

Comparative Study of Efficacy of *Dhattura Beeja* Ointment & *Sarshapa* Ointment in the Management of *Vipadika* (Cracked heel)

Research Article

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Abstract

Background: *Vipadika* is one of the *Vataja Nanatmaja Vikara* which is also considered as *Kshudra Kustha*. The patient suffering with disease feel severe pain and it increases with the progression of disease. Ayurveda described various therapeutic approaches for the management of *Vipadika* like; *Shodhana Chikitsa*, *Abhyantara Chikitsa* and *Bahya Chikitsa*, etc. To provide a potent topical drug and to solve the cosmetic problem of the heel the study was undertaken. **Methodology:** A randomized single blinded study was designed to assess efficacy of the topical preparation made from natural drugs for the management of *Vipadika*. *Dhattura beeja* ointment and *Sarshapa* ointment was prepared and standardized. 15 patients were enrolled in each group. Group A received *Sarshapa* ointment and served as control group and group B received *Dhattura beeja* ointment. Both the groups were assessed for number of cracks and pain in cracks. Statistical analysis was conducted using student's paired and unpaired t test at $p < 0.05$ as level of significance. **Result:** *Dhattura Beeja* ointment significantly reduced number of cracks and pain associated with cracks on heel in comparison with *Sarshapa* ointment without any adverse effect. **Conclusion:** *Dhattura beeja* ointment is efficacious and can be used safely in the management of *Vipadika*.

Key Words: *Dhattura Beeja*, *Sarshapa*, *Vipadika*, *Kshudra Kustha*.

Introduction

Ayurveda has described various types of diseases related to skin and *Kustha Roga* is one of them. *Kshudra Kustha* is one of the types of *Kustha Roga*. *Vipadika* is included in the *Kshudra Kustha*, which is also considered as one of the types of *Vataja Nanatmaja Vikaras*. (1,2) *Vipadika* is defined with manifestations as *Pani Sphutana* (Cracks in palm), *Pada Sphutana* (Cracks in feet), *Teevra Vedana* (Severe pain), *Kandu* (Itching), *Daha* (Burning), *Ruja* (Pain), *Raga* (Redness) and *Pidaka* (Rashes). It is treated with *Shodhana* (*Virechana*, *Rakta Mokshana* and *Vamana*), *Abhyantara chikitsa* (*Tundi Ghrita*, *Triphaladi Ghrita*, *Mahakalanala Rasa*, *Vijaya Parpati* & *Rasa Taleshvara Rasa*) and *Bahya Chikitsa* (*Dhattura Beeja Taila*, *Kusthadya Taila*, *Vipadikahara Ghrita Taila*, *Tandula Lepa*, *Lepa* of *Khadira* and *Shatapaki ghrita*). (3-7)

Heel is an integral and important part of foot. Nobody can deny the importance of heel as it is undertaking various physical activities. It is difficult to imagine a person running or walking with injured heels. There are certain diseases associated with foot in

general and heel in particular. Such abnormality may lead to temporary or permanent dysfunction of heel. Cracks in heel seem like a minor breach in the anatomy of the heel but as it progresses, it can produce severe pain and sometimes bleeding. Heel has cosmetic importance as it can be a social stigma especially in females. The pain present in *Vipadika* is so intense that it severely affects the quality of life. There are some remedies available in the market in cream form which only smoothens the heels. Cracks are not completely healed and it has reoccurrence. In Ayurveda, internal as well as external treatment is described for *Vipadika*. But patients want quick relief with less medicine. Hence, *Dhattura beeja* ointment mentioned in *Chakradatta* in *Kushtha Chikitsa* has been selected as external application to study the safety and efficacy in comparison with plain *Sarshapa* ointment.

Materials and Methods

Approval from Institutional Ethics Committee was obtained before conducting the study (Reference no. DMIMS (DU)/IEC/2019/7953). The raw drugs were collected, identified and authenticated from department of Dravyaguna, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha.

Collection of Material

500gm seeds of *Dhattura* (*Datura metel* Linn) were collected from Shaila Pharma, Nagpur and 10Kgs of *Mankanda* (*Alocacia indica* Lour) was procured from Government Ayurved College, Gwalior. 4000ml

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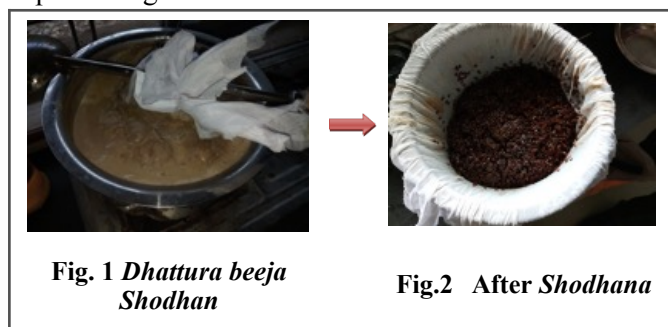
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Sarshapa taila (Mustard oil) and 2 kgs of wax were procured from local market. The study was conducted in two phases: I) Pharmaceutical study and II) Clinical study. The pharmaceutical study included *shodhana* (purification) of *Dhattura*, preparation of *Dhattura Beeja* ointment and *Sarshapa* ointment and their standardization.

Method of Preparation of Dhattura Beeja Ointment (8-11)

Shodhana (Purification) of Dhattura Beeja

Dried *Dhattura* seeds were collected & physical impurities were removed. Seeds were tied in *Pottali* with clean cloth. *Dolayantra* filled with cow's milk was used for *Swedana* purpose of seeds for three hrs. After *Shodhana*, *Dhattura* seeds were taken out from the *Pottali* and washed under tap water. Seeds were dried & kept in airtight container.



Preparation of Maankanda Ksharajala

Dried *Maankanda* was burnt as per standard procedure to prepare *Kshara* (Alkaline powder) and ash was kept in water for overnight. Next day clear water was collected and filtered seven times through a clean cotton cloth. The water obtained after filtration is considered as *Maankanda Ksharajala*.



Fig. 3 Maankanda kshariya jala

Preparation of Dattura Beeja Taila

2 litres of *Sarshapa taila* was poured in a vessel kept on fire and it was boiled until it became free from froth. 500gms of *Dhattura Beeja Kalka* was mixed in it. *Maanakanda Ksharajala* was added & boiled on moderate heat until all water content gets evaporated. After observing the *Taila Siddha Lakshana*, it was allowed to cool. Finally, it was filtered with clean cotton cloth.



Fig. 4 Preparation of Dhattura beeja taila

Preparation of Dattura Beeja Ointment

500gm wax was heated and liquefied wax was mixed with *Dhattura Beeja Taila* and stirred to make it homogenous mixture, finally semisolid ointment preparation was obtained with uniform consistency. The dose form was modified from oil to ointment for the convenience, better and quick absorption.

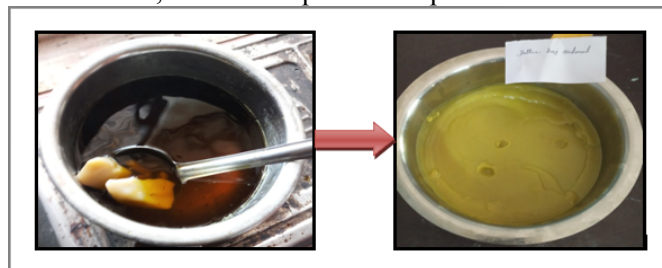


Fig. 5 Preparation of Dattura beeja ointment

Preparation of Sarshapa Ointment

Sarshapa Taila (2000 ml) was heated until it became free from froth. 500gm Wax was heated till it gets liquefied. It was then mixed in *Sarshapa Taila* and stirred up to the formation of homogenous mixture.



Fig. 6 Final product *Sarshapa* ointment and *Dattura beeja* ointment

Analytical Study

Both the ointments were subjected to physicochemical analysis and microbial load with the help of microbial limit test.

Clinical Intervention

A randomized controlled single blinded trial was conducted to compare the efficacy of *Dhattura Beeja* ointment and *Sarshapa* ointment. The patients of *Vipadika* were selected from to Kayachikitsa O.P.D of M.G.A.C.H. and R.C. Salod (H), Wardha. Informed written consent was taken after due consultation with patients. Total 30 patients were participated in this study & registered patients were distributed in two groups A and group B randomly by lottery method. Fifteen patients were enrolled in each group. Patient of *Vipadika* having age between 20-60 years with cracks associated with pain (*Saruja*) were included in the study. Patients under other treatment for *Vipadika* and having bleeding cracks, open wound, ulcer in feet, diabetic foot and infectious wound on feet were excluded from the study. Group A was considered as control group and treated with *Sarshapa* ointment whereas group B was considered as trial group and treated with *Dhattura Beeja* ointment. As *Sarshapa* oil is one the ingredients in *Dhattura beeja* ointment, it was used a common ingredient for both groups for comparison.

Number of cracks per foot, number of cracks associated with pain per foot were noted and photographs of the feet in exposure of light in prone position were taken before and after the intervention. Sensitivity test was conducted to observe any rash, itching, redness, burning or ulcer formation. First application was performed under the physician's

supervision and for subsequent applications, patients were asked to apply the *lepa* at home every day for seven consecutive days at bedtime. The patients were advised to apply ointment with an applicator and to retain the ointment overnight and then to wash the feet in the morning with lukewarm water. They were also advised to wash the hands immediately after application and not to touch eyes and other external orifices.

Assessment parameter

Number of cracks of both the feet was counted and minute fissures were ignored.

Table No 1: Number of Cracks on feet

Cracks on feet	Grades
No cracks	1
1 to 3 cracks	2
4 to 6 cracks	3
More than 6 cracks	4

Table No.2: Cracks associated with pain

Pain in Cracks	Grades
No Pain	1
Pain on digital pressure	2
Pain while walking	3
Pains more / constant pain	4

Statistical analysis

Statistical analysis was done by using descriptive and inferential statistics using student's paired and unpaired 't' test, and software used in the analysis were SPSS 22.0 version and Graph Pad Prism 6.0 version and $p < 0.05$ is considered as level of significance.

Observations and Results

Table No 3: Organoleptic and physicochemical analysis

SN	Test parameter	Test Result	
		<i>Sarshapa</i> ointment	<i>Dhattura Beeja</i> ointment
1	Color	Yellow	Yellow
2	Odor	Pungent	Pungent
3	Ph	6.18	7.86
4	Fatty matter	59%	57%
5	Loss on drying at 105 ⁰ C	2.9%	3.4%

Table No 4: Microbial Load/ Specifications

SN	Test parameter	Test Result		API Value
		<i>Sarshapa</i> ointment	<i>Dhattura Beeja</i> ointment	
1	Enterobacteria	Absent	Absent	10 ³ /gm
2	Total fungus count	Absent	Absent	Maximum 10 ³ /gm
3	E – coli	Absent	Absent	Maximum 10 /gm
4	Salmonella spp	Absent	Absent	None
5	Staphylococcus aureus	Absent	Absent	Absent
6	Pseudomonas aeruginosa	Absent	Absent	Absent
7	Total viable count	Absent	Absent	Maximum 10 ⁵ /gm

Table No 5: Categorization of patients according to Sex

Sex	Group A Patients		Group B Patients		Total Patients	Total Patients in %
	No.	%	No.	%		
Male	2	13.33	8	53.33	10	33.3
Female	13	86.67	7	46.67	20	66.7

Table No. 6: Categorization of patients according to their age group.

Range of Age	No. of patients				Total Patients	
	Group-A	%	Group-B	%	Number	Percentage
19-28	6	40	6	40	12	40
29-38	6	40	6	40	12	40
39-48	0	0	0	0	0	0
49-58	1	6.67	2	13.33	3	10
59-68	2	13.33	2	13.33	4	13.33

Table No. 7: Categorization of patients according to Agni

Agni	Number of patients				Total Patients	
	Group-A	%	Group-B	%	Number	Percentage
Sama	1	6.66	2	13.33	3	10
Vishama	6	40	5	33.33	11	36.66
Manda	6	40	6	40	12	40
Tikshna	2	13.33	2	13.33	4	13.33

Table No. 8: Categorization of patients according to Koshtha

Kostha	No. of patients				Total Patients	
	Group-A	%	Group-B	%	Number	Percentage
Mrudu	3	20.00	5	33.33	8	26.66
Maddhyam	5	33.33	3	2.000	8	26.66
Krura	7	46.67	7	46.67	14	46.66

Table No. 9: Assessment of Number of Cracks in group A with Sarshapa Ointment

Group A	Mean	n	SD	SE	Mean difference	% Improvement	t value	p value
BT	2.86	15	0.83	0.21	1.4	45	5.95	<0.05*
AT	1.46		0.51	0.13				

Table No 10: Assessment of Pain in cracks in group A with Sarshapa Ointment

Group A	Mean	n	SD	SE	Mean difference	% Improvement	t value	p value
BT	2.8	15	0.94	0.24	1.4	46.11	6.5479	<0.05*
AT	1.4		0.50	0.13				

Table No 11: Assessment of Number of cracks in group B with Dhattura beeja Ointment

Number of cracks	Mean	n	SD	SE	Mean Difference	% Improvement	t value	p value
BT	2.66	15	0.8165	0.2108	1.93	61.42	9.5	<0.05*
AT	0.73		0.7213	0.1862				

Table No 12: Assessment of Pain in cracks in group B with Dhattura beeja Ointment

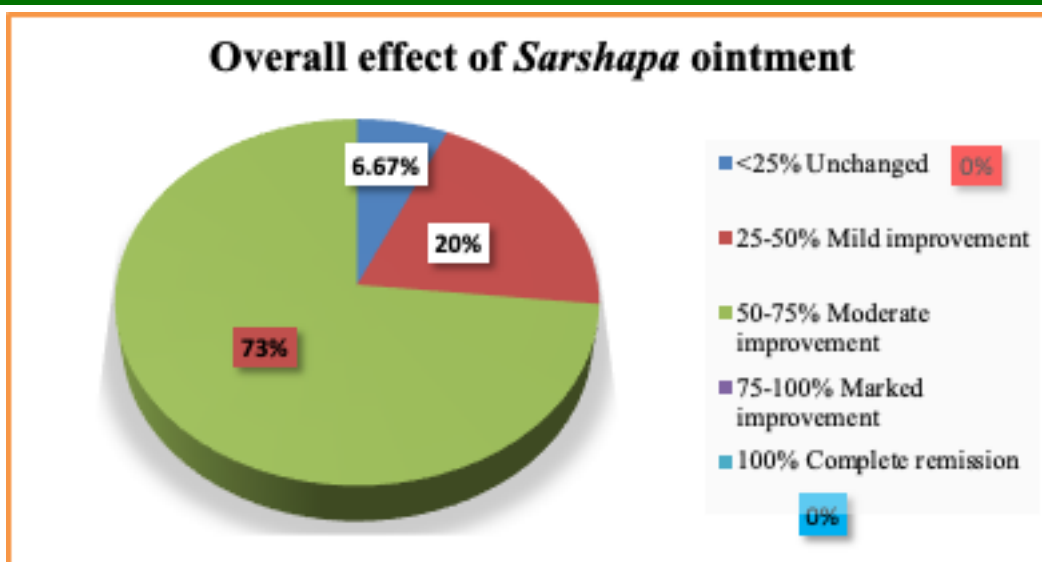
Pain in cracks	Mean	n	SD	SE	Mean Difference	% Improvement	t value	p value
BT	2.53	15	0.91	0.23	1.73	60	8.64	<0.05*
AT	0.8		0.80	0.20				

Table No. 13: Comparison of both groups for number of cracks

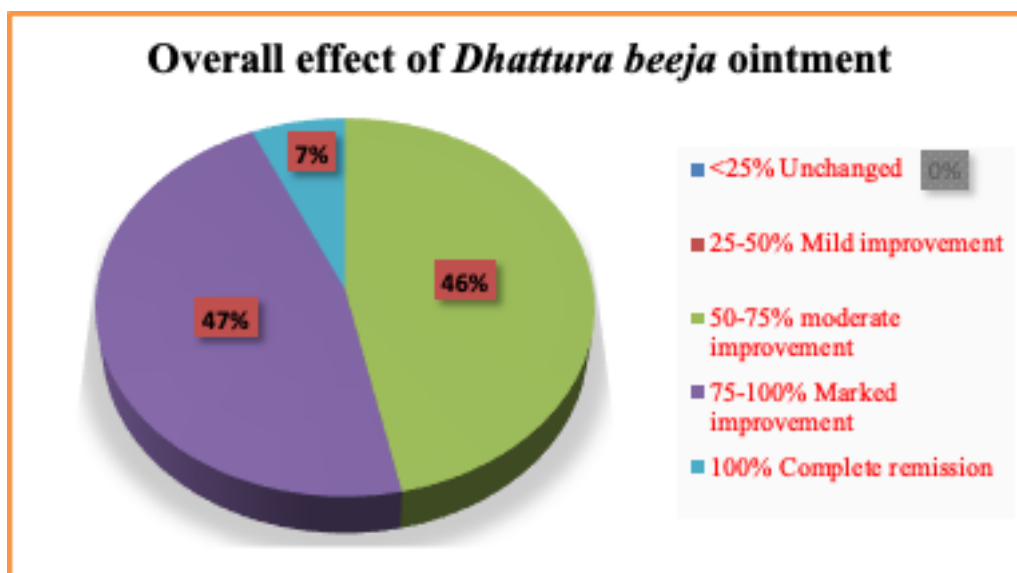
Group	n	Mean	Standard Deviation	Standard Error of Mean	t-value	P-value
A-Sarshapa ointment	15	1.46	0.5164	0.13333	1.31	<0.05*
B-Dhattura beeja ointment	15	0.73	0.59362	0.15327		

Table No.14: Comparison of both groups for pain in cracks

Group	N	Mean	Standard Deviation	Standard Error of Mean	t-value	P-value
A-Sarshapa ointment	15	1.4	0.50709	0.13093	2.04	<0.05*
B-Dhattura beeja ointment	15	0.8	0.56061	0.14475		



Graph 1: Overall effect of Sarshapa ointment in the management of disease



Graph 2: Overall effect of Dhattura beeja ointment in the management of disease

Discussion

Leaves, roots, fruit and seeds of *Dhatura* (*Datura metel* Linn) belonging to solanaceae family are used in treatment for various purposes, though they are toxic. The parts are known to reduce pain and inflammation. They are used in Jwara (fever), *shwasa* (asthma), *kasa* (cough), *amlapitta* (acidity), *parinamshool* (abdominal pain), *pittaashmari* (gall stones), *shotha* (inflammation), dandruff etc. Sharangdhara, Bhava Mishra and Chakradatta have mentioned about *Dhatura beeja taila* in the treatment of *Vipadika*.

After physicochemical analysis, it was observed that the parameters of both ointments are within normal limits and there was no bacterial contamination in the study drugs. In the present study, most of the registered patients belong from *Manda Agni* while *Sama Agni* was observed only in 10% registered patients. It was observed that maximum patients belong from *Krura Kostha* as compared to *Mrudu* and *Maddhyam Kostha*.

The study was carried out to measure effect of *Dhatura Beeja* ointment in the management of

Vipadika in comparison with *Sarshapa* ointment. The mean score of number of cracks was 2.86 before treatment which reduced to 1.46 after treatment with *Sarshapa* ointment which is statistically significant ($p < 0.05$) and the relief is 45%. The mean score of pain in cracks was 2.8 before treatment which reduced to 1.8 after treatment with *Sarshapa* ointment which is statistically significant ($p < 0.05$) and the relief is 46.11%. The mean score of number of cracks was 2.66 before treatment which reduced to 0.73 after treatment with *Dhatura Beeja* ointment which is statistically significant ($p < 0.05$) and the relief is 61.42%.

The mean score of pain in cracks was 2.53 before treatment which reduced to 0.8 after treatment with *Dhatura Beeja* ointment which is statistically significant ($p < 0.05$) and the relief is 60%. When both the groups were compared for the effect of drug on number of cracks and pain in cracks, it was found that pain and number of cracks and pain reduced significantly in group B with *Dhatura Beeja* ointment in comparison with Group A (*Sarshapa* ointment).

Overall Effect of Sarshapa Ointment

It was observed that after treatment with *Sarshapa* ointment, 73% patient received moderate improvement, 20% patients received mild improvement while 6.67% patients remain unchanged. Marked improvement and complete remission were not observed (Graph No. 1).

Overall Effect of Dattura beeja Ointment

It was observed that after treatment with *Dattura beeja* ointment, 7% patients has complete remission, 47% of patients received marked improvement while 46% received moderate improvement (Graph No. 2).

The findings of study suggested that *Dhattura beeja* ointment offers more beneficial effects in reducing pain and number of cracks on heel in comparison with *Sarshapa* ointment. The *Dhattura beeja* ointment contains *Dhattura* and *Mankanda*, these components of formulations offers healing and soothing effects thus provide better relief in the management of pain and cracks on heel.

Apart from this, no patient was found sensitive to *Dhattura Beeja* ointment and any local adverse effects like rash, redness, itching burning etc was not observed during the study. *Dhattura beeja* ointment is found to be safe for local application in comparison with other *upavisha* like *Gunja* (*Abrus preatorius* Linn). (12, 13)

Probable mode of action of Dhattura Beeja ointment

The *Snigdha guna* of *Mankanda* might have helped to control *Vata* thus prevent *Rukshata* and *Kharasparsha* in *Vipadika*. The lubrication helps for moistening and softening of skin. The *Dhattura Beeja* ointment subsided *Kandu* by virtue of *Vishagna*, *Kaphagna* and *Kandughna* properties of *Dhattura*. *Krimigna* property of *Dhattura* & *Mankanda* also helps to reduce *Kandu*. *Vedana* might have subsided by the *Vedanasthapaka* action of *Mankanda* while *Srava* might have been cured by the *Sthambaka* action of *Mankanda*. *Kashaya rasa* and *Sandhaneeya* properties of *Dhattura* also pacify *Srava*. *Daha* might have subsided by the *Pitta Shamaka* properties of *Mankanda* while *Kustaghna* & *Kandughna* properties of *Dhattura* & *Mankanda* along with *Sneha dravyas* help to relief symptoms of *Vipadika*.

Conclusion

Study concluded that prevalence of *Vipadika* is irrespective of age, sex and *prakruti* but predominantly seen in *Madhyama vaya* and patients with *Vatakapha prakriti*. *Kala*, *Desha*, *Vihara* plays an important role in occurrence of *Vipadika*. The topical herbal formulations can offer beneficial effects in the management of the disease. *Dhattura beeja* ointment is one of such types of herbal topical formulation that offers beneficial effects

in the management of *Vipadika*. *Dhattura beeja* ointment can relief symptoms like; number of cracks & pain associated with *Vipadika*. Study compared effect of *Dhattura beeja* ointment with *Sarshapa* ointment in the management of *Vipadika* and it may be concluded that *Dhattura beeja* ointment can be used safely in the management of *Vipadika* as it offers better results than *Sarshapa* ointment.

Acknowledgement

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Images of patients

Fig. 1: Crack heel treated with *Dhattura Beeja* ointment



Before t/t

After t/t

Fig. 2: Crack heel treated with *Dhattura Beeja* ointment



Before t/t

After t/t

Before t/t

After t/t

Fig. 3: Crack heel treated with *Dhattura Beeja* ointment



Fig. 4: Crack heel treated with *Dhattura Beeja* ointment



Before t/t

After t/t
