16.73	P<0.001	S
	Burning sensation	2.27	0.00	2.267	100%	0.967	0.248	9.134	P<0.001	S
Group II	Oedema	2.8	0.33	2.467	88.21%	0.640	0.165	14.269	P<0.001	S
	Pain	3.06	1.13	1.933	63.07%	0.258	0.667	29.00	P<0.001	S
	Burning sensation	2.400	0.00	2.400	100%	0.632	0.163	14.167	P<0.001	S
	Oedema	2.867	0.867	2.0	69.75%	0.378	0.097	20.49	P<0.001	S

The result showed that symptom scale on pain after treating with *Hingwadi lepa* and *Bilwadi gutika* combination reached from 2.269 to 0.267 and reduced significantly about 91.07% (P<0.001). While *Jeerakadi lepa* and *Hingwadi lepa* reduced pain for about 63.07% and symptom score was reduced from 3.06 to 1.13 (P<0.001). The combined effect reduced burning sensation from 2.267 to 0.00 (P<0.001) in Group I while in Group

II, it was reduced from 2.400 to 0.00 (P<0.001) **Table 6.** In both groups, 100% relief was recorded in the scheduled treatment period. *Hingwadi Lepa* and *Bilwadi gutika* combination reduced oedema from 2.8 to 0.33 on day 7 with a substantial reduction of 88.21% (P<0.001) whereas *Jeerakadi Lepa* and *Bilwadi gutika* combination reduced the symptom score from 2.867 to 0.867, and for about 69.28% of relief.

At the end of the study, the study showed highly significant results within the group in reducing the three cardinal symptoms with $P < 0.001$. On account of percentage of relief *Hingwadi lepa* with *Bilwadi gutika* was more effective (92.74%) as compared to *jeerakadi lepa* with *Bilwadi gutika* (75.99%) in the management of mild scorpion sting.

The details are tabulated in **Table 6**. When trial drugs were compared between the group, the study showed insignificant results in reducing pain and burning sensation while statistically significant results were obtained for Oedema ($P < 0.05$). The details are tabulated in **Table 7**.

TABLE 7: COMPARATIVE EFFECT BETWEEN TWO GROUPS. (UNPAIRED T-TEST)

Parameters	Groups	M. diff.	SD	t – value	P value	Remarks
Pain	Group I	2.667	0.617	4.245	$P > 0.001$	NS
	Group II	1.993	0.258			
Burning sensation	Group I	2.267	0.961	-0.449	$P = 0.657$	NS
	Group II	2.400	0.632			
Oedema	Group I	2.467	0.640	2.432	$P < 0.02$	S
	Group II	2.00	0.378			

Both the regimen showed significant improvement in the Total leukocytes count as well as in Lymphocyte count ($P < 0.05$). TLC in Group I was decreased by 9.23%, and in Group II it was found

up to 9.64%. Lymphocytes in Group I were reduced by 11.11%, and in group II the reduction was found by 6.54% **Table 8**.

TABLE 8: EFFECT OF THE THERAPIES ON BLOOD PARAMETERS

Parameter	Group	Mean BT	SD	Mean AT	SD	Mean Diff.	t - value	P value	Remark
ESR	I	15.33	2.35	13.93	2.21	1.4	1.678	$P > 0.05$	NS
	II	14.13	2.72	12.73	2.57	7	1.447	$P > 0.05$	NS
N	I	58.133	2.475	58.133	3.021	0.00	0.00	$P > 0.05$	NS
	II	57.00	2.970	57.333	2.024	0.333	0.412	$P > 0.05$	NS
E	I	2.400	0.737	2.000	0.926	0.400	1.309	$P > 0.05$	NS
	II	2.267	0.884	1.733	1.033	0.534	1.520	$P > 0.05$	NS
L	I	40.200	1.265	35.733	1.486	4.467	8.863	$P < 0.001$	S
	II	36.667	3.579	34.267	1.624	2.400	2.365	$P < 0.05$	S
M	I	0.467	0.664	0.667	0.724	0.200	0.802	$P > 0.05$	NS
	II	0.800	0.775	1.00	1.069	0.200	0.587	$P > 0.05$	NS
RBS	I	126.667	15.43	117.86	13.78	8.8	1.647	$P > 0.05$	NS
	II	123.8	15.71	115.73	11.47	8.06	1.16	$P > 0.05$	NS
TLC	I	8520	886.56	7733.33	907.27	786.66	2.405	$P < 0.05$	S
	II	7880	637.18	7120	570.76	760	3.44	$P < 0.05$	S

TABLE 9: OVERALL EFFECT OF TEST DRUG GROUP I ON COLLECTIVE MEASURE OF CHIEF COMPLAINTS AND LAB INVESTIGATION IN COMPARISON TO GROUP II (CHI SQUARE X²)

	Group	NSI	SI	Row Total	Chi Square x ²	P value	Remark
Overall effect of Drug	Group I	0	15	15(50%)	6.00	$P = 0.0143$	S
	Group II	4	11	15(50%)			
	TOTAL	4	26	30			

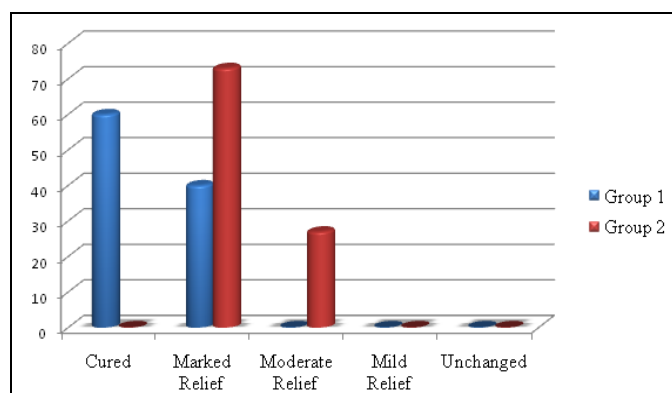


FIG. 2: OVERALL EFFECT OF THERAPY

The overall effect shows a significant difference between the two groups **Table 9**. Concerning the percentage of improvement, the result showed that 60% of subjects got cured after the stipulated period of the treatment in Group I. In Group I 40% of subjects got marked relief, while in group II 73% had marked relief. 27% of group II got moderate relief on 7th day. Here though none of the group showed 100% cure rate, the results obtained by the therapies of group I was more effective which is depicted in **Fig. 2**.

DISCUSSION: The study was designed to investigate the effect of *Hingwadi lepa* against *Jeerakadi lepa* with *Bilwadi gutika* pana in the management of manda vrishchika damsha (mild scorpion sting). *Hingwadi lepa* is vata-kapha lowering, alexeterics, and vedanasthapaka (analgesic). Pharmacological property shows anti-inflammatory, anti-bacterial, analgesic activity and vasodilatation action^{19,20}. The other arm *Jeerakadi Lepa* is tridosha lowering and alexeterics. Pharmacological property shows anti-inflammatory, antihistamine action²¹. *Bilwadi Gutika* is a potent alexeterics, tridosha lowering, reduces inflammatory and pain. Pharmacological property shows anti-allergic, Antipyretic, Analgesic, and Anti-inflammatory action²². So these therapeutic combinations are beneficial in scorpion sting. The study observed a high incidence of scorpion sting in the male population, as the incident rate is directly proportional to the geographical area¹.

At the end of the clinical trial, *i.e.* on seventh day, results were assessed and are discussed compared to a previous study on scorpion sting managed with oral administration of *Vilwadi gulika* alone²³. Therapeutic combination of *Hingwadi lepa* and *Bilwadi vati* showed better result than sole *Bilwadi gutika*²³ and its combination with *Jeerakadi lepa* in reducing pain and oedema. The ingredients like *Hingu*¹⁹, *Matulunga*²⁰ in *Hingwadi Lepa* and *Bilwa*, *Pippali*, *Kupilu*, *Haritaki*, *Tulasi* in *Bilwadi Gutika*²² possess a potent analgesic property. The combined effect might have yielded a better result. The effectiveness of *Bilwadi gutika*²³ was better compared to both the regimen in reducing the burning sensation of scorpion sting. *Pippali*, *Haritaki*, *Tulasi* in *Bilwadi gutika* are anti-inflammatory, antihistaminic, antipyretic²². However, in this study, all the subjects were completely relieved from the symptom.

The current study showed significant improvement of a few blood parameters. Both trial drugs showed significant improvement in Total Leucocytes count as well as in Lymphocyte count. An increase in the number of Lymphocytes in almost all the subjects suggests an involvement of the immune system against the antigen *i.e.*, scorpion venom. And its reduction after the completion of the treatment shows that the drugs may also possess anti-inflammatory, antihistamine, and immune

regulatory action. The previous study also reports effectiveness of *Bilwadi gutika* on Lymphocytes and Total Leucocytes count²³. Overall effect showed a significant difference between the groups and previous study by Sandeep *et al.*,²³ also reports the same.

Further, implementing the same medicines on larger sample size and or for the longer treatment duration can précis the results. Probable mode of action of *Lepa* therapy: Infusion of active ingredients of *lepa* gets absorbed into the hair root followed by *Shiramukhand*, *Swedavahi srotas* and passed to the deeper layers²⁴. This can be understood by percutaneous absorption such as pilosebaceous, trans-follicular absorption. Active principles of medicines in *lepa* thus get absorbed and enter the bloodstream and remove the pathology. Absorption enhances when applied in lipid form²⁴. *Lepa* of *saindhava* and *gritha* mainly subside *vata*, which is dominant in scorpion sting.

CONCLUSION: In the present study, both the drugs, *Hingwadi lepa* and *Jeerakadi lepa* along with *Bilwadi gutika* are highly significant ($P < 0.001$) in reducing the cardinal symptoms *viz.* Pain, Burning sensation and Swelling. When the results were compared by unpaired t test, it was found that the efficacy of the drugs was comparatively significant ($P < 0.05$). On the Chi Square test, it was found that the efficacy of the drug (a collective measure of chief complaints and lab investigation) was comparatively significant ($P < 0.05$). On account of the percentage of relief, *Hingwadi lepa* with *Bilwadi gutika* was more effective in the management of mild scorpion sting than *Jeerakadi lepa* with *Bilwadi gulika*. No adverse drug reactions were reported during the study. It is important to replicate this study using larger samples and more rigorous methods.

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CONFLICTS OF INTEREST: The authors confirm that there is no conflict of interest.

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